

Performance Characteristics of an Elastomeric Half-mask Respirator Modified with a Polymer Micro-Patterned Adhesive

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ABSTRACT

The objectives of this study were: to evaluate the fitting characteristics of an elastomeric half-mask respirator modified with a polymer micro-patterned adhesive applied to the sealing surface; to compare the performance of the modified respirator to that of a conventional (non-modified) one. Twenty-five adult subjects representing a NIOSH bivariate panel were tested with a modified and non-modified elastomeric half-mask respirators while participating in a standard OSHA fit testing protocol. NaCl particles were generated as the challenge aerosol and the concentrations inside and outside of the respirator were measured to determine the fit factor for each subject. Additional tests were performed with one subject under challenge facial conditions, including wet and/or unshaved face. The modified respirator produced a geometric mean (GM) fit factor of 7,907 with a geometric standard deviation (GSD) of 4.9 compared to GM=4,779 and GSD = 9.1 for the non-modified respirator ($p=0.07$, paired t-test). For all challenge facial conditions, the modified half-mask prototype was consistently achieving significantly ($p<0.05$) higher fit factors than the conventional half-mask. Applying a polymer micro-patterned adhesive to the sealing surface of an elastomeric half-mask respirator was found to improve respirator fit and showed promise towards improving performance with challenge facial conditions.

Keywords: elastomeric half-mask, polymer micro-patterned adhesive, fit testing

INTRODUCTION

Elastomeric respirators are commonly used to protect workers from various hazardous airborne particulates, e.g., firefighters are reported to use elastomeric half-masks equipped with highly efficient P100 filters during fire overhaul (after the fire has been extinguished) (Bolstad-Johnson et al., 2000; Burgess et al., 2001). Unlike filtering facepiece respirators (FFRs), elastomeric half-masks offer the benefits of reusability, enhanced user seal check capability, improved face seal, and can be decontaminated multiple times (Roberge et al., 2010).

According to the U.S. Occupational Safety and Health Administration (OSHA), every worker required to wear a tight fitting respirator such as the elastomeric half-mask shall be fit tested prior to initial use of the respirator (OSHA, 2006). There are two categories of fit testing: 1) qualitative fit test (QLFT), which relies on the wearer's ability to sense a test agent by taste, smell, or irritation, and 2) quantitative fit

test (QNFT), which assesses the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator, such as measuring the concentration of a test agent outside (C_{out}) and inside (C_{in}) the respirator. The ratio of the two (C_{out}/C_{in}) is called the fit factor (FF) (OSHA, 2006). A fit factor of 100 is the OSHA pass criterion for negative pressure elastomeric half-mask respirators.

One study involving three half-masks and ten FFRs tested on a panel of ten human subjects concluded that the FFs of elastomeric half-masks are higher than those of FFRs (Han et al., 2005). Considering that elastomeric respirators are equipped with P-100 filters that offer a collection efficiency at least as high as 99.97%, the overall performance of these respirators is largely dependent on their fit (Eshbaugh et al., 2008; Rengasamy et al., 2008; He et al., 2013a). Thus, efforts should be directed towards improving the fit of elastomeric respirators by reducing faceseal leakage. Many factors can interfere with a good face-to-respirator seal, e.g., positioning, strap adjustment, facial hair, facial scars, high cheekbones, excessive makeup, etc. Prior to the fit testing, a subject shall be free of stubble beard growth, beard, mustache or sideburns which cross the respirator sealing surface; no wetness on the subject's face is allowed. Accordingly, respirator fit-testing studies have usually been conducted under normal skin conditions (dry and clean-shaved). Thus, there are less data on respirator performance using other challenge conditions such as wet and/or unshaved skin.

Conventional elastomeric respirators have a flexible smooth sealing surface extending around the periphery and exhibit a uniform seal surface contour, which aims at creating a good faceseal (Beard, 1994; Starr et al., 1996; Barnett et al., 1999; Belfer et al., 1999). One component of obtaining an effective seal is to be clean shaven prior to respirator donning. However, this requirement, cannot be met consistently in certain situations, e.g., in the battlefield or when respirators are needed during unforeseen emergency situations. The presence of sweat, facial hair, oil, dirt, or acne on facial skin could compromise the effectiveness of peripheral seals and thus negatively affect the performance of a conventional elastomeric respirator. To address the faceseal leakage issues, a conventional elastomeric half-mask was modified to reduce the faceseal leakage. A polymer micro-patterned adhesive (PMA) inspired by gecko-foot was applied to the peripheral area of the half-mask to improve its fit performance. The micro-and nano-fibrillar structure and unique capabilities of gecko-foot have intrigued biologists and engineers for many years. Development of PMA has been actively pursued in recent years (Del Campo and Arzt, 2007; Del Campo, Greiner, et al., 2007; Greiner et al., 2007; Murphy et al., 2009); PMAs based on arrays of relatively soft elastomeric fibrils such as polydimethylsiloxane (PDMS) and polyurethane (PU) have been fabricated to mimic gecko's adhesion mechanism (Kim et al., 2006; Del Campo and Arzt, 2007). The adhesion capacity of these synthetic adhesives can reach or even surpass that of gecko-foot (Qu et al., 2008). However, PMAs are not inherently leak-resistant; permeation can occur through the gaps between the micro-fibrils, compromising their sealing qualities (Lu et al., 2012).

For this study, the sealing qualities of PMA was enhanced through patterning of polymer microfibrillar structure by incorporating continuous micro-ribbons around fibrillar regions (Lu et al., 2012); and a conventional elastomeric respirator was modified with the PMA applied to the sealing surface. The modified respirator was then fit tested on a NIOSH bivariate (face length and width) 25-subject panel using the standard OSHA fit testing protocol (OSHA, 2006; Zhuang et al., 2007). One of these 25 subjects then participated in a pilot study designed to investigate the fitting characteristics of the modified respirator with less than ideal facial conditions.

MATERIALS AND METHODS

Fabrication of Polymer Micro-patterned Adhesive (PMA)

PMA was produced by soft-molding of elastomeric precursors on a photolithographically formed master template. The template was fabricated following a procedure described elsewhere (Del Campo, Greiner, et al., 2007). Fibrillar arrays were made with PU (ST-3040, Tustin, Inc., Tustin, CA, USA). The templates were silanized with heptadecafluoro-1,1,2,2-tetrahydrooctyltrichlorosilane (hepta-fluorosilane). Gas-phase silanization was performed in an evacuated desiccator for one hour, followed by baking at 95°C for one hour. The PU ST-3040 A and B (20:17 by weight) mixture was degassed and poured on the silanized template. After curing at room temperature in light vacuum over 24 hours, the PU was demolded to avoid rupture of the polymer micro-fibrillar array. The micro-patterned structure had micro-fibrils 20 μm in diameter and 20 μm long with a center-to-center distance of 30 μm . In addition, every 60 rows of micro-fibrils were incorporated with one continuous micro-ribbon 20 μm wide, as shown in Figure 1. The total thickness of the elastomer sheet (with fibrillar surface) was approximately 1 mm.

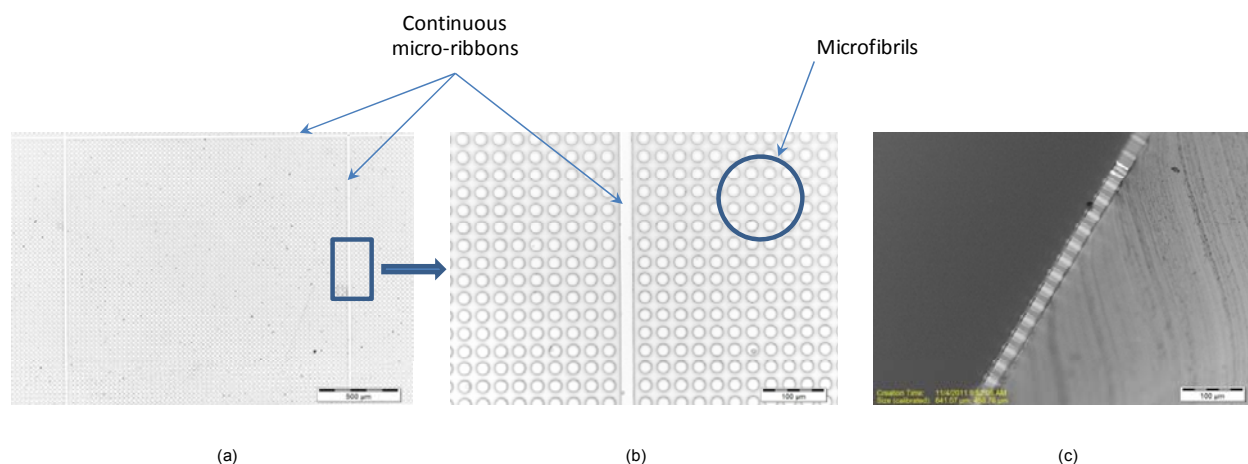


Figure 1. Optical microscope images of PU microfibrillar arrays incorporating micro-ribbons: (a) top view at a magnification of 40 $\times$ – presents the structure inside the area bordered by the continuous micro-ribbons, (b) insert magnified at 400 $\times$; and (c) side view.

Respirators

This study was performed using a conventional elastomeric half-mask respirator equipped with two P100 pancake-shaped filters (Model: 2091, 3M, Minneapolis, MN, USA). The chosen respirator model (Model: 6000 series, 3M) is widely used in a variety of occupational environments; it was examined in our recent studies (He et al., 2013a; 2013b) and available in three sizes (small, medium and large). The respirator was modified by manually attaching PMA strips on the sealing surface of the half-mask respirator (see Figure 2). A non-modified version of the same respirator model and size was used for comparison. The two half-masks (conventional and modified) are shown in Figure 2. An 11 mm long flush probe with a 14 mm diameter flange and a 4 mm diameter inlet was mounted on the surface of the respirator centerline approximately 25 mm from the manikin's nose/mouth. The end of the probe (14 mm flange) was flush with the interior surface of the half-mask.



Figure 2. A conventional and modified elastomeric half-mask respirators (same model).

Human Subjects and Test Conditions

Initially, 120 subjects were identified as available for screening. Twenty-five of these adult subjects were selected for fit testing. The selected subjects included all ten cells of the NIOSH bivariate 25-subject panel (see Figure 3). Of the selected subjects, six had relatively small faces (cells # 1, 2, and 3), six had large faces (cells # 8, 9, and 10), and thirteen had medium faces (cells # 4, 5, 6, and 7). The tested cohort included 17 male and 8 female subjects; among them 13 were Caucasians, 8 Asians, and 4 African Americans/African origins. All subjects were medically cleared by completing an OSHA respirator medical clearance questionnaire. The study received an approval from the University of Cincinnati Institutional Review Board.

The subjects were asked not to eat or drink for at least one hour prior to the fit test. The main phase of this study was performed according to the standard OSHA fit testing protocol; accordingly, the 25 subjects involved in this phase were clean-shaved with dry faces and were fit-tested once with each respirator. For the pilot study, one male subject was fit tested with both respirators under the following facial conditions: dry-shaved (non-challenge condition), wet-shaved, dry-unshaved, and wet-unshaved. The “unshaved” facial condition was created after not shaving for ~40 hours with the length of the facial hair < 1 mm covering up to 30% of the subject’s face area. This condition is believed to reflect many real-life respirator usage situations in the military, the general population, and during certain unforeseen emergency situations. The “wet” face condition was created by applying a handful of water to the face using two hands, patting lightly with a napkin to remove large water droplets, and then waited for 30 seconds before donning the respirator. This condition was intended to simulate a wet sealing when a respirator is worn for some time. In this phase of the study, three replicates were conducted for each of the four above-listed combinations.

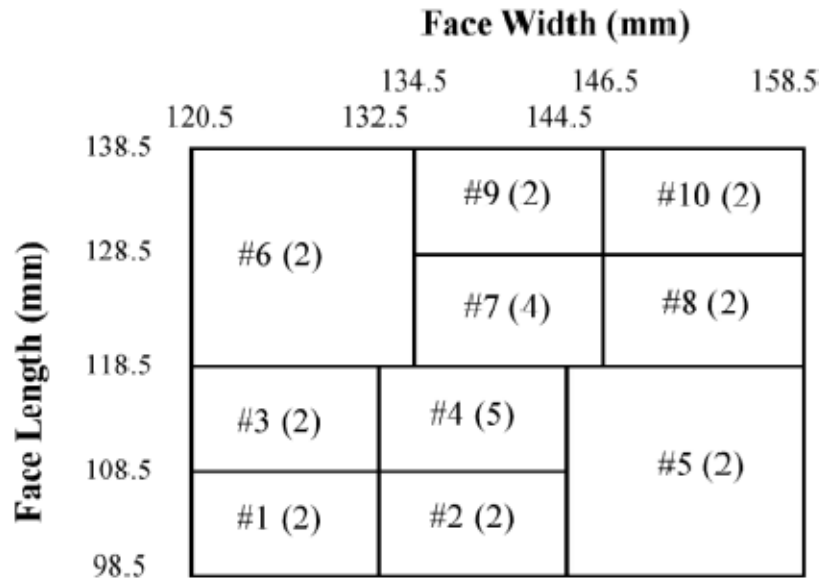


Figure 3. The NIOSH 25-subject bivariate panel. Number of subjects is given in parenthesis after the panel number.

Measurements

The study was conducted in a room-size respirator test chamber (24.3 m³). The challenge aerosol, NaCl, was generated using a particle generator (Model: 8026, TSI Inc., St. Paul, MN, USA). The concentration inside the chamber was maintained at 30,000 to 60,000 particles/cm³ (such high ambient concentrations were chosen to assure that enough particles would be detected inside a well-fit respirator). For each subject, two fit tests were performed: one with the non-modified half-mask respirator and the other modified with the PMA. A PortaCount Plus (Model: 8020, TSI Inc.) was used to measure the aerosol concentrations outside and inside the respirator.

Prior to fit testing, all respirators were visually examined to eliminate any obvious defects or damages. Each tested subject was asked to select the respirator size (small, medium, or large) that provided the most comfortable fit. Prior to donning each subject was shown how to don the respirator and how to adjust strap tension. After the respirator was donned and straps were properly adjusted, a positive pressure user seal check was performed. Subsequently, the subject was fit-tested while performing the standard set of OSHA respiratory fit testing exercises: 1) normal breathing, 2) deep breathing, 3) turning head side to side, 4) moving head up and down, 5) talking, 6) grimace, 7) bending over and 8) returning to normal breathing. The individual and overall FFs were recorded for each subject. Based on the PortaCount-measured concentrations, each exercise-specific FF value was calculated as below:

$$FF_i = \frac{(C_{out})_i}{(C_{in})_i} \quad (1)$$

where FF_i is the fit factor for the i^{th} exercise, $(C_{out})_i$ and $(C_{in})_i$ are the aerosol concentrations measured outside and inside the respirator, respectively, for each exercise. The overall fit factor (FF) was determined according to the OSHA fit testing protocol with exclusion of the fit factor for the grimace exercise (OSHA, 2006).

The modified/non-modified respirator was chosen in random order and tested on a subject. Each subject was fit tested twice (one for each type). After the first fit test the straps and yoke were removed from the respirator body and attached to the alternative respirator; this was accomplished without any adjustment to the straps themselves. We expected that the above procedure would eliminate and/or reduce variability due to strap adjustment.

Data Analysis

Data analysis was performed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). The FF data were log-transformed. For comparison of respirator type (non-modified versus modified), paired t-test was performed using all 25 subjects' FF data. One-way analysis of variance (ANOVA) was performed to study the differences among exercise-specific FFs. For FF results obtained under various facial challenge conditions, paired t-test was performed to compare the difference in FF between the non-modified and the modified respirator.

RESULTS AND DISCUSSION

Tests under Normal Facial Condition (Dry and Shaved Face, 25 Subjects)

The overall fit factor data for the non-modified and modified half-masks are presented in Figure 4. FF values for the modified half-mask ranged from 159 (subject #T06) to 57,700 (subject #T11); geometric mean (GM) = 7,907 and geometric standard deviation (GSD) = 4.9. Since each respirator was equipped with P100 filters that are known to be at least 99.97% efficient when used against NaCl particles (results presented in He *et al.*, 2013a). Therefore, a FF < 3,333 indicates face seal leakage, and 28% of subjects wearing the modified half-mask had FF < 3,333. Consequently, 72% of the tested modified respirators exhibited the particle penetration solely within the filter efficiency limit (allowing no measurable penetration through the face seal leakage). Furthermore, the majority of fit tests on the modified respirators had FF greater than 10,000. Only two subjects (#T06 and #T09) had overall FF's between 100 and 1,000.

The non-modified respirator had overall FF's ranging from 37 (subject #T10) to 92,800 (subject #12), with a GM = 4,779 and GSD = 9.1. The range and variability of the non-modified respirator were considerably greater than those for the modified one. Ten subjects (40%) had FF < 3,333 suggesting facesal leakage was present in the non-modified respirator compared to 28% tested with the modified respirator.

Based on the comparison of the data presented in Figure 4, the performance of the modified half-mask appeared to be better than that of the non-modified. When tested with the modified respirators, FF values exceeded 100 (the OSHA fit test passing criterion) for all 25 subjects, whereas 24 of 25 subjects wearing the non-modified respirators had FF > 100. However, paired *t*-test showed that this difference was not significant ($p = 0.07$, considered to be a boarder-line significance). Very high fit factors and between-subject variability were identified in this study, especially for the non-modified respirator, which presents a challenge in identifying statistical significance.

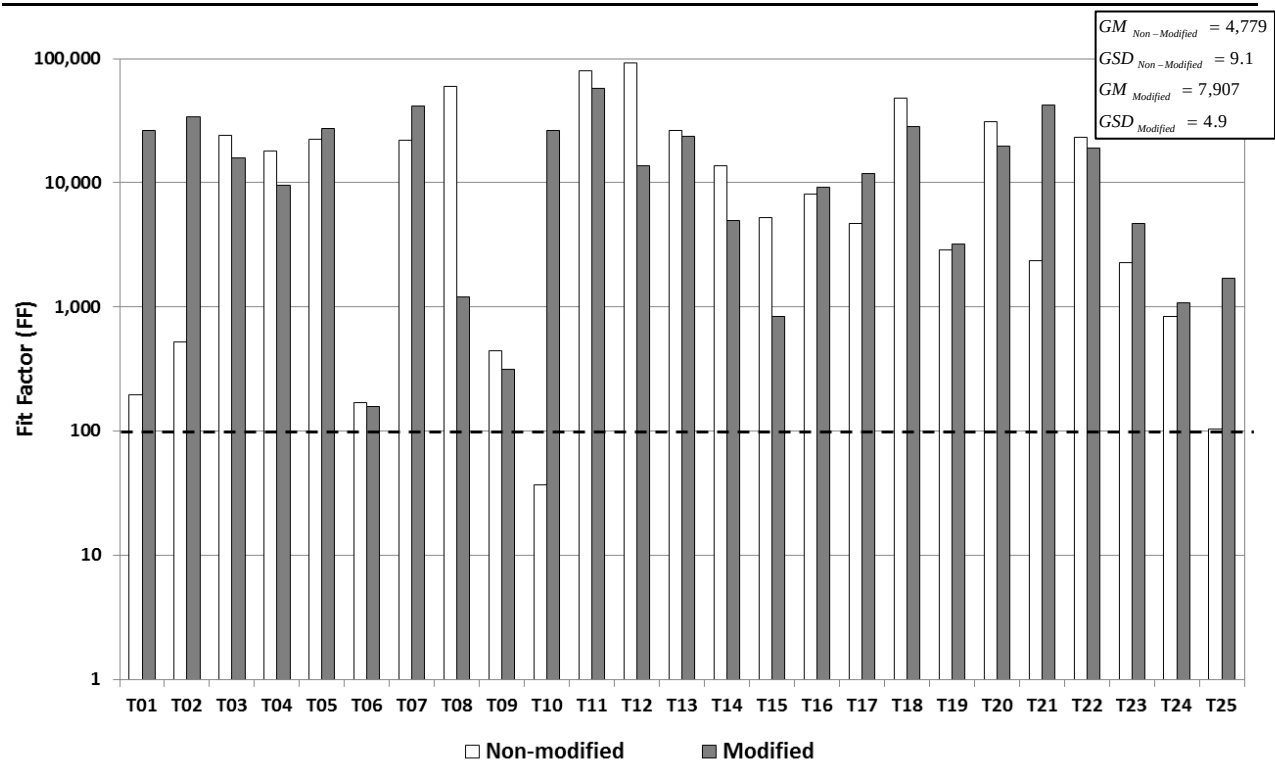


Figure 4. Fit factors (FFs) determined for 25 subjects with dry and clean-shaved faces wearing a conventional (non-modified) and modified elastomeric half-mask respirators.

Comparison of Four Facial Conditions (Dry/Wet, Shaved/Unshaved, One Subject)

Four facial conditions were compared: dry-shaved face, wet-shaved face, dry-unshaved face, and wet-unshaved face. One subject (#T01) participated in this evaluation with the non-modified and modified respirators with three repeats for each condition. The results of this pilot evaluation are presented in Figure 5. The PMA modified respirator produced higher mean FFs under all tested conditions compared to the non-modified respirator. For example, for the wet-shaved facial condition, the modified half-mask achieved a mean FF of 23,241 compared with 267 for the non-modified half-mask. Even the least remarkable difference identified for the dry-unshaved face was an order of magnitude higher for the modified respirator (mean FF = 974 vs. 95). Paired *t*-test results showed that the modified respirator had significantly ($p < 0.05$) higher mean FFs for all facial conditions (dry-shaved, wet-shaved, dry-unshaved, and wet-unshaved). These test results indicate that the surface of the PMA material improved contact against a facial skin under various challenge conditions (shaved, unshaved, dry, and wet).

When the non-modified respirator was tested with the dry skin condition, the fit was higher for the unshaved face than for the shaved face condition (mean FF = 95 vs. 74). This observation was made from a single subject and contradicts the conventional wisdom and our own experience that an unshaved facial condition will compromise respirator fit. However, the difference was not statistically significant ($p > 0.05$). In the clean-shaved condition, the non-modified respirator fit this subject poorly with a mean FF below 100. The effect of facial hair may be less significant when respirators fit poorly. When the same subject participated in the 25-subject panel with a clean shaven face, his fit factor was higher (FF = 197 from Figure 4). This demonstrates the potentially high variability between donnings and the limitation of single-subject generated data. With respect to facial hair, it was an important observation that the PMA

modified respirator initially fit very well, but FF dropped significantly ($p < 0.05$) after 40 hours of stubble. Although this finding is once again from a single subject, it demonstrates the potentially adverse effect of facial hair when respirators initially fit well in a clean shaven condition.

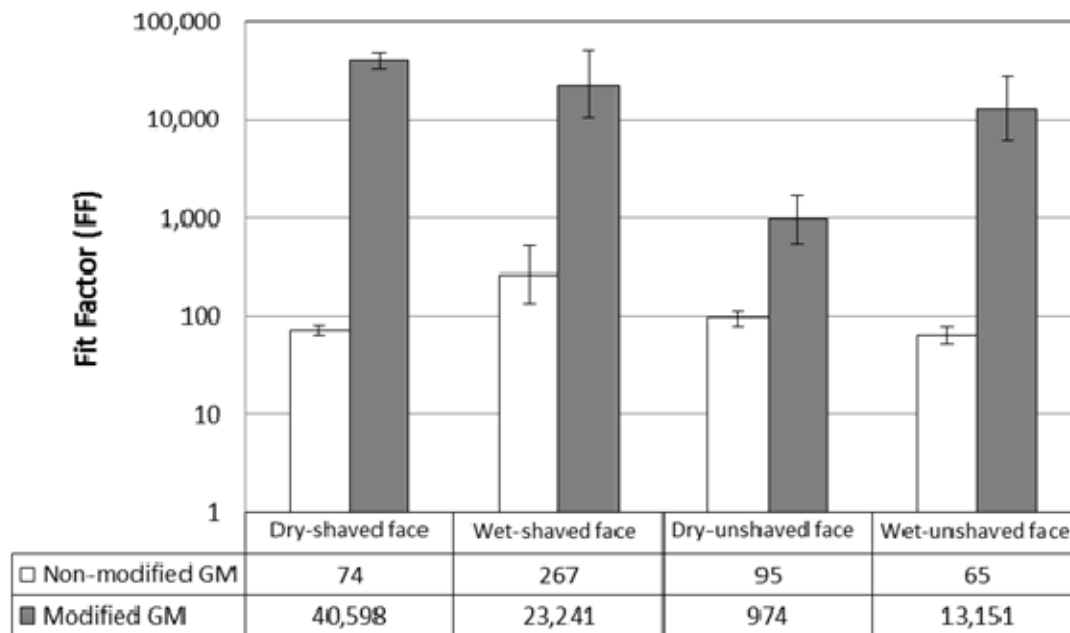


Figure 5. Fit factors (FFs) determined for a subject with four facial conditions while wearing a conventional (non-modified) and modified elastomeric half-mask respirators. The bars represent geometric means; error bars represent the geometric standard deviations of three replicates. (GM: geometric mean).

LIMITATIONS

The non-modified respirator selected for this study had very good fitting characteristics prior to adding the adhesive surface. It is challenging to demonstrate statistically significant improvement in fit when the “referenced” respirator already fitted well in most of the tests. Additionally, improvement in fit created a situation whereby the number of in-facepiece particles detected by the instrument was very small, which increased the margin of error and decreased the confidence in the measured FFs. However, this concern should have affected both the modified and non-modified respirators similarly since the donning order was randomized. Another limitation was the lack of a “control” respirator consisting of a material with similar thickness and width applied to the sealing surfaces but without the surface characteristics of the PMA. Lastly, conclusions regarding improved performance of the modified respirator using different facial (un-shave and/or wet) are preliminary as they derived from only a single subject with three replicate measurements. A follow-up study seems to be warranted to address the above limitations.

CONCLUSIONS

An elastomeric half-mask respirator was modified by applying a polymer micro-patterned adhesive (PMA) material to the sealing surface. Twenty-five subjects with dry and clean-shaven faces and facial dimensions representing the NIOSH bivariate panel were fit tested using the modified respirator and its non-modified version. The modified respirator produced a geometric mean fit factor of 7,907 with a GSD of 4.9 compared to 4,779 (GSD = 9.1) for the non-modified respirator ($p = 0.07$, paired t-test). In addition, pilot data were generated by testing a single subject under various facial conditions (shaved, unshaved, dry, and wet). The modified half-mask prototype was consistently achieving significantly ($p < 0.05$) higher fit factors than the conventional half-mask. Future studies are needed to include more subjects with various face dimensions along with quantified shaving and wetting/sweating conditions.

Overall, the addition of a polymer micro-patterned adhesive to the sealing surface of an elastomeric half-mask respirator showed potential for improving the fitting characteristics and possibly respirator performance with less than ideal facial conditions.

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