FACTORS THAT AFFECT RESPIRATOR FIT – TESTING PROGRAMS

by

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DEDICATION

I dedicate this work to the soul of my father who took me to my first day of school and to the soul of my mother who was with me at the airport for the first flight to the United States to earn my Ph.D., and who prayed and hoped for my success.

I dedicate this work to my wife for her strength and love throughout my studies, to my children, Ahmed and Omar, and to my brothers and sister.

And I dedicate this work to all the rest of my family and friends who supported and prayed for me.
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ABSTRACT

Respirators are used to minimize the exposure to air contaminants. A good fit is essential for the effective functioning of a respirator. The Occupational Safety and Health Administration (OSHA) requires an annual respirator fit testing. Respirator fit can be assessed either qualitatively or quantitatively. Two studies were conducted to assess the fit testing program with specific objectives to: 1) assess leak rates in full and half mask respirators, 2) assess the effectiveness of "feedback" on the quality of fit; 3) evaluate the effect of daily beard growth on respirator leak rates.

In the first study, it was found that the half mask respirator has a significantly lower leak rate than the full face respirator. A significant reduction in leak rate in both respirator types with "feedback" was also observed. The finding that half mask respirators have lower leak rates directly contradicts American National Standard Institute's (ANSI) guidelines of higher Assigned Protection Factor (APF) for full mask respirator. Further studies are necessary to determine these findings and to amend respirator recommendations in the future.

As expected beard growth was associated with respirator leak rate. The effect of daily growth on leak rate over a period of twelve days could be defined by a second order regression equation. An attempt was made to describe some characteristics of beard that affect the leak rate. After 12 days of beard growth, it was found that the aspect ratio (length/diameter) of hair was inversely correlated with leak rate (r = 0.64).

1 Feedback: A numerical value measuring the minimum leak rate that can be gotten from a respirator fitting with a normal donning.
CHAPTER 1

INTRODUCTION

The idea of a protective device, such as a respirator for eliminating hazardous exposures to problematic chemical contaminants, dates back to the time of the Romans when mine workers were experiencing exposure to red oxide in lead. Around the 1700s, the forerunner of the present day masks were developed. Then as now, the performance of respirator devices was based on two purposes: 1) The removal of dangerous substances in the air, such as dust, toxic particles, vapors, gases, fumes, mists, smoke or oxygen-deficient atmosphere, and 2) providing a clean air supply from an unpolluted source.

After the First World War in which chemical warfare was used, the respirator became even more important. One of the last major improvements in respirators occurred in 1930 when dust filters were developed which provided efficient and inexpensive protection from particles suspended in air. The most recent improvement has been the development of very efficient filters from fine glass fibers (Respiratory Protection, 1994).

Purpose of the Study

All respirators must achieve a good facepiece to face seal to be effective. Facial hair, such as beards and sideburns affect the effectiveness of the mask seal.

The Occupational Safety and Health Administration (OSHA) requires that instruction and training are important components for respirator use. This training must include a proper fitting of the mask with a fit test which includes the wearer receiving instructions, demonstrations, practice wearing, and adjustment. As suggested by the American National Standard Institute (ANSI), the facepiece fit test should be evaluated
annually although few criteria have yet been established which determines appropriate
intervals for fit testing. In 1997, for some chemical hazards, such as asbestos, lead,
cadmium, benzene and others, one fit test was deemed ineffective. At that time, OSHA
required three successful independent fit tests to determine leakage (OSHA, 1997). The
new rules also state: “The employee needs to pass one good fit test, if the employee fails
the fit test, then at least 3 (three) respirators (different manufacturers and sizes) must be
available for the employee to ensure a successful fit test. Only 1 (one) successful fit test
is required” (Weberman, personal correspondence, 2003).

Background

Where high concentrations of hazardous contaminants exist in the workplace,
such as chemicals, biological contaminants, or where there is a lack of fresh air or
insufficient ventilation respirators are necessary to limit exposure to contaminants. In
addition, occupational diseases, which may develop as a result of breathing contaminated
air, may also be controlled by the use of respirators. Therefore, the main purpose of a
respirator is to provide protection to the respiratory system from inhalation of hazardous
materials in the environment. The respirator’s function is to remove, prevent and purify
contaminants from the air before they are inhaled. Specific respirator types also may be
used to overcome lack of oxygen and thus provide protection by supplying respirable air
from an independent source.

Although there have been elementary type masks used for protection for
centuries, it was not until the middle 1800s that serious on-going efforts were expended
to develop a respirator mask. In the early 1800’s when first utilized, the mask as a
filtering element was a simple device, such as a bag-like screen placed over the head, or a
piece of cloth or a sponge used over the nose and mouth. Improvements continued
through the years and there were a number of respirator devices invented and patented that were used to provide breathable air for underwater divers, miners and firemen. For instance, in 1823, the Deane brothers patented an apparatus for smoke protection used by firemen that later became a device used by underwater divers (Held 1970). In 1847, Lewis P. Haslett invented a device similar to a gas mask, but the problem with this device was its filter materials could only trap solid substances, such as dust. It was not effective against dangerous gases (Smart 2000). Later, in 1849, Haslett patented his “Lung Protector” as a protective breathing device. In 1854, John Stenhouse invented a mask that used charcoal granules to trap and filter out noxious gases (Bellis). From that time on, charcoal became the filtering medium of choice for gas masks. Stenhouse’s mask covered the nose and mouth and was practical and effective and was adopted by many chemical factories in London.

In 1871, the “fireman’s respirator” was developed by John Tyndall (Davis 1947). Its main function was to filter air against smoke and gas. The elements that made this respirator effective were the use of lime to absorb carbonic acid, glycerin which acted on smoke particles, and charcoal which filtered out hydrocarbons. It was protective for 30 minutes. In 1874, Samuel Barton invented a design that is similar to what is used today (Smart 2000). It had a metal canister that was positioned at the front of the mask and contained glycerin-saturated cotton wool, granulated charcoal and granulated lime. The device also had a metal and rubber face cover, head cover, eyepieces and independent valves for inhaling and exhaling. This device performed a dual duty. It could also be used as a rebreather in which the wearer could breathe through tubes attached to an air tank on the wearer’s back. George Neally later developed a smoke mask in which filtered air was breathed through rubber tubes attached to a filter on the chest. The device was later improved by placing a filter directly in front of the facepiece (Held 1970). In the 1880’s
and 1890's there were a number of masks designed to prevent breathing noxious gas as well as dust. Some were masks that covered only the nose and mouth and some were full facemasks. The chemical agents in the filter chamber removed gaseous contaminants. These devices became popular for industrial use. In 1902, Louis Muntz invented a gas mask with a full head covering (Held 1970). In 1914, Garret Morgan patented his Morgan Safety Hood. There is some speculation about whether Morgan also designed the army gas masks used during World War I (The Invention of the Gas Mask).

The first patent for a self-contained breathing device was given to Benjamin Lane in 1850. The purpose was to protect the person from suffocating when working in places filled with noxious gases or impure air (Smart 2000). Next came the Fleuss Apparatus in 1878 which turned out to be very practical for mine rescues. The mask covered the entire face, was connected by tubes to a breathing container and an oxygen tube. Fleuss and his partner Robert Davis made an immense impact on the design of respirators with its carbon dioxide absorbent chamber which permitted the recirculation of breathable air (Davis 1947). The design was the precursor of the masks used during World War I. In 1915, Cluny MacPherson designed a smoke helmet that was capable of resisting poison gases. This helmet was the first one used by the British Army for gas protection in World War I (Bellis). As mentioned, recent developments are very efficient filters made from fine glass fibers (Respiratory Protection, 1994).

After nearly 200 years, today's sophistication of respirators have made them extremely efficient, capable of eliminating very small particles, and present almost no breathing problems. They have smaller facepieces, provide better vision, and can fit under other protective gear (OSHA Technical Manual, Section VIII: Chapter 2). At the present time there are two categories of respirators available in different sizes and shapes: atmosphere-supplying respirators (ASR) and air-purifying respirators (APR)

In this study, an APR device was studied, which is smaller, easier to maintain, least restrictive, and used most often in routine work practices. It is manufactured in three types of face pieces: full, half and quarter.
The full-mask respirator provides a great level of protection, covering from the hairline to below the chin. It seals most reliably and also provides an enhanced amount of eye protection. (See Figure 1).

Figure 1. Design of Full Face Piece Respirator

(Source: Health Effects Group, Inc., 1997)
The half-mask respirator is one that covers half the face from the nose to under the chin. The half mask seals more readily than the quarter-mask and is preferred for more toxic material. This mask covers under the chin and has two air purifying elements (See Figure 2).

Figure 2. Basic configuration of a half-face piece respirator.
(Source: Health Effects Group, Inc., 1997)
The Quarter-mask only covers the mouth and nose and the area sealed is between the chin and mouth. While a quarter-mask provides good protection, it is more easily dislodged than the full or half mask. Quarter-masks are used mostly for dust and are usually disposable. (See Figure 3).

Figure 3. Design of a quarter face piece mask

(Source: Health Effects Group, Inc., 1997).
Air Purifying Respirator Use

APR respirators have set criteria and may be used only in the following circumstances:

1. The contaminant and its concentration are known.
2. The mask being used is approved for the contaminant and its concentration.
3. The content of oxygen is at least 19.5% and the area is under intermittent monitoring.
4. The respirator has been fit tested on the wearer.
5. The wearer must have a pulmonary lung function test and approval by a physician to wear the APR.
6. The mask has been matched to the hazard.

The APR respirator may not be used for sandblasting, firefighting, protection from fumigants and in oxygen-deficient atmospheres. Other places not approved for the APR respirator are poorly ventilated areas, where the concentrations of toxic contaminants are unknown and without a cartledge for protection against gas or vapor contaminants, for particulates more toxic than indicated by National Institute of Safety and Health (NIOSH) (Health Effects Group 1997).

Fit Testing

Fit testing of a respirator is necessary to ensure that the wearer is adequately protected with a proper fit. This can only be done by determining how much leakage occurs when the mask is worn in the work place with hazardous environment. The test results can be altered by a number of anthropomorphic conditions; for example, an
extreme weight gain or loss, dental work such as tooth extraction or dentures, a facial scar, even hair growth, such as a beard or sideburns. Not all these changes will affect a respirator's fit, but if it does, leakage value will rise and the mask may become useless to the wearer (Johanson & Morgan, 1984).

Contaminate control is dependent upon respirator leakage. Therefore, fit tests are used to assess whether a respirator is capable of giving a fit that provides adequate protection. This approach does not always provide a satisfactory fit test function. In fact, "current fit testing does not measure the degree of protection from contaminants; it evaluates only the degree of fit as a surrogate respirator of a certain brand to a certain face" (Willeke, 1990, p. 764). At this time, different approaches to fit testing are now challenging long held assumptions about the procedures because the emphasis has been on fit test exercises on a singular donning rather than on multiple donning (Crutchfield, unpublished manuscript).

Fit testing is the only way to determine if a respirator meets the requirement of a respiratory protection program. Fit testing of a facepiece provides the wearer with the opportunity to don the equipment correctly and provide protection from a hazardous atmosphere. It also verifies that the make, model and size of a facepiece properly fits an individual's facial characteristics and thereby provides the greatest amount of protection.

Under current exercise fit testing requirements, the test indicates that a respirator that is correctly donned will provide adequate protection based on an acceptable leakage rate. This test does not assure that the worker’s respirator is the best fitting one for the
worker or that he or she knows how to don it properly, only that the respirator has passed
the exercise fit test.

**Qualitative and Quantitative Fit Testing**

There are two methods of fit testing: qualitative fit test (QLFT) and quantitative
fit test (QNFT) (Han, Willeke, & Colton 1997). A qualitative test calls for a challenge
agent to be introduced about the respirator while the worker is wearing it. A qualitative
test assesses the adequacy of the respirator being tested based on the responses of the
individual wearing the respirator. An agent with properties such as an odor, taste, or
nasal or throat irritation, is introduced around the respirator as it is being worn to
determine if an agent is detected. If the challenge agent is detected, the respirator fit is not
acceptable because the challenge agent has entered the mask, rendering it ineffective for
the wearer. If per chance, the wearer is incapable of detecting an odor, this makes it even
more ineffective and the test is invalid (Han et al., 1997). The protocols that govern
detection are based on a subject’s own opinion and, as such, are totally subjective and
many times unreliable.

On the other hand, the quantitative test is recommended when the respirator
leakage must be minimized when the worker is in a more toxic atmosphere (Johanson &
Morgan, 1984). The ability to measure leakage based on the effectiveness of the seal of a
respirator is an essential function of a quantitative fit test. This is done by assessing the
adequacy of the fit of the respirator by a numerical indicator called a fit factor. Although
this common practice has been used for some time, unfortunately, there is yet to be
established a statistical relationship between fit test results and respirator performance (Crutchfield, unpublished manuscript).

The QNFT should both quantify and differentiate respirator leakage. It should be used:

1) to help select the better fitting respirator from the available pool for each individual worker, 2) to gain some assurance that the selected respirator will provide an adequate level of protection for its intended use, and 3) to provide quantitative feedback on respirator donning effectiveness (Crutchfield, unpublished manuscript).

Controlled Negative Pressure (CNP)

Where pressure-based quantitative tests are selected, air is used as the test agent. Measurement of the leak flow to the total air flow of air both outside and inside the respirator is used to find the ratio which is the fit factor between those concentrations. When the quantitative test is performed using this principle, it is called the Controlled Negative Pressure (CNP), which works by replacing the air-purifying cartridges with a pressure-sensing attachment and a valve (Han, Xu, Foo, Pilacinski, & Willeke, 1991). As the wearer holds his or her breath, a steady state pressure occurs in 1 to 2 seconds as a small pump extracts air from the respirator cavity. “The flow rate through the face seal leak is a unique function of this pressure, which is determined once for all respirators, regardless of the respirator’s cavity volume or deformation because of pliability” (Han et al., 1991).
CNP has the ability to effectively monitor respirator leakage, because this method eliminates most of the problems that have become apparent with the current standard method of a quantitative test with aerosols (Crutchfield & Van Ert, 1993). The CNP system is desirable because it is often near 100% accuracy in detecting leakage, and the leak location or mask type does not affect or interfere with the results (Crutchfield, & Park, 1997). Because the test exhausts the air from the inside of the respirator, balance is maintained by replacing the removed air pressure inside the facepiece with a constant, negative pressure. With the pressure held constant, air flow remains the same inside the respirator during the fit test. If there is a difference, this will yield a direct measure of the leakage air flow based on a numerical leak rate assigned to it.

The CNP test versus the Condensation Nuclei Counter (CNC) test shows the following advantages:

1. Produces a direct measurement of leakage
2. Air molecules provide a more regulated test
3. Differential of mask leak penetration is eliminated
4. Greatly enhances fit test precision
5. Speeds up testing
6. Allows use of pressure more accurately occurring during actual conditions
7. Easily calibrated
8. Cost effective (Crutchfield, 1995)

There are three questions the CNP tests are capable of answering:

1. Does the respirator meet the fundamental fit of the wearer?
Fundamental fit is the most important information achieved during a fit test.

2. Does the type of work cause a shift in the fundamental fit?

In the workplace, a small leak is minor compared to a less reliable fit that does not return to a fundamental fit. This change causes a shift to a lower fundamental fit in which most of the time in the workplace is then spent at a greater risk of contamination because of the lower fit.

3. Does the donning test match the donning in the workplace?

If the donning test does not closely match the donning in the workplace, the fit test has no value. Cost benefits accrue in the CNP test because measuring fundamental fit, even several times before and after a “challenge of the facepiece seal,” is time saving translating into dollars and cents and thus is a vital consideration in the workplace (Crutchfield, unpublished manuscript).

**Mask Donning**

Skretvedt and Loschiavo (1984) note that all respiratory users experience a change of fit from one donning to another. This change occurs from donning to donning because of a number of variables such as “strap tension, positioning on the face, and a host of other variables. Donning-to-donning fit variability for bearded individuals will be even greater since additional variables, such as “moisture, natural oils and debris from the workplace” (p. 66) will be introduced.

Fit test exercises are based on a single mask donning and the act of mask donning in fit testing has been given very little attention. Once a mask has been correctly donned,
there has been no effort made to determine if it continues to be correctly donned or what
affect this has on the fit test.

To date, it appears there is only one study that has been performed which shows
the importance of donning. Crutchfield, Fairbank and Greenstein (1999), showed that
"donning affects respiratory fit to a greater degree than fit test exercises" (p. 827). In fact,
in their study, it appeared that multiple donnings were better for use as variables in
determining respirator fit than fit test exercises currently specified by OSHA’s
quantitative fit test protocol.

Fit test exercises can be costly, sometimes taking up to 75 minutes to complete,
during which time an employee is away from the job. Crutchfield and Peate (1999) and
Crutchfield, Fairbanks, et al. (1999) showed that multiple donnings, even over single
donning, can reduce test time, be less costly and more efficient than the fit test exercises
presently being conducted.

Facial Hair Growth

Respirators without a good facepiece-to-face seal may not be used for protection
in hazardous environments. The factors that might contribute to this condition are beard
growth, facial hair, moustaches and sideburns that break the seal between the sealing
flange and the wearer’s face (HEG, 1997). Hair that interferes with the sealing of a
respirator places it in question as a protective device, and the individual wearing the
respirator cannot expect the same kind of performance as someone who is clean shaven.

For instance, Hyatt, Pritchard, Richards and Geoffrion (1973) studied facial hair
and respirator performance in which subjects with beards were investigated. They found
that wearers with different amounts of hair, whether from stubble, sideburns, or beards, had an effect on the performance of the respirator. The degree of interference was predicated upon how the hair interfered with the sealing capabilities of the mask and the type of mask worn because some masks are more “roomy” than others and can accommodate more facial hair growth than others.

Hyatt, et al (1973) believed that a small moustache, small Van Dyke beard or short to medium length sideburns would not cause difficulty with the sealing surface of the mask. They examined day to day beard growth during normal and deep breathing and its effect on the seal. The subjects were four men who were clean shaven and who were tested over a period of 7 to 8 days while their stubble was growing. Results showed that the first three days were the most crucial in that maximum penetration occurred during that time, but that increases in penetration continued to show variations from day to day.

Hyatt et al. (1973) used three different types of full face mask pieces that showed variation of penetrations in the first 2 or 3 days, but by the end of 8 days, penetration was comparable. They concluded there was no way a wearer could expect adequate protection while wearing a very full 2- 2 1/2” long wiry beard that extended back under his chin and was long at the jaw line.

While the study did not include facial characteristics, the authors discovered this made a difference on a fit and needed to be considered a factor in hair growth and respirator fit. It is their contention that length, texture and density also need to be taken into account when investigating facial hair growth and sealing surface of respirators (Hyatt et al., 1973).
McGee and Oestenstad (1983) investigated facial hair growth and respirator seal protection using the Biopak 60, a Self Contained Breathing Apparatus (SCBA). The respirator is designed to maintain a positive pressure, reducing the possibility of a contaminant from entering the breathing apparatus. Eight individuals started off clean shaven and their beards were allowed to grow for a total of eight weeks. They were tested every two weeks. Facial dimensions had to fall within those stated by the Los Alamos Scientific Laboratory for full facemasks. No beard was shaved or trimmed for the duration of the study. One important factor emerged. The effect of time on the growth of a beard is not the same for each participant.

The results shows that beard growth has a definite affect on respirator facepiece to face seal and that individuals with beards could be placing themselves in a dangerous situation, particularly firefighters or others who are in confined space entry situations (McGee & Oesterstad, 1983).

Skretvedt and Loschiavo (1984) tested a variety of facial hair length, shape, density and texture. They determined that a 330 fold drop in protection was experienced by bearded employees and that 77% of bearded individuals wearing full facepiece respirators had fit factors below OSHA’s requirement of 50 and that 100% of them achieved fit factors below 100. None of the clean shaven wearers fit factors fell below 100. This fit figure for beaded individuals is so great that no confidence can be placed in respirator protection.

Skretvedt and Loschiavo (1984) also point out a beard is not a static factor. It keeps changing every day along with the orientation of the hair in the sealing surface. It
is their belief that although an individual with a beard may achieve OSHA’s minimum requirements during a specific test, when it comes to a “the drop in protection caused by a beard coupled with the large fit variability from donning to donning makes it quite likely that the individual will not obtain the minimum required protection in the workplace” (p. 66).

Stobbe, deRoza and Watkins (1988) reviewed 14 studies conducted between 1964 and 1987 on facial hair and respirator leakage. All but two of the studies showed that leakage in respirators increases from 20 to 1000 times as a result of facial hair. Of the two that did not show leakage, one was on a self-contained breathing apparatus (SCBA) and the other in the workplace. Neither of these was statistically significant. Results showed that leakage generally occurred as facial hair increased. A beard provided the greatest degree of fit variability. The problem with this review, as suggested by the authors, is that comparisons between the studies were difficult because of different protocol used for the individual studies, such as length of a beard grew between measurement, the kinds of respirators tested and the subjects as bearded or clean shaven. Stobbe et al. (1988) concluded that for negative pressure masks a beard’s affect on respirators was highly variable and that hair growth was highly variable from person to person for a given respirator. They found “for a given subject respirator to respirator leakage varied by factors of four to ten, while for a given respirator the intersubject variability varied by factors of one to twenty and up” (p. 202).

On clean shaven men, the percentage of leak was 0.01% or less, but increases rapidly the second or third day, stabilized around the fifth and sixth day and increased
again by the eighth or ninth day and then again stabilized. While this was occurring leakage continued to increase from 50 to 1000 times from 0 day to the ninth day (Stobbe et al., 1988).

Studies clearly demonstrated that negative pressure supplied-air respirators suffer the same problems as negative pressure (air purifying) respirators. A danger lies in the fact that although negative pressure supplied-air respirators usually are more protective, they are generally used in very dangerous situations. Since beards pose as serious a problem with this type of respirators as with others, the wearer who has a beard may be in a life threatening situation with a respirator with even a small percentage of leakage (Stobbe, et al, 1988).

It was Stobbe et al. (1988) opinion that for a negative pressure respirator, facial hair is a health hazard and no beards should be permitted. The times when facial hair may be permitted should be very restrictive and needs to be accompanied by training and meet all the requirements of a complete respirator program.

Randall and Ebling (1991) call attention to another important variable in the growth of facial hair. Their research on healthy Caucasian men showed that for the winter months of January and February, hair growth was lowest, increased in the spring to summer, from March to July where it “reach[ed] a peak about 60% above the winter level” (p. 146).

They attribute the hair follicle activity to cyclical causes influenced by hormones. Their explanation is that facial hair is “androgen-dependent” and they believe these
changes are related to testosterone which has been proven to have a low ebb during January and February and rise very high in July and August (Randall and Ebling 1991).

Nagl (1995) investigated the growth of pigmented and non-pigmented facial hair. His finding was that “white hairs were always longer than coloured hairs after the same period of growth” (p. 95). Actually, the white hair grew at twice the rate of pigmented hair with some hairs showing a growth rate of three times that of colored hair. This is all due to stage of hair growth cycle, the part of the body the hair is taken from and genetic as well as environmental factors. Nagl agrees with Randall and Ebling (1991), that hair growth is “apparently under the control of testosterone” (p. 97).

Objective of the Study

This research consisted of two studies. One study focused on measurement of the leak rate of the respirator on human participants with a multidonning for five days and measured the leakage feedback for the best fit without any enforcement. This research also measured the learning effect of each participant with the respirator (Appendix 2). The second study examined the effect of beard growth of two ethnic groups on respirator fit over a 12 day period of time (Appendix 3).

Major calibrations for pressure and flow-rate transducers of the Fit Tester Model 3000 Control Negative-Pressure QNFT System (Supplement A in Appendix 2 and Supplement A and B in Appendix 3) were performed at the beginning of the trials for each day.

Appendix 4 contains an Approval of Consent Letter and Appendix 5 contains an Approval Form.
Present Study

The methods, findings and conclusions of two different studies are presented in Appendices 2 and 3. The first study describes the quality of the fit for full face and half face respirators. It also evaluates the effect of feedback and the “donning effect” of respirators on the fit test.

Ten subjects consisting of five males and five females were involved in the study. They were tested for daily leak rate of full and half face respirators for a five day period. Full face respirators were found to have a higher leak rate and that the use of feedback reduces the leak rate of both respirators. However, the quality of fit, based on feedback, was greater for half face respirators than full face respirators.

The second study was performed on ten volunteers, five Middle Easterners and five Anglo Saxons, to assess the effect of the growth of a beard on half face respirator leak rate. The study was conducted on a daily basis for a two week period (excluding the weekends).

On the last day of the study, beard hair was collected and the hair's diameter and length were measured to determine the association between hair characteristics and respirator leak rates.

In study two, the findings were that daily respirator leak rates increased exponentially over a twelve-day period with a significant change occurring between day 4 and day 5. In plotting a second order regression equation, the equation accurately predicted the respirator leak rate with the age of the beard.
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APPENDIX 1

Glossary of Terms

Air-purifying respirator: A respirator in which ambient air is passed through an air-purifying element by either the breathing action of the wearer, or by means of a blower.

Ambient Aerosol Condensation Nuclei Counter (CNC): CNC Quantitative fit testing protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. In the CNC, the small particles, which are undetectable to conservative photometric techniques, are expanded by vapor condensation. A probed respirator has a special sampling device, installed on the respirator that allows the probe to sample the air from inside the mask. The particles are detected by a photometric light scattering or an optical single-particle counting technique. A probed respirator is required for each make, style model, and size that the employer uses and can be obtained from the respirator manufacturer or distributor (OSHA-Accepted Fit Test Protocols).

Contaminant: A harmful, irritating, or nuisance airborne material.

Controlled Negative Pressure (CNP): The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean
inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator (OSHA-Accepted Fir Test Protocols).

Feedback: A numerical value measuring the minimum leak rate that can be gotten from a respirator fitting with a normal donning.

Fit Factor: Fit factor has two different definitions: A) fit factor on the method of CNC is defined as a numeric assessment and B) fit factor on the method of CNP is defined as dividing a representative flow rate.

A: Aerosol (Controlled Negative Pressure) (CNP)

A numeric assessment of how well a tight-fitting respirator facepiece fits a wearer during a quantitative fit test. It is the ratio of the concentration outside the facepiece ($C_{out}$) to the concentration inside the facepiece ($C_{in}$) ($\text{fit factor} = \frac{C_{out}}{C_{in}}$). It can also be expressed as 100% penetration.

B. Ambient Aerosol Condensation Nuclei Counter (CNC)

The fit factor is determined by dividing a representative inhalation flow rate by the measured leak flow rate.

Fit Test: The use of a challenge agent to determine an individual’s ability to obtain an adequate seal with a specific respirator.
Hazardous atmosphere: An atmosphere that contains a contaminant(s) in excess of the exposure limit or that is oxygen deficient.

Multi-donning: Putting on and removing the respirator many times

Qualitative fit test: A pass/fail fit test that relies on the subject's sensory response to detect the challenge agent.

Quantitative fit test: Quantitative negative fit test is defined as the physical measure of air penetration or leakage into the respirator facepiece in the case of negative control pressure.

Respirator: A personal protective device designed to protect the wearer from the inhalation of hazardous atmospheres.

Tight-fitting facepiece: A respiratory inlet covering that is designed to form a complete seal with the face. A half-facepiece (includes quarter masks, filtering facepiece, and masks with elastomeric [synthetic polymer] facepieces) cover the nose and mouth; a full facepiece cover the nose, mouth, and eyes (ANSI Z88.2 Standard. American National Standard Practices for Respiratory Protection 2000).
APPENDIX 2

EFFECT OF FEEDBACK ON REDUCTION OF RESPIRATOR LEAKAGE ASSOCIATED WITH MASK DONNING

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Abstract

The purpose of this study was to 1) assess the quality of fit for full face and half face respirators; 2) evaluate the effect of "feedback"* on respirator leak rate; and 3) evaluate the "donning effect" (see Appendix 1). Ten study volunteers consisting of five males and five females were recruited for this study. They were subjected to daily leak rate measurements for full and half face respirators for a period of five consecutive days.

Half mask respirators have significantly lower leak rate than full face respirators (p-value < 0.0001). Feedback provided during the fit testing significantly improved the respirator fit and reduced leak rates by several hundredfold (p-value <0.0001). Multiple donnings performed each day had no significant effect on daily leak rate measurements for both respirator types.

The findings indicate that the respirator leak rates are significantly lower in half mask respirators, especially when subjects were given feedback about their fit testing. The finding is contradictory to American National Standard Institute's (ANSI) guidelines of higher Assigned Protection Factor (APF) for full mask respirator. Further studies are necessary to assess this finding and to amend respirator recommendations in the future.

* Feedback: A numerical value measuring the minimum leak rate that can be gotten from a respirator fitting with a normal donning.
Introduction

The success of human protection by an industrial respirator is associated with how much leakage occurs when it is worn in the workplace. Quantitative fit tests are conducted to determine if a respirator can offer a proper level of fit for a test participant. Even though donning has a major impact on respirator functioning, the extensive number of variables related to respirator donning is all too often overlooked during fit testing.\(^{(1)}\)

The fit of the respirator can be determined by qualitative and quantitative fit test methods which are used for industrial respirator fit testing. Fit Test (QLFT) (See Appendix 1) methods produce a detectable agent outside the respirator to determine if there is leakage into the respirator during a fit test.\(^{(2)}\) Current QLFT protocols are based on personal perception of odor, taste, or irritation and provide a pass/fail decision of respirator fit. Quantitative respirator fit testing (QNFT) (See Appendix 1) involves the physical measurement of detectable agent leakage into the respirator facepiece. For pressure-based QNFT systems, air is used as the test agent to measure leakage rate to total airflow into the respirator.\(^{(3)}\)

Quantitative Fit Test protocols of respirators are usually defined as a series of fit test exercises with a single mask donning. The issue of mask donning was not addressed in the Occupational Safety and Health Administration (OSHA) respirator protection standards.\(^{(4)}\) Likewise, the rationale for the protocol that is used is generally not available and there is little information accessible that describes the effectiveness of multiple mask donnings for protection in a hazardous atmosphere.\(^{(3)}\)
Controlled Negative Pressure (CNP) technology exhausts air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The controlled rate of air exhaust provides a constant negative pressure that is maintained in the respirator during the fit test. The level of pressure selected replicates the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is exactly equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator.\(^5\)

The need for multiple donnings is important because of the variables that change the fit of a respirator, i.e., there is strap tension, positioning on the face, facial hair and other variable such as “moisture, natural oils and debris from the work place.”\(^5\)

Fit testing usually involves only one test based on a single mask donning. Once the masked is donned, it is no longer considered a variable in the fit test. However, findings show that “donning affects respiratory fit to a greater degree than fit test exercises.”\(^2\)

QNFT outcomes need to be redetermined in terms of respirator leakage based on best fit (feedback), which are apt to magnify small changes in leakage. Multiple mask donnings have been shown to be more successful in pinpointing inadequate respirator fit.\(^1\)
Test Procedure

A facial fit test to determine leakage by creating a negative pressure inside the facepiece similar to normal inspiratory pressures was conducted using a half-mask respirator and full facepiece respirator. This study investigated the donning effect of the respirator on the fit test by five male and five female participants donning the mask five times each. Men were asked to shave their beards everyday before the test. This test used three trial readings of the leak rate of the respirator. Second the study involved the same test on the same participants with a feedback fitting.

Study Objective

The two major objectives of this study were to: (1) examine the effects of feedback on respirator donning on measured leak rate, best fit effect, and (2) assess the capability of a modified protocol to efficiently detect poor respirator fit with different levels of fit.

Methods and Materials

A Fit Tester Model 3000 Control Negative-Pressure QNFT System (Dynatech Nevada, Carson City, NV) was used during the study (see photograph 1). Leak rate of air to the respirator was measured directly in ml/min for each number of tests, trials, and feedback and provided an individual measurement.

These measurements for mask leak rate were considered one test and this test was applied to two different mask types (full face and half mask) (Mine Safety Appliance Co., Pittsburg, Pa., Code #471329 full face and Code# 490492 half mask) (see Photography 2 and 3).
Photograph 1. Fit Tester 3000 Control Negative-Pressure QNFT System
Photograph 2. A subject performing a fit test with half-face respirator
Photograph 3. A subject performing a fit test with a full-face respirator
Measurements were repeated for five separate days during the study for the purpose of determining the learning by the volunteer subjects after training for the fit test measurements.

**Human Subject Tests**

Ten human test volunteers, 5 males, one Middle Eastern, two Anglos and two Hispanics, ages 20-60, and 5 females, one Middle Eastern, two Anglos and two Hispanics, ages 20-35) were engaged in multiple donnings of medium and large full-face and half mask respirators. They also engaged in best fit and non best fit (Appendix 1).

Each subject, who participated in the study, had completed a respirator/fit-test familiarization course. The training course involved 5-10 minutes of donning the mask, holding the breath and measuring the leak rate. Men were asked to shave daily to prevent any growth of hair that could interfere with the respirator seal. Each subject was asked to maintain a calm exterior position (not moving) while sitting on a chair with a straightforward look during the test.

A study objective was to acquire relatively extensive data by having each subject repeat 15 times each type of respirator, for each donning for five times, and for each feedback (with or without) for each day over a period of five days.

Three different mask sizes, small, medium, and large, were examined with all participants. The small size was inadequate for all 10 subjects. Eight of the 10 were fitted with large size masks and two with the medium size ones.
The series consisted of repeated sequential fit tests for three times on the same donning for the same type of respirator on the same day for each feedback and no feedback.

Two different sizes of the MSA air purifying respirator model and elastometric (synthetic polymer) type (full-face, half-mask) were given to each subject. Each subject completed five donning fit tests per day of both assigned respirators (full-face and half-mask) for a period of 5 consecutive days (i.e., 10 subjects x two masks/subject x three trials/fit test/mask/day x five donning fit tests x 2 (feedback or no feedback) x five days = 3000 total fit tests. The respirator was removed and re-donned by the subject between each fit test. This study design allowed the fit of each subject’s two assigned respirators to be assessed on the basis of 25 individual mask donnings over the course of a 5 day period.

Major calibrations of the CNP system for pressure and flow-rate transducers were performed at the beginning of the study for each day. The calibration involves installing test manifolds in the cartridge receptacles of the test respirator to temporarily seal its air-purifying path.

Statistical Analysis

Statistical analyses were performed using STATA® 8.0 (College Station, TX). Graphics were produced using Microsoft Excel® or NCSS 97 (Orem, Utah). Independent two-sample t-tests were used to compare mean leak rates between males and females, between full- and half-face mask types, and for each mask type with and without feedback. A paired sample t-test was used to evaluate potential learning effects. All tests were two-tailed unless otherwise specified.
Results and Discussion

Table 1 shows the mean measured leak rate as a function of gender, respirator type and feedback status. The measured mean leak rate for half-mask respirators was 88% lower than the mean leakage measured with full-face respirators. Also, the mean leak rate in the group that received feedback on donning effectiveness was 78% lower than measurements made without feedback.

Table 1. Mean Leak rate by Gender, Respirator Type and Feedback Status

<table>
<thead>
<tr>
<th>Category</th>
<th>Leak Rate, cc/min</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>191.62 ± 421.74</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>189.58 ± 383.54</td>
<td></td>
</tr>
<tr>
<td>Respirator Type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full Face</td>
<td>339.96 ± 514.09</td>
<td></td>
</tr>
<tr>
<td>Half Mask</td>
<td>41.25 ± 126.63</td>
<td></td>
</tr>
<tr>
<td>Feedback</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>68.51 ± 77.20</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>312.70 ± 537.75</td>
<td></td>
</tr>
</tbody>
</table>

Notes:

'Includes leak rate data from two types of respirators and two different feedback statuses.

"Includes leak rate data from two feedback statuses, and both male and female subjects.

"Includes data from two types of respirators and both male and female subjects.

'Mine Safety Appliances Co., Pittsburgh, Pennsylvania

A histogram of measured respirator leak rate data is shown in Figure 1. As the distribution of these leak rates is highly skewed to the right, a lognormal transformation was performed to normalize the distribution for subsequent statistical comparisons using parametric methods. A distribution of In-transformed data are shown in Figure 2.
Figure 1. Histogram of Untransformed Leak Rate Data (n=3000)

Figure 2. Histogram of Untransformed Leak Rate Data (n = 3000)
To compare the differences in leak rate by gender, a series of normality tests were performed on log transformed leak rates. The results are provided in Table 2. In case of females, normality of ln-transformed leak rates was not significant. At least one normality test for each gender confirmed the assumption of normality of ln-transformed data for each gender. One test of equality of variance indicates that the variance is equal in both groups.

Table 2. Assumptions about Measured Leak Rate Data

<table>
<thead>
<tr>
<th>Assumption Test</th>
<th>Test Value</th>
<th>Probability</th>
<th>Decision (5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normality in Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skewness Normality Test</td>
<td>0.9454</td>
<td>0.344</td>
<td>Cannot reject normality</td>
</tr>
<tr>
<td>Kurtosis Normality Test</td>
<td>-3.2229</td>
<td>0.001</td>
<td>Reject normality</td>
</tr>
<tr>
<td>Omnibus Normality Test</td>
<td>11.2806</td>
<td>0.003</td>
<td>Reject normality</td>
</tr>
<tr>
<td>Normality in Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skewness Normality Test</td>
<td>2.2453</td>
<td>0.024</td>
<td>Reject normality</td>
</tr>
<tr>
<td>Kurtosis Normality Test</td>
<td>-0.6276</td>
<td>0.530</td>
<td>Cannot reject normality</td>
</tr>
<tr>
<td>Omnibus Normality Test</td>
<td>5.4351</td>
<td>0.066</td>
<td>Cannot reject normality</td>
</tr>
<tr>
<td>Variance by Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variance-Ratio Equal Variance Test</td>
<td>1.0928</td>
<td>0.086</td>
<td>Cannot reject equal variances</td>
</tr>
<tr>
<td>Modified-Levine Equal-Variance Test</td>
<td>9.0086</td>
<td>0.002</td>
<td>Reject equal variances</td>
</tr>
</tbody>
</table>

\(^{1}\)Normality assumption tests were performed using NCSS97 (Orem, Utah) statistical software
The In-transformed mean respirator leak rates for males and females were not found to be significantly different by an independent two-sample t-test (p-value = 0.53, α = 0.05). Since no significant difference was found between gender-specific leak rates, these two groups were combined into a single group for further analyses.

The mean leak rate for half-mask respirators is approximately 88% lower than that measured for full-face respirators. The In-transformed leak rate for half-mask respirators is significantly less than In-transformed full-face respirator leak rates (p-value = <0.0001, α = 0.05). These data indicate that half-mask respirators fit this study population much better with significantly lower leak rates. The perimeter of a full-face mask is approximately twice as large as that of a half mask, and the area of contact may be more irregular. This could contribute to the higher leak rates observed in the full-face mask type. This finding directly contradicts the respirator use recommendations of ANSI, which suggest a higher assigned protection factor (APF = 50) and lower leak rates for a full-face respirator. Further studies are necessary to more adequately quantify the differences in leak rates between these respirator types in a larger population. To evaluate the effect of feedback on measured respirator leak rates, an independent t-test was performed on In-transformed leak rates of both mask types. The leak rates are significantly lower in the group where feedback was provided (p-value <0.0001, α = 0.05). Minor adjustments to mask fit achieved with feedback resulted in a significant reduction in leak rates in both full and half face respirators. Table 3 shows the mean leak rate of each group by mask type and feedback status.
Table 3. Measured Respirator Leak Rate by Mask Type and Feedback Status

<table>
<thead>
<tr>
<th>Mask Type</th>
<th>N</th>
<th>Feedback</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Half Mask(^1)</td>
<td>750</td>
<td>21.85 ± (37.09)</td>
<td>60.65 ± (173.09)</td>
</tr>
<tr>
<td>Full Face Mask(^1)</td>
<td>750</td>
<td>115.16 ± (78.70)</td>
<td>564.76 ± (649.26)</td>
</tr>
</tbody>
</table>

* The differences are highly significant on two-sample t-test (parametric) on log transformed leak rate data assuming unequal variances (\(\alpha = 0.05\))

Data from: Mine Safety Appliances Co., Pittsburgh, Pennsylvania

The measured leak rate was lowest in half-mask groups when feedback was provided, and it was highest in full-face respirators where feedback was not provided. Feedback alone provided approximately 80% and 64% reductions in measured leak rates of full- and half-mask respirators respectively. Figure 3 provides a graphical representation of leak rates in both mask types by feedback status.

Figure 3. Leak Rates by Mask Type and Feedback Status (FB)
Feedback appeared to substantially reduce the donning effect variation associated with removing and re-donning respirators by effectively reducing the leak rates in both respirator types.

Table 4 shows daily mean leak rates of all subjects by mask type and feedback status. The leak rates did not change over multiple days in most cases, indicating that there was no learning effect.

Table 4. Daily Mean Leak Rate by Mask Type and Feedback

<table>
<thead>
<tr>
<th>Mask</th>
<th>Feedback</th>
<th>Day (Leak Rate: cc/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>FF</td>
<td>No</td>
<td>385.29</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>131.82</td>
</tr>
<tr>
<td>HM</td>
<td>No</td>
<td>48.61</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>17.57</td>
</tr>
</tbody>
</table>

*FF = Full Face Mask, HM = Half Face Mask

Figure 4 shows daily changes in leak rate over five days with no feedback provided. Figure 5 shows daily changes in leak rate when feedback was provided. Although leak rates are much lower than in the no-feedback group, there is no learning effect involved due to adjusting masks for repeated trials of mask fit testing over different days.
Figure 4. Daily Leak Rates by Mask Type with No Feedback
(FF = Full Face Mask, HM = Half Face Mask)

Figure 5. Daily Leak Rates by Mask Type with Feedback
(FF = Full Face Mask, HM = Half Face Mask)
Overall, the leak rates did not decrease significantly from day 1 to day 5, indicating that there was no learning effect involved in repeated test trials over multiple days.

Conclusion

Overall no significant differences were found for male or female participants. However, respirator leak rates are significantly lower in half face mask respirators, indicating a higher quality of fit. Feedback provided during fit testing significantly improved the fit and reduced leak rates in both respirator types. Contrary to expectations, multiple donnings performed each day seemed to have no significant effect on leak rates.

Recommendations

Although the full face respirator is recommended by ANSI as offering better protection against hazardous materials, the current research indicates that the half mask respirator provides better protection by using the feedback method. Feedback is important because it improves the fit testing procedure and is recommended for determining the quality of fit. Another recommendation is to use goggles with the half mask respirator to protect the eye.
### Table A: Fit Tester Orifice Calibration Data (Study 1)

<table>
<thead>
<tr>
<th>Day</th>
<th>50</th>
<th>80</th>
<th>110</th>
<th>140</th>
<th>170</th>
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<td>43</td>
<td>77</td>
<td>119</td>
<td>169</td>
<td>226</td>
<td>290</td>
<td>361</td>
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<td>2</td>
<td>19</td>
<td>43</td>
<td>76</td>
<td>118</td>
<td>167</td>
<td>224</td>
<td>288</td>
<td>360</td>
</tr>
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<td>3</td>
<td>18</td>
<td>42</td>
<td>76</td>
<td>118</td>
<td>167</td>
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SD = Standard Deviation  
COV = Coefficient of Variation = (SD*100/Mean)
References


APPENDIX 3

COMPARISON OF RESPIRATOR LEAKAGE ASSOCIATED WITH FACIAL HAIR GROWTH IN TWO ETHNIC GROUPS

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Clifton D. Crutchfield²

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Environmental and Occupational Health, College of Public Health²

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*Corresponding author
Abstract

The purpose of this study was to assess the effect of various physical attributes of beard on respirator leak rates in two ethnic groups. Five study volunteers each of Middle Eastern and Anglo-Saxon ethnicity were selected for this study. They were asked not to shave for a period of two weeks and subjected to a daily leak rate measurement using a Control Negative Pressure (CNP) fit tester (see Appendix 1). At the end of the study the beard hair was collected and hair length and diameter were measured to study the association between hair characteristics and respirator leak rates.

A significantly higher length and diameter was observed in the Anglo-Saxon group. However, the leak rate was not significantly different between these ethnic groups. Independently, both hair length and diameter were not significantly correlated to leak rate but an interaction term generated to explain the aspect ratio was inversely correlated with leak rate on day ($r=0.64$, p-value = 0.048). The daily respirator leak rates increased exponentially over a twelve-day period with a significant change occurring between day 4 and day 5. A second order regression equation was plotted to accurately predict the respirator leak rate with the age of beard. We conclude that beard hair attributes can be used to predict respirator leak rate.
Introduction

Respirators are used for protection in hazardous environments. To be effective they must have a good facepiece to facepiece seal between the flange and the wearer's face. Factors that can interfere with this seal are beard growth, facial hair, moustaches and sideburns, thus calling into question the protective value of the respirator for the wearer. It has been found that wearers with different amounts of hair have an effect on the performance of a respirator and that the degree is based on the hair interference, the sealing capacities of the mask and the type of mask worn because some masks are roomier than others.\(^{(1)}\)

In a study of the effect of facial hair on the face seal of negative-pressure respirator on bearded subjects, it was found that the presence of a beard greatly increases the leakage of the respirator face seal.\(^{(2)}\) The explanation for this is found in three components: diameter, length and density of the beard. The conclusion was that beards should not be permitted when employees are required to wear a respirator. Another study\(^{(2)}\) found that there was a difference in rate of beard growth of pigmented and white anagen beard hair (0.47 mm/day vs. 1.12 mm/day).\(^{(3)}\) On average beard growth produces hair length of half a millimeter per day. \(^{(4)}\) Also hair diameter is classified from very fine which is less than 60 micrometers to more than 80 micrometers which is coarse hair. \(^{(5)}\) In a study of four clean shaven men, the first three days showed that hair penetration through the mask was greatest but continued to show variations from day to day. This indicated that even small moustaches, small Van Dyke beards and short to medium length sideburns would cause difficulty with the sealing surface of the mask. It was concluded
that the most vulnerable wearer was the one with a very full 2 to 2 ½" long wiry beard that extended back under the chin and was long at the jaw line. In reviewing a series of studies from 1964 to 1987, all but two studies showed a 20 to 1000 times leakage rate due to hair presence compared to a clean shaven face. Another factor is that hair growth is greater in summer than winter. For this reason hair appears to be under the cyclical influence of hormones which are known to be more active in summer than winter, but can vary from individual to individual.

Several factors have emerged from these studies. (1) The effect of time on the growth of a beard is not the same for each participant. (2) A beard is not static because it keeps changing from day to day. (3) Because hair interferes with respirator seal, individuals with a beard may be placing themselves in jeopardy.

Two types of respirators, Elastomeric Respirators and particulate Filter Respirators (half-mask [Fig 1] and full facepiece [Fig. 2]), used by workers in industry, fire fighters, military men and health care professionals for protection against chemical or biological agents or airborne diseases, are not effective with facial hair. While the Occupational Safety and Health Administration (OSHA) have granted the usage of these rubber respirators by industry workers, fire fighters, military men and health care professionals, studies conducted by OSHA show that there is some leakage caused by facial hair (beard). The purpose of this study was to examine the leakage rate on best fit between two ethnic groups to determine the impact beard growth will cause on leakage of the hazardous atmosphere into the interior of the respiratory-inlet covering.
Controlled Negative Pressure (CNP) technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is exactly equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator.\(^\text{(11)}\)

**Materials and Methods**

A fit Tester Model 3000 Control Negative Pressure QNFT (Dynatech Nevada, Carson, NV) was used during the study (see photograph 1). Leak rate of the air in ml/min was measured directly for each fit test with a feedback.\(^2\) For each day during the 12 day period, the half-mask respirator was used only to determine beard growth effect on the seal of the respirator (see photograph 2).

Measurements were repeated for five times every day during the 12 day period except for the weekend (day 6 and day 7) during the study. Therefore, the total is 10 different days.

Major calibrations of the CNP system for pressure and flow-rate transducers were performed at the beginning of the study each day (Crutchfield, Park, Hensel, Kvesic, &

\(^2\) Feedback: A numerical value measuring the minimum leak rate that can be gotten from a respirator fitting with a normal donning.
Photograph 1. Fit Tester 3000 Control Negative-Pressure QNFT System
Photograph 2. A subject performing a fit test with half-face respirator
Calibrations involve installing test manifolds in the cartridge receptacles of the test respirator to temporarily seal its air-purifying path. Optimum leakage of the respirator and the type of beard/hair that caused the leakage was obtained by comparing the results of the fit tests in relation to beard growth. These results were then compared between the two ethnic groups to determine which group had more leakage.

**Experimental Approach**

A facial fit test to determine leakage by creating a negative pressure inside the facepiece similar to normal inspiratory pressures was conducted using a half mask respirator. This study was performed to investigate the effectiveness of a respirator for the protection of a worker from a hazardous atmosphere. The study involved the same test on the same participants with a best fit for two ethnic groups to record the least amount of leak rate measurement for each. Trials were conducted until a minimum leak rate was established.

Ten men from two different ethnic groups: five Anglo-Saxons, ages 23 – 60, and five Middle Easterners, ages 23-40, were fit tested.

The test was conducted for a period of 12 days, starting from the shaven face to the end of the test in which the men had not shaven. Every day the Quantitative Fit Test (QNFT) (see Appendix 1) was performed, except for the first week end (Saturday and Sunday). At the end of the period, the facial hair was razor-shaved in a one inch square and 10 hairs were collected. The diameter and length of the facial hair were described under the light of the microscope.

The QNFT was used as the fundamental component for selecting the best fitting respirator for a given worker to achieve a desired level of protection in the workplace. QNFT is based on the use of controlled negative pressure (CNP).
Human Subject Tests

The human subject protocol involved 10 volunteer subjects: 10 males with a mature beard from two different ethnic groups 1) Middle Eastern and 2) Anglo-Saxon, and a control sample of 5 females.

Each male who participated in the study completed a 5-10 minute respirator/fit-test familiarization training course which involved donning the mask, holding the breath, measuring the leak rate and maintaining a calm exterior position (not moving) while sitting on a chair with a straightforward look during the test (see photograph 2).

All subjects were required to razor-shave on the first day of the study only and then to refrain from shaving any facial hair growth for the rest of the 12 day period. (See photographs 3a, 3b, 4a, and 4b). At the end of the 12 days, the male subjects were required to shave or collect 10 hairs as a minimum sample size. These collected hairs were measured in mm as to length with the Peak Scale Lupe 7X (Tohkai Sangyo Co., Ltd., Tokyo Japan).

The diameter of the collected hairs was measured with the light microscope with a 10 X 40 Power. Calibrations were done to the scale of the ocular lens of the microscope, thus giving the width of hair in millimeters.

Two different sizes, medium and large, of the MSA air purifying respirator model and elastometric (synthetic polymer) type (half-mask) (Mine Safety Appliances Co., Pittsburg, Pa., Code# 490492) were given to each subject. Two wore a medium half-mask and eight wore a large half-mask Each subject completed 5 fit tests per day of the
Photograph 3a. A Middle Eastern subject with a 12 day beard growth
Photograph 3b. A Middle Eastern subject with a 12 day beard growth
Photograph 4a. An Anglo Saxon subject with a 12 day beard growth
Photograph 4b. An Anglo Saxon subject with a 12 day beard growth
assigned half-mask respirator for a period of 12 days (i.e., 10 subjects/one mask/subject/5
trials/fit test/mask/five day = 250 total fit tests for subjects.

A comparison was done at the end of the study between the two ethnic groups.
Measurements were taken to determine which group had more leakage everyday and for
each day in which there was a noticeable peak of the leak rate. The results were then
compared for both ethnic groups.

Statistical Analysis

Statistical analyses were performed using STATA® 8.0 (College Station, TX).
Graphics were produced using Microsoft Excel® or NCSS 97 (Orem, Utah). A two-
sample t-test was used to compare the mean leak rate, hair length, and diameter between
Middle Eastern and Anglo-Saxon ethnic groups. All tests were two-tailed unless
otherwise specified. Correlations were evaluated using Spearman’s correlation
coefficient.

Results and Discussion

A series of statistical tests were performed to assess the effect of beard length and
diameter on respirator leak rate. A histogram of length and diameter of beard hair
collected on day 12 was plotted to assess the normality of the distribution in each group.
(Figure 1 through 4).
Figure 1. Histogram of Hair Length in Middle Eastern Group

Figure 2. Histogram of Hair Length in Anglo-Saxon Group
Figure 3. Histogram of Hair Diameter in Middle Eastern Group

Figure 4. Histogram of Hair Diameter in Anglo-Saxon Group
Since these distributions appear to be normal, a two-sample t-test was performed to assess the differences among these ethnic groups. Both length and diameter are significantly higher in Anglo-Saxon group (p-value <0.001 and <0.002 respectively). The data is provided in Table 1.

Table 1. Hair Length and Diameter on Study Day 12

<table>
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<th>Group</th>
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<td>Middle Eastern</td>
<td>Anglo-Saxon</td>
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<tr>
<td>Length mm</td>
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<td>5.0 ± 0.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diameter mm</td>
<td>0.14 ± 0.02</td>
<td>0.16 ± 0.01</td>
<td>&lt;0.002</td>
</tr>
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</table>

The following histograms show the distribution of day 12 respirator leak rates in Middle Eastern and Anglo-Saxon group. As distribution of this data was not normal, a Wilcoxon Rank-Sum test was performed to assess the differences between these two groups, and the difference is not significant (p-value 0.92).
Figure 5. Leak Rate on day 12 cc/min

Figure 6. Leak Rate on Day 12 cc/min
Subjects from both ethnic groups were combined to examine the correlation among leak rate, beard hair length, and diameter. Neither hair length nor diameter, measured on 12 day of the study, were correlated with the respective study day's respirator leak rate. An interaction term of diameter over length (related to the aspect ratio of beard stubble) was positively correlated with measured leak rate ($r = 0.64$, $p = 0.048$). Figure 7 shows an exponential relationship between day 12 measured leak rate and diameter/length of stubble.

Figure 7. Correlation Between Leak Rate and Diameter Length

Figure 8 shows daily leak rate changes over a period of 12 days excluding weekend days. As expected, the mean leak rate was lowest on days 1 and 2 (22.9 and
22.5 cc/min) and highest on day 12 (491.8 cc/min). The largest daily leak rate change occurred between day 4 and 5 (increase of 137%). As shown in Figure 8, a second order regression appears to more than adequately describe the relationship observed between leak rate and beard growth over the twelve-day period. Added effects of beard hair characteristics such as texture and density could also contribute to the observed relationship, which is described by the following equation:

\[ y = 4.77x^{2} - 19.53x + 43.43 \quad (R^2 = 0.98) \]

Where:

- \( y \) = Respirator leak rate
- \( x \) = age of beard in days

![Figure 8. Mean Daily Leak Rate, cc/min (n = 10)](image)
Study Limitations

A larger sample size is necessary to compensate for inter-subject variability. Further studies are also needed to more fully quantify the effect of daily beard growth and its characteristics on respirator leak rate, and to compare and quantify the effects of various beard hair characteristics on respirator leak rate in other ethnic groups as well. The effect of beard growth on leakage into other types of respirators would also be useful.

Conclusions

Although individual hair characteristics are significantly different in these two groups, the study did not reveal significant differences in respirator leak rates. A higher sample size with daily hair sampling for a longer period of time might be necessary to accurately predict relative usefulness of respirators on an unshaven face. Irrespective of either group, the age of beard growth was positively correlated to respirator leak rate. Because of their higher functional interference with beard growth, only half face respirators were used in the study with appropriate fit. Further studies are needed to quantify the effect of beard growth on full face and quarter face respirators.
### Table A: Fit Tester Orifice Calibration Data (Anglo-Saxon)

| Day | Flow Rate (cc/min) / Pressure (Inches of H₂O) | 50  | 80  | 110 | 140 | 170 | 200 | 230 | 260 |
|-----|---------------------------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| 1   |                                             | 0.19| 0.43| 0.77| 1.18| 1.67| 2.24| 2.88| 3.58|
| 2   |                                             | 0.19| 0.42| 0.75| 1.14| 1.61| 2.16| 2.81| 3.49|
| 3   |                                             | 0.18| 0.42| 0.75| 1.16| 1.65| 2.21| 2.84| 3.56|
| 4   |                                             | 0.18| 0.43| 0.76| 1.17| 1.66| 2.11| 2.85| 3.57|
| 5   |                                             | 0.19| 0.42| 0.75| 1.15| 1.63| 2.18| 2.78| 3.47|
| 8   |                                             | 0.18| 0.42| 0.75| 1.17| 1.65| 2.22| 2.87| 3.59|
| 9   |                                             | 0.18| 0.42| 0.75| 1.17| 1.67| 2.22| 2.84| 3.52|
| 10  |                                             | 0.19| 0.43| 0.76| 1.1 | 1.67| 2.23| 2.84| 3.56|
| 11  |                                             | 0.19| 0.44| 0.77| 1.19| 1.68| 2.24| 2.86| 3.54|
| 12  |                                             | 0.18| 0.44| 0.76| 1.16| 1.64| 2.21| 2.86| 3.58|

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**SD** = Standard Deviation  
**COV%** = Coefficient of Variation = (SD*100/Mean)
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Mean: 0.19  0.43  0.77  1.17  1.68  2.24  2.87  3.58  
SD: 0.00  0.01  0.01  0.03  0.01  0.01  0.02  0.03  
COV%: 2.27  1.46  0.83  2.61  0.48  0.48  0.53  0.85  

SD = Standard Deviation  
COV = Coefficient of Variation = (SD*100/Mean)
References


(5) Retrieved 10/15/03 from www.forhair.com


APPENDIX 4

APPROVAL OF CONSENT LETTER
Mansour Balkhyour, M.S.
Advisor: Charles Gerba, Ph.D.
Department of Soil, Water/Environmental Science
Shantz Building, Room 217
PO BOX 210038

RE: HSC A00.53 EFFECT OF FACIAL HAIR ON RESPIRATOR PERFORMANCE

Dear Mr. Balkhyour:

We received your 23 May 2003 letter and accompanying revised Consent Form for the above referenced project. The submitted Consent Form has been revised to reflect that testing will be performed 10 times over 12 days versus 5 times during an 8-day period. Approval for use of the submitted Consent Form is granted effective 28 May 2003.

The Institutional Review Board (IRB) of the University of Arizona has a current Federalwide Assurance of compliance, FWA00004218, which is on file with the Department of Health and Human Services and covers this activity.

Approval is granted with the understanding that no further changes or additions will be made either to the procedures followed or to the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee (IRB) and your College or Departmental Review Committee. Any research related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

David G. Johnson, Ph.D.
Chairman
Biomedical Committee
UA Institutional Review Board (IRB)

cc: Departmental/College Review Committee
APPENDIX 5

CONSENT FORM
SUBJECT'S CONSENT FORM

EFFECT OF FACIAL HAIR GROWTH ON RESPIRATOR PERFORMANCE

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND OF HOW I WILL PARTICIPATE IN IT. IF I CONSENT TO DO SO, SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I GIVE MY CONSENT. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION IN THIS RESEARCH STUDY SO THAT I CAN KNOW THE NATURE AND RISKS OF MY PARTICIPATION AND CAN DECIDE TO PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

PURPOSE

I am being invited to participate voluntarily in the above-titled research project. The purpose of this project is to find what type of beard will cause more leakage of the atmosphere into the interior of the respiratory-inlet covering and when the beard will cause more leakage.

SELECTION CRITERIA

I am being invited to participate because I am one of 15 men who have a mature beard; or because I am one of 5 women (as control).

PROCEDURE

If I agree to participate, I will be asked to do a Quantitative Fit Test (QNFT). This test is done by wearing a mask connected with the Fit Tester. I will be asked to take a breath and hold it for 8 seconds pumping a negative air pressure from inside the mask. The Fit Tester will then give an average percentage leak rate of the air inside the mask. Men will be tested 10 times during a 12-day period of beard growth. At the end of that period of time I will be asked to shave my beard and let the Investigator collect my facial hair and characterize its weight, hair length diameter and other physical properties. Women will be tested 1 time only [as a control subject].

RISKS

There are no risks, and the test procedure is performed by industry on regular basis for product evaluation.
BENEFITS

There are no direct benefits to me personally from participating in this research.

CONFIDENTIALITY

The test results will not be identified by names; only by subject numbers.

PARTICIPATION COSTS AND SUBJECT COMPENSATION

There are no monetary costs. Testing time for men will be 120 minutes, and 10 minutes for women. I will not be compensated financially for my participation.

CONTACTS

I can obtain further information from the principal investigator MANSOUR BALKHYOUR, MS at (520)742-1111. If I have questions concerning my rights as a research subject, I may call the Human Subjects Committee office at (520)626-6721.

AUTHORIZATION

BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS, AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I MAY ASK QUESTIONS AT ANY TIME AND I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT CAUSING BAD FEELINGS. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT MY WILLINGNESS TO CONTINUE IN THIS RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECTS COMMITTEE WITH ACCESS RESTRICTED TO THE PRINCIPAL INVESTIGATOR, MANSOUR BALKHYOUR OR AUTHORIZED REPRESENTATIVE OF THE
SOIL, WATER AND ENVIRONMENTAL SCIENCE
DEPARTMENT. I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.

__________________________  ________________
Subject's Signature Date

INVESTIGATOR'S AFFIDAVIT

I have carefully explained to the subject the nature of the above project. I hereby certify to the best of my knowledge the person who is signing this consent form understands the nature, demands, benefits, and risks involved in his/her participation and his/her signature is legally valid. A medical problem or language or educational barrier has not precluded this understanding.

__________________________  ________________
Signature of Investigator Date