

Physical Fabrication and Verification of New NIOSH Digital Headform Designs with Skin-analog for Use in Fit Testing

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ABSTRACT

In order to ensure adequate respiratory protection for the US workforce, NIOSH has developed a new fit test panel and corresponding headform designs. These headform designs, combine three-dimensional data collected during the large anthropometric survey conducted to construct the new panel. Between the novelty of these new headform designs and the high cost of prototyping them, little testing has been performed to evaluate commercially available respirator facepieces. This study aims to develop silicone-skinned prototypes of the new NIOSH headforms for use in respirator fit testing. The silicone skin is used to better replicate the interaction between the respirator facepiece and the human face. The only complete set of headform prototypes were lent from Texas Tech to make molds. These molds were used for casting the prototypes tested in this study using methods adapted from the special effects industry. These test casts of the molds were then verified for anthropometric accuracy against the original NIOSH digital models and Texas Tech prototypes. After the mold dimensions were verified, silicone-skinned prototypes were constructed for use in controlled negative pressure fit testing. Commonly used, commercially available respirators will then be fit tested on the generated prototypes. Preliminary fit testing results indicate that facepieces tested do not adequately fit the headform prototypes developed in this study. Further evaluation is needed to determine if this indicates poorly fitting respirators, an issue with the prototyping methods used, or the design of the headforms themselves.

Keywords: respiratory protection, new NIOSH fit panel, respirator testing, ppe testing, facial anthropometry, respirator, fit testing

INTRODUCTION

An estimated five million US workers are required to employ respiratory protection to prevent injury and/or illness while perform their jobs (OSHA). With so many workers depending on this protection, it is crucial to ensure the accuracy of the fit test panels used to design respirator facepieces. Fit test panels are distributions of respirator-related facial anthropometric measurements and include the expected proportion of the US population to fall into each sizing category. Traditionally, face length and lip width have been used to construct a bivariate distribution for the US fit test panel. Over several studies, it has been found that other measurements, particularly those measuring facial width, can be more accurate at determining respirator sizing (Oestenstad, 1990; Oestenstad, 1992; Zhuang, Coffey et al., 2005).

In 2007, the National Institute for Occupational Safety and Health (NIOSH) released an updated respirator fit test panel (Zhuang, Guan et al. 2004). Prior to this, the anthropometric survey used for respirator sizing was collected in the late 1960s by the Los Alamos National Laboratory (LANL). The LANL panel was comprised of a 1967 to 1968 anthropometric survey of a predominantly young, Caucasian male population of US Air Force personnel. NIOSH recognized the need to update the fit test panel to ensure adequate protection for the increased number of female workers and greater racial diversity.

To better represent the current workforce, the new NIOSH panel population was weighted for race based on the 2000 US Census (Zhuang, Guan et al. 2004; Zhuang, Bradtmiller 2005). Two new fit test panels were created based on the study population: a traditional bivariate distribution, using face length and face width, and a principle component analysis (PCA) panel. The PCA was designed to create a more accurate fit test panel by incorporating 10 dimensions in its distribution: minimum frontal breadth, face width, bigonial breadth, face length, interpupillary distance, head breadth, nose protrusion, nose breadth, nasal root breadth, and subnasal-sellion length. The PCA panel created 2 equations each weighting the 10 facial dimensions based on the influence the measurement had on overall face length and face width. These 2 equations were then applied to the survey population and used to form the distribution of the PCA panel (Zhuang, Bradtmiller et al., 2007). From the results that were obtained, it was determined that the introduction of 2 additional sizes would more adequately represent the modern workforce. Together with the traditional Small, Medium and Large sizes, the addition of Short/Wide and Long/Narrow expanded respirator sizing to 5 options.

NIOSH also created new headform designs based on the three-dimensional data that was collected on a subset of subjects during the anthropometric survey (Zhuang, Benson et al. 2010). Stereophotogrammetric data of five subjects within each of the five sizing categories were merged to create digital headform computer models conforming to the new fit test panel. Previous studies using headforms for fit testing have used single-sized models of an "average" male or based on three-dimensional data collected on a single individual using particulate fit testing. Tuomi, using a commercially available European respirator headform, found that the headform was not a suitable analog to human testing when evaluating the filtration capabilities of half face respirators and surgical masks. Cooper et al. used a U.S. Army designed "average" male headform, coated with a thin film of PVC to be more life-like. In their study, it was found that the fit of filter facepiece on a headform could be improved by increasing the face seal area with additional pressure holding it to the face. Golshahi et al. worked to develop a headform design with a more skin-like exterior, using a number of elastomeric and rigid prototyping materials, based on three-dimensional recreation a single subject. It was found that the softest elastomeric material afforded the best fit when evaluating N95 facepieces.

While the new NIOSH headforms were designed for use in the development and testing of respirators, their use in fit testing commercially available respirators has been limited. The majority of testing has been performed through digital modeling due to the lack of availability of physical versions of the headforms. One such study, performed pressure analysis between digital models of filtering facepieces and the digital headforms (Dai, Yang et al. 2011). The evaluation of tight-fitting air purifying respirators has yet to be tested, either digitally or physically. The goal of this study is to develop testable models of the new NIOSH headforms with silicone skin-analog outer layer for use in half-face respirator fit testing.

METHODS

Mold Making

Due to the cost prohibitive nature of rapid prototyping at this size scale, particularly incorporating elastomeric materials, mold making was employed to create models of the new NIOSH headforms in this study. The only complete set of physical headforms, formed by stereolithography (SLA), were borrowed from Dr. James Yang, of Texas Tech University, to cast molds. These prototypes were fabricated using stereolithography (SLA), a rapid prototyping process that uses a laser to solidify a vat of liquid polymer to create a three-dimensional design. Silicone molds were made by applying multiple layers of Rebound 25 (Smooth-On, Easton, PA), a brushable platinum cure silicone, to the exterior of each headform size in the new NIOSH panel (Figure 1a and 1b). A supporting shell of Plasti-Paste II trowable plastic (Smooth-On, Easton, PA) was then applied to the exterior of each silicone mold prior to removing from the headform; this ensured support of the silicone and correct dimensions of resulting casts (Figure 1c).

Mold Verification

To ensure the accuracy of the brush-on silicone molds and their resulting to the original digital models created by NIOSH, surface laser scanning for anthropometric analysis was performed. Casts were made from rigid expanding urethane foam (Foam-it 5 (Smooth On, Easton, PA)) to evaluate the molds. The foam casts and SLA plastic prototypes were surface laser scanned (Vivid 9i, Konica Minolta, Ramsey, NJ) for digital anthropometric measurement and compared to measurements taken directly from the original NIOSH digital headform designs. All five sizes of both the SLA and expanding foam casts were surface laser scanned at 8 different angles to obtain a 360-degree model. The angled scans were trimmed, aligned, and combined in the RapidForm XOR software (RapidForm, Inc., Lakewood, CO), following the method described in Joe et al. 2012, to create a complete three-dimensional model. Ten digital facial anthropometric measurements were taken in triplicate using RapidForm on each of the 15 three-dimensional headform models (five sizes of each: NIOSH digital models, SLA, and foam). The ten dimensions collected included: menton-sellion length, subnasal-sellion length, subnasal-menton length, nose breadth, nose protrusion, lip breadth, binocular breadth, bizygomatic breadth, bitragion-chin arc, and bitragion-subnasal arc. ANOVA analysis was performed on each measurement comparing the three model types within each size (50 total tests).

Headform Fabrication

After mold verification measurements were collected and analyzed, fit testable casts of the headforms were constructed. The method used to create anthropometric headforms with a skin analog surface was modeled after processes to create prop heads in special effects. This process entailed lining the silicone molds with 0.25 inch layer of clay, creating a void space for silicone to be cast in a later step (Fig. 2a). An expanding foam core was then cast in the clay lined mold (Fig 2b). After removal from the mold, all clay was removed from the foam core, the resulting void space can be seen in Figure 2c, when compared to a non-lined casting with the same mold. The foam core was then overcast with EcoFlex 0030 (Smooth-On, Easton PA), a platinum cure silicone with a shore value of 00-30 when unsupported by other materials, to replicate human skin (Fig 2d). The shore value of facial tissue of the cheek has been found to be 2.7, while supported by musculature and bone structure in vivo (Wolff et al. 2005). This silicone was selected for its flexibility, durability, and its ability to be poured in molds of the size used in this study. This formulation has low viscosity for getting into the various areas of the mold and does not need to be put under vacuum to prevent the trapping of air which distorts the exterior surface of the finished casting. The process was repeated for each size headform.

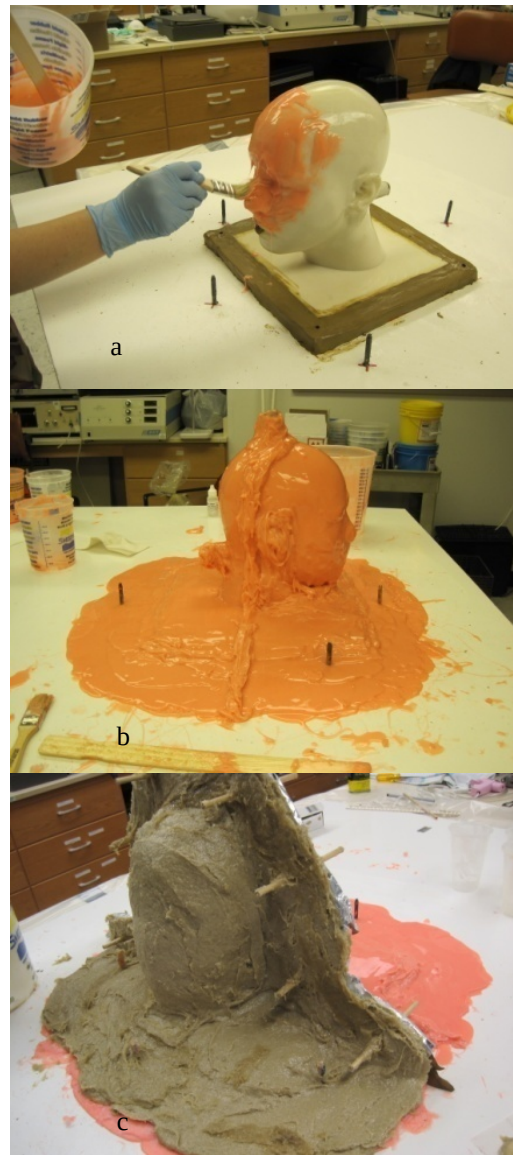


Figure 1. Headform mold making: (a) Applying silicone to SLA prototypes, (b) Completed silicone mold, (c) Creating support shell for silicone mold.



Figure 2. Headform fabrication: (a) Mold lined with clay to create void space, (b) Clay lined mold filled with expanding foam to form supporting core and base, (c) Expanding foam cast (left) and expanding foam core with clay removed, (d) Expanding foam core overcast with skin-analog silicone.

Preliminary Facepiece Testing

Commercially available facepieces tested in this study were the 3M 6000 series (3M, St. Paul, MN), MSA Advantage200 series (MSA, Cranberry Township, PA), and North 7500 series (Honeywell, Cranston, RI); all respirators tested were three size system designs (S, M, L). Fit testing was performed using the FitTester3000 (Occupational Health Dynamics, Birmingham, AL) and the OSHA-approved Controlled Negative Pressure REDON procedure (29 CFR 1910.134 Appendix A). The FitTester3000 operates by replacing the facepiece cartridges with 2 adaptors: one connected to the machine for pressure measurement and the other to a bulb to seal the inhalation valve. When the respirator is donned and the valve is sealed, the FitTester3000 will then generate a negative pressure within the facepiece. The changes in pressure are measured over a 10 second interval. The change in measured internal facepiece pressure is then correlated to a leak rate and fit factor, providing a direct measure of facesal leakage by eliminating the possibility of particle penetration through filtering cartridges.

The exercises performed in each fit testing cycle followed the OSHA protocol and included: an upright measurement, a measurement with headform parallel to floor, a head shaking measurement using a pneumatic shaker table, and 2 complete redonnings. The only deviation from the testing protocol was the removal of the shouting component during headshaking. The effects of breathing during testing (i.e. deep breathing) are disregarded in negative pressure fit testing as a human subject would be instructed to hold their breath while closing the inhalation valves of the respirator to maintain interior pressure during

testing. These individual fit factors are then used to determine the overall fit factor for the test using the following equation:

$$\text{Overall Fit Factor} = \frac{N}{\left[\frac{1}{FF_1} + \frac{1}{FF_2} + \dots + \frac{1}{FF_N} \right]}$$

Where:

N = number of exercises

FF_1 = fit factor for first exercise

FF_2 = fit factor for second exercise

FF_N = fit factor for N^{th} exercise

A pneumatic shaker table was fabricated for this test and used to standardize the rotation of the headform simulating a subject moving their head side-side between tests (Figure 3). The table rotates the headform 45 degrees off center (facing forward) once per second for three seconds. The shaker table also tilts forward 90 degrees, simulating a subject bending at the waist. Nine respirators (three sizes in three different models) were fit tested 10 times on each of the five sizes of headform for statistical analysis. For half-face respirators, an Overall Fit Factor of 100 or greater is considered a passing test. Six fit tests with fit factors less than 100 were considered indicative of a facepiece failing to fit to the headform.

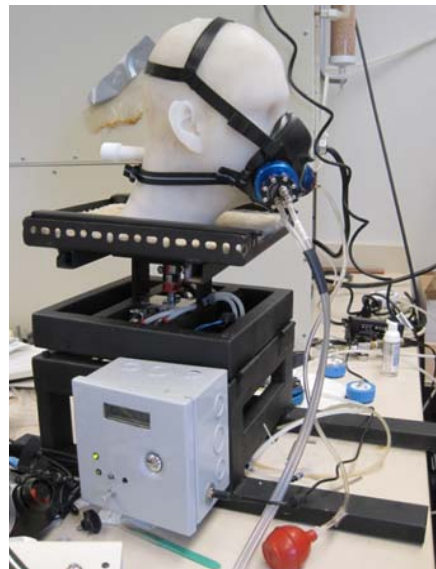


Figure 3. Headform Testing Set-up.

RESULTS AND DISCUSSION

Mold Verification

One-way ANOVA was performed as outlined by Farkas et al. (2005), where a measurement is only of anthropometric significance when p-value is less than 0.009. Using this significance level, it was found that the molds, represented by the foam casts, were accurate to both the original NIOSH digital models and the SLA plastic prototypes. The measurements that were found to be significantly different are indicated in Figures 4 through 8. These measurements, while being found to be significant, are congruent with the results of a previous study using the same scanning process (Joe et al., 2012).

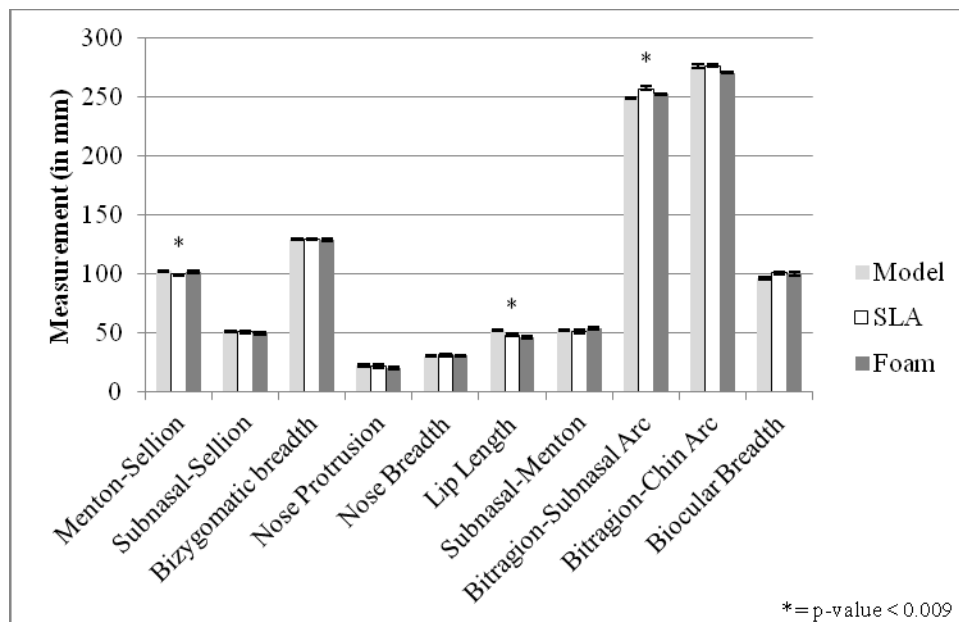


Figure 4. Small Headforms Anthropometric Comparison.

A limitation of combining multiple scans of faces/headforms, is the effect of shadows on the final merged model. The variation in lighting between the separate scans proves difficult for RapidForm when merging, and can lead to aberrations in the model surface. This effect is of particular significance in regards to horizontally oriented measurements, like Bizygomatic breadth, Bitrignon arcs, and Nose Breadth. Facial arc measurements are particularly susceptible to these model surface errors. The arc generated in digital measurement is virtually “drawn” onto the model surface, often leading to a sinusoidal line as opposed to the linear one that a traditional tape measure would follow. Additionally, due to the high precision of digital measurement methods, values that are found to be statistically different can be well within acceptable 1 to 3mm tolerance level for anthropometry (Zhuang et al, 2007).

The molds generated in this study, and their resulting headform casts, were anthropometrically suitable for use in respirator testing. Compared to the costs of prototyping designs of this size, once the initial cost of generating the molds is overcome, mold casting of the headforms can be a viable and cost effective method of production.

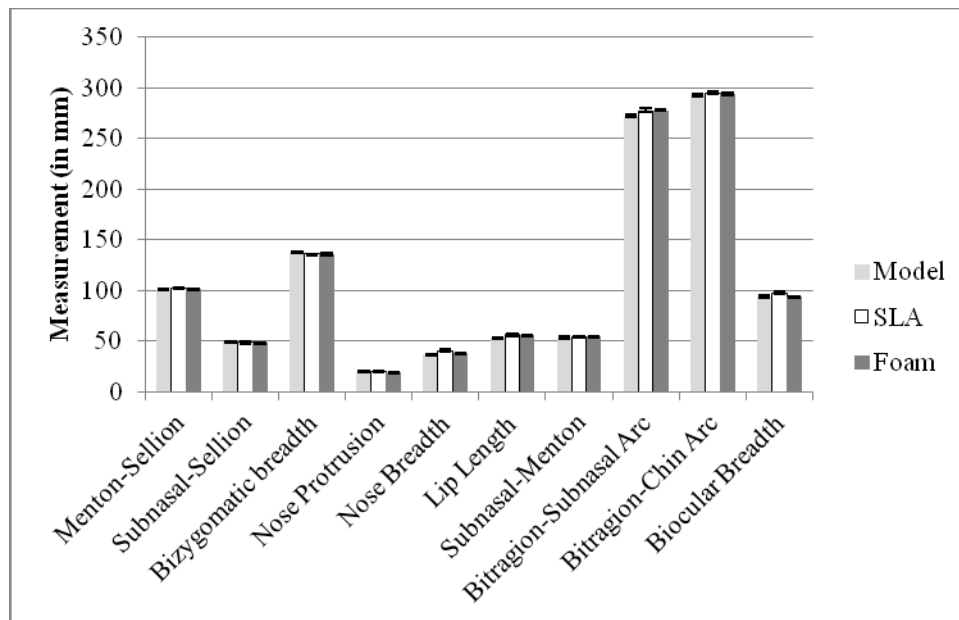


Figure 5. Short/Wide Headforms Anthropometric Comparison.

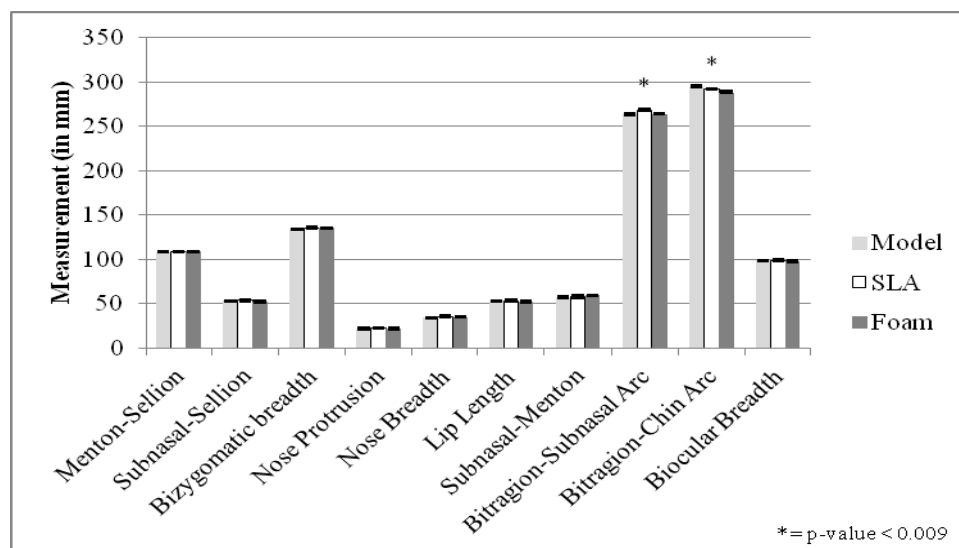


Figure 6. Medium Headform Anthropometric Comparison.

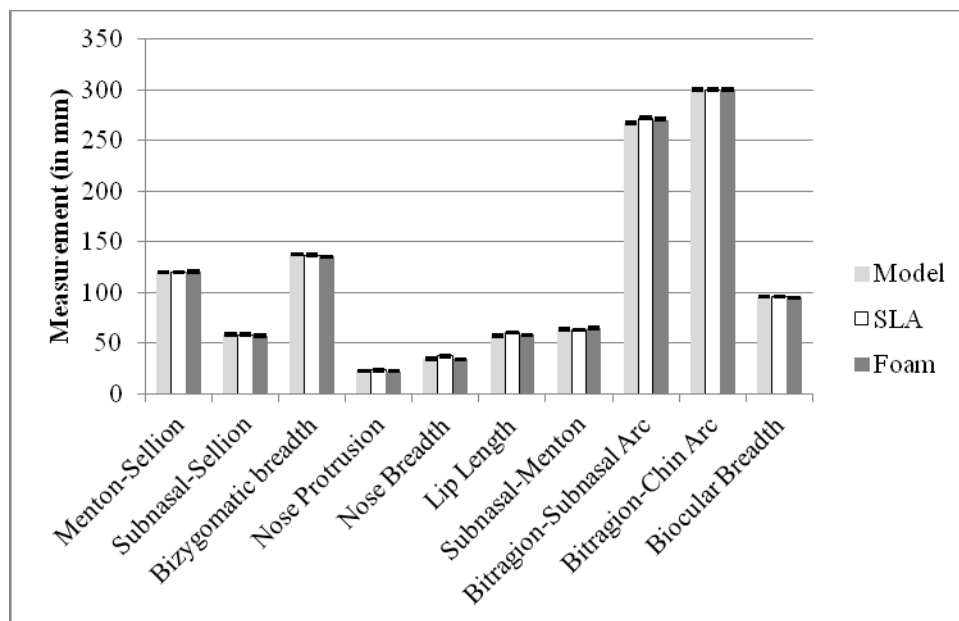


Figure 7. Long/Narrow Headform Anthropometric Comparison.

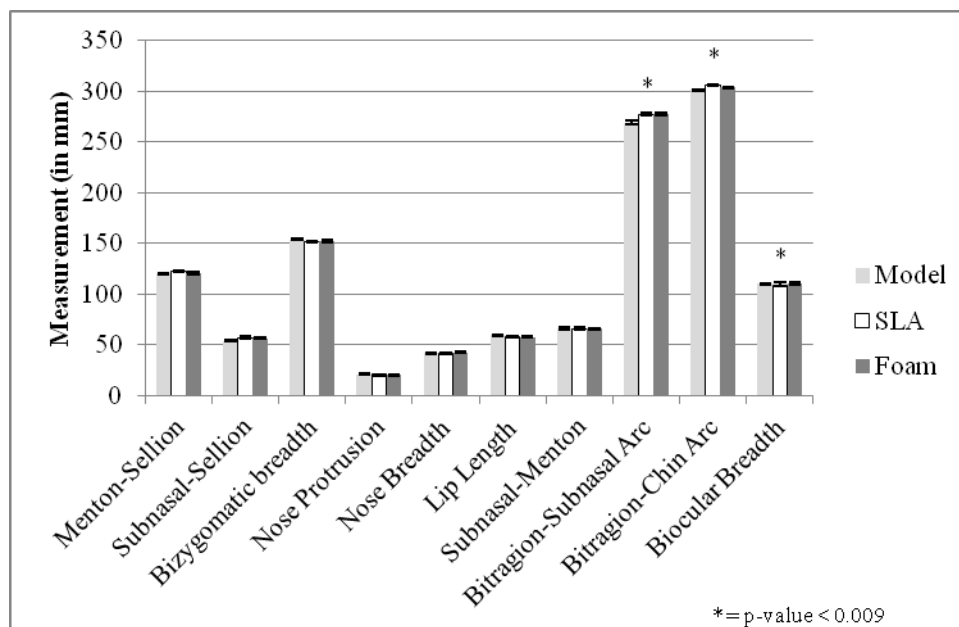


Figure 8. Large Headform Anthropometric Comparison.

Facepiece Testing

Based on preliminary results, the commercially available facepieces fit tested in this study were unable to adequately seal to the new NIOSH headforms. While it was expected that some sizes would be unable to maintain a face seal (e.g. a small size facepiece on Large headform), the extent to which these facepieces did not seal was unexpected. Of the nine type/size combinations of facepieces tested, only 2 were able to generate a measureable face seal: the MSA Advantage200 small and medium on the Short/Wide headform. The small MSA facepiece produced fit factors ranging from 18 to 1037 after 10 fit tests (Figure 9). This combination of headform and facepiece had an overall fit factor with a geometric mean of 102.17 and a geometric standard deviation of 382.01. While the medium MSA facepiece was capable of creating adequate and passable seals (up to a fit factor of 576), it had six failing fit tests, including two tests being immeasurable (fit factor < 11), after the completion of 10 testing cycles.

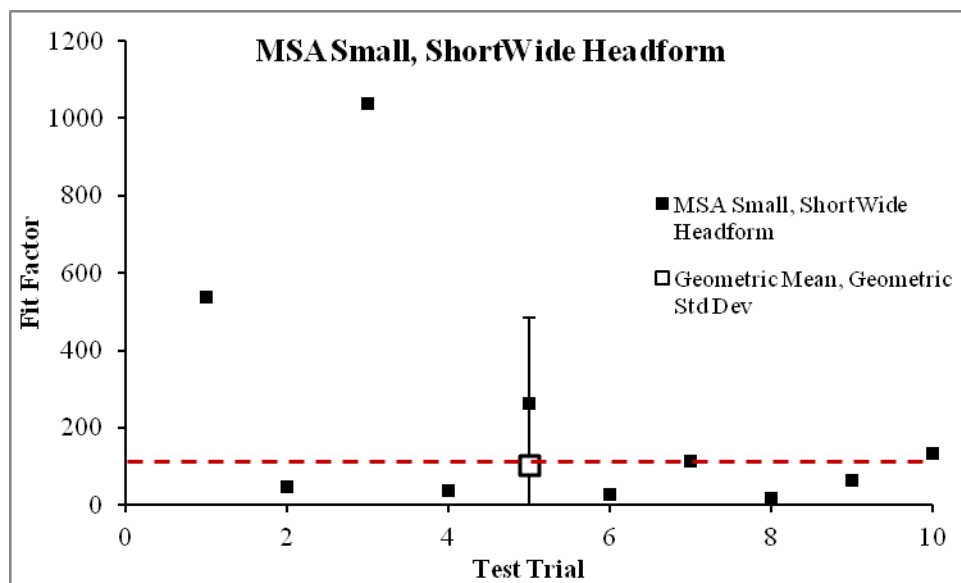


Figure 9. Short/Wide Headform and Small MSA Advantage200 Fit Test Results.

The most surprising result of these initial tests was that a vast majority of the fit tests were immeasurable. An immeasurable fit test indicates that the face seals were so poor that the FitTester was unable to establish an adequate negative pressure in order to perform the test.

These results generate four possibilities in regards to the use of the new headform models in respirator design and testing. First, is that the facepieces tested are unrepresentative of the current US working population. While they may be adequately protective on a portion of the workforce, they may be unsuitable to the population as a whole. The second possibility is that the materials used for these headform prototypes are unsuitable for use in fit testing. For instance, the silicone of the headform and the elastomeric materials of the facepieces may "grab" onto each other in certain places creating gaps once the facepiece is fully donned. There is a possibility that the new headform models themselves are not suitable for extrapolation by limitations in their use in fit testing or While every effort was made to replicate fit testing on a human being, the movements of the headform during testing exercises were not as fluid as they would be with a live person, possibly inducing breaks in face seal that would not have occurred during movement. Finally, there is the possibility that the headform designs are not

representative of the workforce, as these respirator designs are known to be able to pass fit tests on workers.

CONCLUSIONS

While the methods used to recreate the new NIOSH headforms were shown to be anthropometrically accurate, further evaluation is necessary to ensure accuracy of fit test results using these headform designs as human surrogates. Additional fit tests with the currently tested facepieces and additional models/sizes may verify the failure of fit or indicate the need to alter headform construction methods. A different formulation of silicone or other type of elastomeric material may prove to be a better skin analog for headform construction.

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