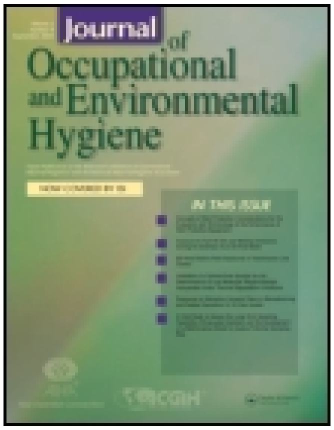

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A Novel Method for Designing and Fabricating Low-cost Facepiece Prototypes

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In 2010, the National Institute for Occupational Safety and Health (NIOSH) published new digital head form models based on their recently updated fit-test panel. The new panel, based on the 2000 census to better represent the modern work force, created two additional sizes: Short/Wide and Long/Narrow. While collecting the anthropometric data that comprised the panel, additional three-dimensional data were collected on a subset of the subjects. Within each sizing category, five individuals' three-dimensional data were used to create the new head form models. While NIOSH has recommended a switch to a five-size system for designing respirators, little has been done in assessing the potential benefits of this change. With commercially available elastomeric facepieces available in only three or four size systems, it was necessary to develop the facepieces to enable testing. This study aims to develop a method for designing and fabricating elastomeric facepieces tailored to the new head form designs for use in fit-testing studies. This novel method used computed tomography of a solid silicone facepiece and a number of computer-aided design programs (VolView, ParaView, MEGG3D, and Rapid-Form XOR) to develop a facepiece model to accommodate the Short/Wide head form. The generated model was given a physical form by means of three-dimensional printing using stereolithography (SLA). The printed model was then used to create a silicone mold from which elastomeric prototypes can be cast. The prototype facepieces were cast in two types of silicone for use in future fit-testing.

Keywords facepiece design, PCA fit-test panel, 3D printing, head forms, respiratory protection

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INTRODUCTION

In 2007, the National Institute for Occupational Safety and Health (NIOSH) created a new type of fit-test panel based on its recent anthropometric survey. The principle component analysis (PCA)-based panel is intended to be more representative than the previous bivariate fit-test panel that had been in use for almost 40 years.[1] The previous panel, based on the 1967–1968 Los Alamos National Laboratory (LANL) anthropometric survey of U.S. Air Force Personnel, uses a bivariate distribution of face length and lip width. These measurements were selected as they would provide the minimal dimensions that a half-face respirator would need to cover.[2] However, studies performed since the implementation of the LANL panel have shown that other facial dimensions can provide a better indication to overall facial sizing.[3,4]

Based on these studies along with changes in working age American demographics, NIOSH embarked on a new anthropometric survey that formed the basis of the new fit-test panel.[5,6] NIOSH's anthropometric survey was weighted for gender and race in working age Americans based on the 2000 census results. The survey found that the original LANL panel, intended to be representative of 95% of the U.S. work force, excluded 15.3% of the modern work force. Additionally, the modern work force exhibited larger and wider facial dimensions than those found in the LANL panel. Further analysis of the survey found that female subjects tended to have smaller and narrower facial dimensions than males.[7]

The new PCA panel is based on two summation equations that weight ten facial dimensions based on their predictiveness of overall face length and face width. From, RPHB 530, 1720 2nd Ave. S., Birmingham AL 35294 the resulting distribution, NIOSH determined that the U.S. work force is best represented by five facial sizing categories: Small, Medium, Large, Short/Wide, and Long/Narrow. NIOSH has recommended that future facepiece designs be based on this new five-face size system, rather than the current three-size system. This recommendation is aimed at improving the faceseal for the user, as faceseal leakage is the primary source of contaminant infiltration into a facepiece.[8]

To accommodate this recommendation, NIOSH developed digital head form models to correspond to the face size categories of the PCA panel. These new head forms are intended to be more representative of the modern work force as they were developed using three-dimensional data collected from a subset of the anthropometric survey used to develop the panel. The head form models were created by merging five subjects' data to create a single face model to represent each size category.[9] Once fabricated, these head forms can be used for both the design of a variety of protective equipment and for computer models and their testing.. For this study, they will be used for designing and future testing of tight-fitting elastomeric respirator facepieces tailored specifically to their anthropometric dimensions.

Due to the newness of the five-size system recommendation, manufacturers have not begun to produce respirators in five sizes. However, a previous study by Joe et al. have evaluated the protection afforded to the five facial sizes by commercially available facepieces in three- and four-size systems.[10] Six different manufacturer/models of half-face elastomerics were fit-tested on silicone-skinned PCA panel head form prototypes using Controlled Negative Pressure (CNP) (Occupational Health Dynamics, Birmingham, Ala.) and a subset by PortaCount (TSI, Minneapolis, Minn.). Results of this study indicate that commercially available facepieces may not be able to provide adequate protection under the new five-facial-size paradigm. When tested with CNP, most facepieces were unable to achieve sufficient faceseal to allow for fit-testing. Fit-testing with PortaCount allowed for the test exercises to be executed, however, most head form/facepiece combinations had failing overall fit factors. Of the five sizes of head forms, the Short/Wide head form was best able to achieve sufficient faceseal to enable fit-testing, in both methods, with the facepieces tested.

To our knowledge, there are no manufacturers marketing facepieces with this new sizing scheme. To evaluate whether a switch to the five-facepiece-size system is actually needed, a method for generating facepieces customized to the new head form dimensions needed to be devised. This study aims to develop a method for designing facepieces to accommodate the head forms, as well as a low-cost method for fabricating these designs for use in fit-test comparisons to commercially available facepieces.

METHODS AND RESULTS

Computed Tomography Scans (CT)

CT scans were conducted on North 7700 series facepieces by the Department of Radiology at the University of Alabama at Birmingham (UAB). This brand/model facepiece was selected for its entirely silicone body, as many others require a rigid secondary support material to maintain shape. This type of construction would provide greater ease in fabricating the final prototype. CT scans were conducted to obtain the varying thicknesses of silicone present throughout the facepiece and providing an internal support system (Figure 1). CT scans obtain this information by collecting a series of transverse cross-sections of the object of interest through the performance of multiple angled x-rays.

FIGURE 1. Example excerpts from North 7700 series computed tomography scan DICOM Data demonstrating changes in thickness at various sites.

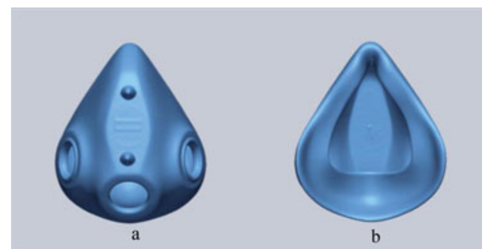

FIGURE 2. Surface model of North 7700 series facepiece (a: outer surface; b: sealing edge). (color figure available online).

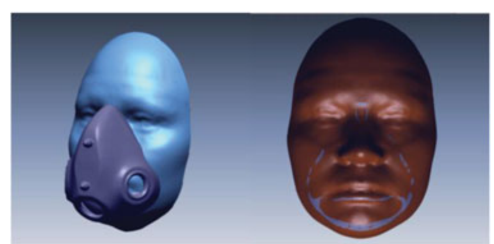

FIGURE 3. Aligning facepiece and head form models. (color figure available online).

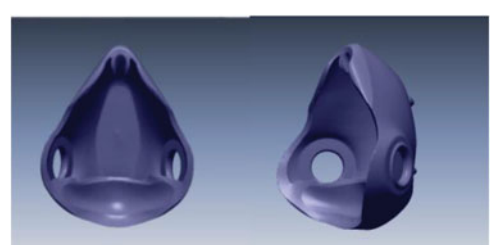

FIGURE 4. Outer surface of altered to the contour of the head form. (color figure available online).

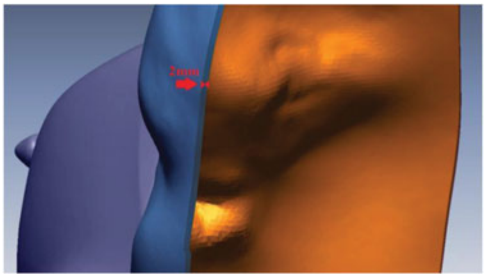

FIGURE 5. Head form surface thickened to form prototype sealing edge contour. (color figure available online).

Once collected, the scanned Digital Imaging and Communications in Medicine (DICOM) images were loaded in Volview (KitWare Inc., Clifton Park, N.Y.) for conversion to a single volume file. The contour filter in Paraview (KitWare Inc., Clifton Park, N.Y.) is then applied to the volumetric file, generating the isometric surfaces that render a water-tight, three-dimensional model (Figure 2).

Customizing Model

As an initial prototype, the small-size CT-scanned facepiece and Short/Wide NIOSH Head form model were selected for this study. These sizes were selected based on a previous fit-testing study's results.[10] The original NIOSH head form model was constructed with two connected layers to provide structure. The back and neck of the head form as well as the inner lining layer of the face were trimmed in MEGG3D, to obtain the outer most facial surface to aid in facepiece alignment.[11–14] In RapidForm XOR (3DSystems, Rock Hill, S.C.), the two models were aligned to be abutting but with minimal complete overlap (Figure 3). Boolean Union operations were performed to remove overlapping portions of the facepiece model.[11] The resulting facepiece model presents a surface matching the profile of the head form model at the points where overlap occurred(Figure 4).

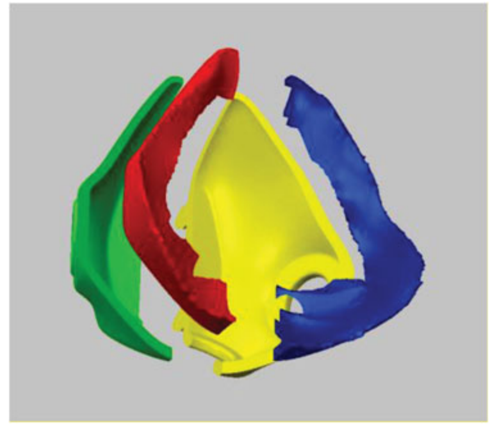

FIGURE 7. Facepiece model quartered for SLA printing. (color figure available online).

The resulting model creates altered the outer surface of the facepiece to conform to the contours of the head form, but removed the majority of the sealing edge. To create a new sealing edge that accommodates the head form's features, the head form surface was thickened to a depth of 2mm to form the new sealing edge of the respirator prototype (Figure 5). An additional Boolean Union operation was performed to join the thickened head form surface to the tailored facepiece model, removing the facial surface outside the facepiece. The remaining head form surface was trimmed to the shape of the opening in the original facepiece sealing edge. Portions of the original sealing edge remained after these processes and would be removed manually after 3D printing (Figure 6). The model was then cut into four segments to ease both 3D printing and subsequent mold making (Figure 7).

Prototype Facepiece Fabrication

Three-Dimensional Printing

Once the altered facepiece model was generated and quartered, it was 3D printed using an IPro 9000 stereolithography (SLA) printer (3DSystems, Rock Hill, S.C.). SLA produces a

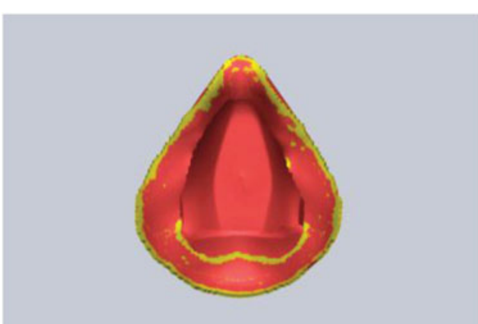

FIGURE 6. Facepiece model with modified sealing edge tailored to head form. (color figure available online).

FIGURE 8. Manually finished sealing edge halves. (color figure available online).

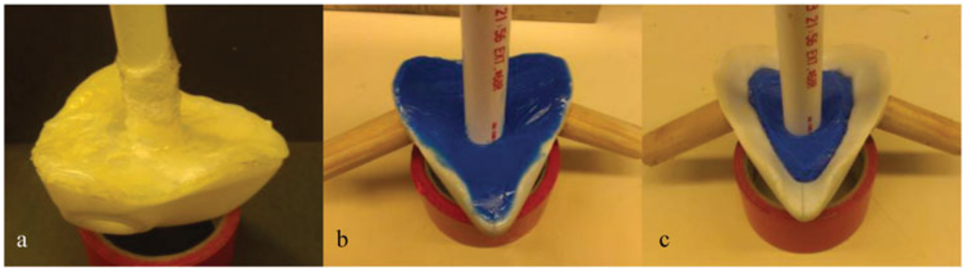

FIGURE 9. Casting male mold (a: epoxy backing plate; b: untrimmed; c: trimmed of excess silicone to expose sealing edge). (color figure available online).

tangible object through the additive process of curing thin layers of liquid polymer with ultraviolet (UV) light. Each successive layer, with an average resolution of 0.005 in, was built and adhered to the previous with a shallowly penetrative UV laser until the final product was formed. Once printing was completed, the piece was removed from the vat, rinsed of excess liquid polymer, and placed in a UV oven for final curing.[15].

Mold Making

After the parts were printed, they were used to create a silicon block mold from which a silicone facepiece could be cast. A rotary tool was used to remove excess material from the Boolean Union and to smooth the rough edges present in the printed model (Figure 8). Once manual surface finishing was completed, the parts were adhered with Super Instant Epoxy (Smooth-On, Easton, Pa.) to form the outer and sealing edge halves of the facepiece model. A length of PVC pipe was adhered to the inner surface of the outer half of the facepiece to act as a pour spout in the mold. A backing plate was fabricated with Super Instant Epoxy to seal the opening in the sealing edge for use in casting the male portion of the mold that will form the void space within the facepiece (Figure 9a). Dowels were fitted to the inhalation valve ports to support the male mold in the completed mold system.

The printed facepiece pieces, epoxy backing plate, and dowels were then assembled and sealed together with elastic bands, clay, and plastic wrap for casting the male portion of the mold. The surfaces of the printed pieces, PVC piping, and epoxy backing plate were coated with Ease-Release 200 (Mann Formulated Products, Easton, Pa.) and the dowels were sealed with Sonite Release Wax (Smooth-On, Easton, Pa.) prior to assembly. The assembly was positioned to have the exhalation valve parallel to the counter surface. Vacuumed Mold-Star 30 (Smooth-On, Easton, Pa.), a two-part platinum cure silicone, was poured through the exhalation valve port to cast the male mold. Upon curing, the facepiece assembly was unwrapped and the backing plate removed to trim the excess silicone from the male mold (Figure 9a,c and c). Special care was taken to not disturb the dowels and printed pieces relative to the cast male mold.

The trimmed mold and facepiece assembly was then suspended in a mold box by embedding the dowels in clay. The clay ensures a distance of 1.5 in between the box and the lowest point of the assembly as well as access to the dowels upon curing (Figure 10a). The mold box was sealed with Sonite Wax and all surfaces of the box and assembly were coated with

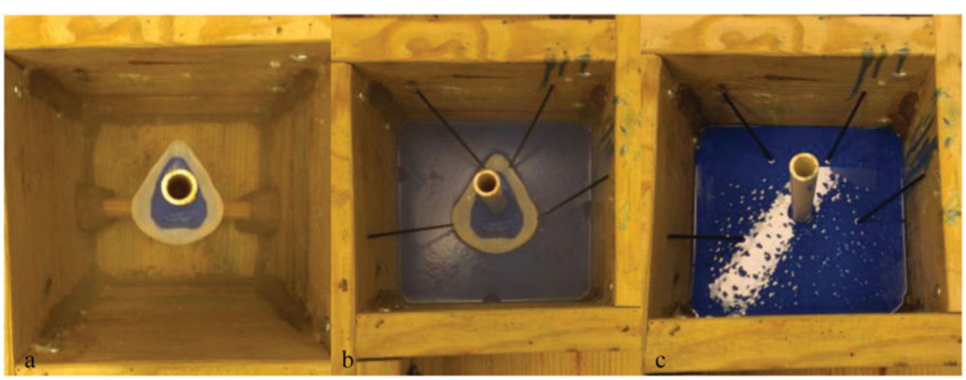

FIGURE 10. Casting the female mold (a: facepiece assembly suspended; b: first half cast and vents attached to facepiece assembly; c: second half cast). (color figure available online).

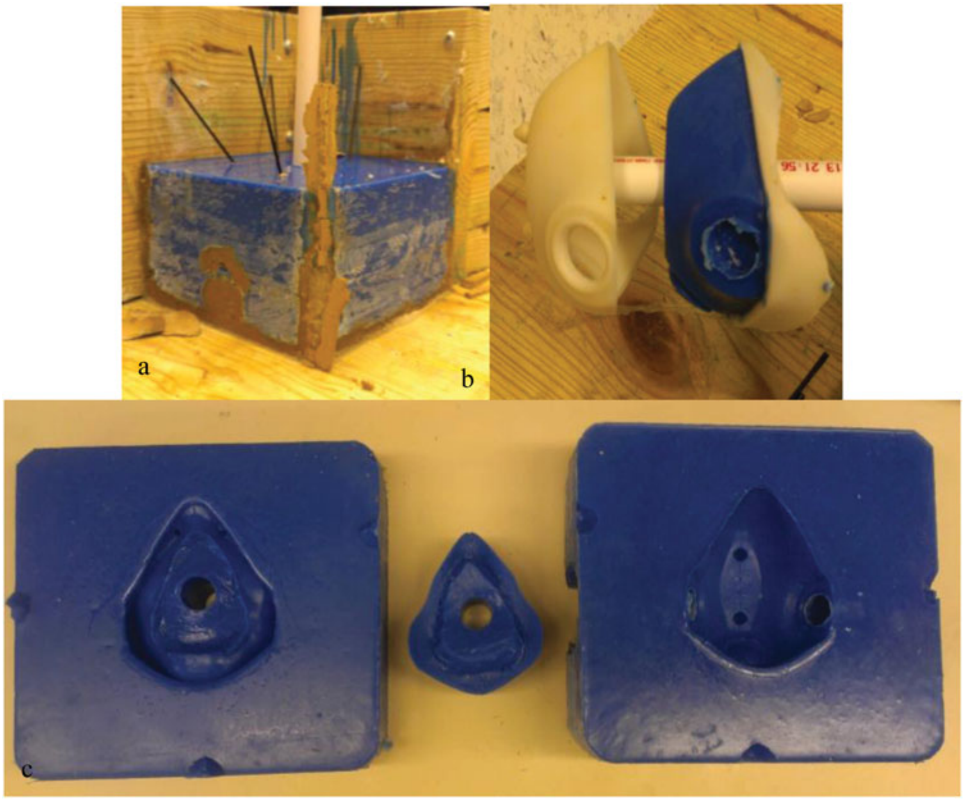

FIGURE 11. Opening mold (a: removing mold system from box; b: retrieving male mold from facepiece assembly; c: completed mold pieces). (color figure available online).

Ease Release. The first half of the female mold was cast by carefully pouring Mold Star 30 in a corner of the mold. The silicone was poured in increments until leveled off at the point where the inner sealing edge transitions to the outer surface. After curing, vents, in the form of straws, were attached to the highest points on the sealing edge (Figure 10b). Registration marks were cut into the edges of the lower half of the mold. All exposed silicone and assembly were coated with Ease Release 200 (Smooth-On, Inc. Easton, Pa.) to ensure the mold halves would separate upon completion. Mold Star 30 was then poured to a depth 1.5 in from the highest point of the sealing edge, forming the second half of the female mold (Figure 10c).

After curing, the mold was removed from the box and the facepiece assembly carefully removed from the mold (Figure 11a). The female portions of the mold and dowels were cleaned, removing all clay. The two halves of the printed model

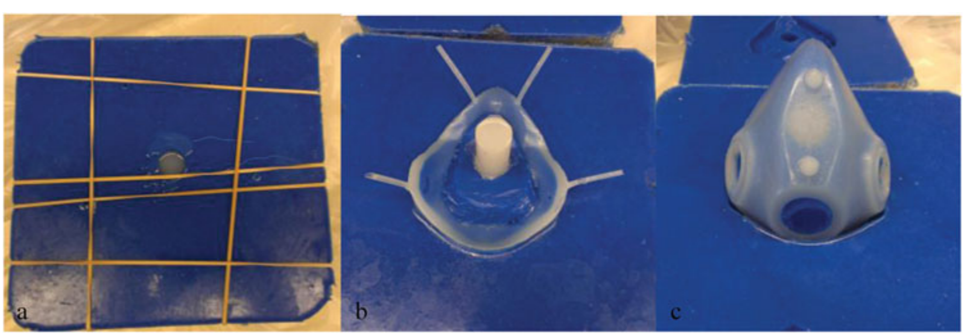

FIGURE 12. Casting prototype facepieces (a: mold system reassembled for casting; b: cast DragonSkin facepiece in mold; c: cast DragonSkin facepiece on male mold). (color figure available online).

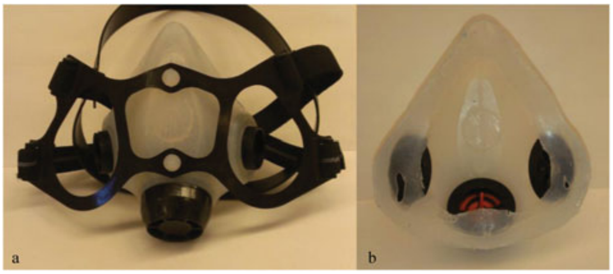

FIGURE 13. Verifying DragonSkin 30 prototype casting (a: fitting valves and harness; b: holes observed in sealing edge). (color figure available online)

were carefully pried apart to retrieve the male portion of the mold (Figure 11b). Flashings were then trimmed from the mold components (Figure 11c).

Facepiece Casting

Two types of silicone with differing shore hardnesses were cast as prototype facepieces. DragonSkin 30 (Smooth-On, Easton, Pa.), a shore 30A platinum cure silicone, was cast as the initial prototype. DragonSkin was mixed with Silicone Thinner (Smooth-On, Easton, Pa.) to lower viscosity in pouring and aid in vacuum degassing. The mold system was sprayed with Ease Release and reassembled and secured with elastic bands. The vacuumed DragonSkin mixture was then poured and allowed to cure for 16 hr. Once removed from the mold, all flashings (Figure 12), vent overflows, and excess silicone in the pour spout were carefully trimmed from the cured facepiece. The inhalation valves, exhalation valve, and harness from the original North 7700 series facepiece were attached to verify their respective fits in the prototype (Figure 13a). Upon inspection of the prototype, there were two air bubbles that were entrapped in the mold, creating holes in the sealing edge (Figure 13b).

A second facepiece was cast using Smooth-Sil 940 (Smooth-On, Easton, Pa.) a shore 40A platinum cure silicone. Again, the mixed silicone was combined with silicone thinner and vacuum degassed prior to pouring it into the prepared mold. After curing for 24 hr, flashings, vent overflows, and spout excess silicone were carefully trimmed. The North 7700 series valves and harness were attached to verify fit in the prototype (Figure 14a). Inspection of the casting found one bubble entrapped in the sealing edge of the prototype (Figure14b).

FIGURE 14. Verifying Smooth-Sil 940 prototype casting (a: fitting valves and harness; b: hole observed in sealing edge). (color figure available online)

CONCLUSION

This study aimed to develop a method to create respirator facepieces customized to the new NIOSH head forms, based on the five face sizes of the PCA fit-test panel. While it has been recommended that the switch to a five-size respirator system would better protect the U.S. work force, there has not been a study of its comparison to the long-used three-size facepiece system. The lack of facepieces matching these five new sizes was the main obstacle in this research.

This study was able to develop a method to tailor a digital model of a respirator facepiece to the new head forms. A novel method combining three-dimensional printing, mold making, and casting in silicone was developed to fabricate the customized facepiece. These techniques have been shown to be capable of providing a quick and low-cost method for designing and fabricating testable prototypes. Further experimentation with silicone composition, viscosity, and vacuuming times could optimize these results.

Future work can apply the methods developed in this study to designing facepieces for the remaining head form sizes. The prototypes should undergo fit-testing on human subjects alongside commercially available facepieces to assess any differences in fit factors between the two. Differences observed in fit-testing could be indicative of whether an increase in the number of standard sizes that commercially produced facepieces are available in is needed.

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