Aerosol Leakage Testing of Additively Manufactured Face Masks

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Abstract

Background: The onset of the coronavirus 19 disease (COVID-19) led to an immediate shortage of personal protective equipment (PPE) and other medical supplies. To bridge the supply chain gap, stakeholders and private citizens alike turned to additive manufacturing (AM) to support these gaps for personal use when U.S. FDA cleared or authorized devices were not readily available. Fabricating face masks for source control and/or respirators to bridge supply shortages or disruptions using AM may have numerous considerations. This necessitates evaluating important quantities of interest such as sealing efficacy using some of the many available face mask frame designs that the community can access.

Purpose: The project consists of three (3) main experimental aims: 1. To evaluate the sealing efficacy of a representative set of as printed and post processed AM face masks on standard NIOSH rigid face forms 2. To evaluate the effect of washing on the sealing efficacy of AM face masks 3. To evaluate the sealing efficacy of pediatric AM face masks. **Methodology:** Four mask designs were selected as representative design models. Adult head forms were obtained from the NIOSH website and the pediatric form was obtained from the FDA Virtual Family project; head forms were additively manufactured in rigid nylon on an EOS P396. Face masks were printed on filament and powder bed fusion printers in rigid Polyethylene terephthalate glycol (PETG), rigid nylon, and flexible thermoplastic polyurethane (TPU). Do-it-yourself filter material was selected based on results from current FDA research efforts. Washing of the face mask frames was performed in a commercial dishwasher using a high and low heat setting. Relative sealing efficacy of the masks were determined by evaluating the total inward leakage (TIL) metric using a dry NaCl aerosol and measuring the face mask's pressure drop.

Results: Post processing the as-printed frames (i.e., form fitting) and adding foam strips reduced the TIL in the rigid PETG face masks. Adding foam strips to the flexible TPU face masks reduced inward leakage. The selected dishwashing cycles appears to increase TIL with increased washes. Selected pediatric AM masks have far greater pressure drops than adult size equivalents, although the TIL was comparable.

Conclusion: Face masks are intended as source control and not as PPE. AM face mask frame design, processing, and filter choices are critical to face mask sealing efficacy. Filter material cross-sectional area should balance breathability with filtration performance. Further testing on elastomeric head forms and with additional designs and filtration materials will be necessary to ascertain absolute performances.

Introduction

The onset of the coronavirus 19 disease (COVID-19) led to an immediate shortage of personal protective equipment (PPE) and other medical supplies. Through the help of the design libraries, such as the NIH print exchange, stakeholders and private citizens turned to AM to fill gaps in personal use face masks for source control and medical use PPE where U.S. FDA cleared or authorized devices were not readily available. To help address this immediate need, the FDA Medical Countermeasures Initiative (MCMi) funded this project to evaluate the sealing efficacy of additively manufactured face masks. Previous work completed by Guha, et. al. on DIY filter materials was referenced to obtain a suitable filter material. Fabricating face masks to bridge supply shortages or disruptions using AM may have numerous considerations and necessitates evaluating critical quantities of interest such as sealing efficacy. This project aims to evaluate the sealing efficacy of (1) a set of as printed and post processed, (2) washing, and (3) select resized pediatric AM face masks.

Materials and Methods

Face Mask Fabrication: Four mask designs were selected from available community COVID-19 model repositories (as of May 2020). Mask Design A was printed in Nylon 12 (PA 2200) on an EOS P396. Mask Designs B-D were printed in PETG and TPU on a PRUSA MK3S. Pediatric sized masks were generated by scaling down Mask B and Mask C to 80% and 75% scale, respectively. The filter material selected consisted of a combination of one layer of 1000 thread count cotton and 3 layers of a polyester hydrophobic mask bandana. This combination was based on results from previous work performed by Guha, et. al. Elastic ties for each mask were made from a ¼" cotton and elastomer blend material.

Face Mask Testing: NIOSH Standard Head Forms were printed in Nylon 12 using an EOS P396. Head forms were placed inside an acrylic chamber. Dried and charge reduced sodium chloride aerosols in the size range of 20 – 300 nanometers were introduced into the chamber with the NIOSH head forms donning the printed masks. Aerosol probes and pressure probes were placed to measure the concentration and pressure in the chamber and behind the mask (Figure 1A, 1B). The Total Inward Leakage (TIL) was calculated by dividing the concentration of aerosols downstream with upstream concentration averaged over the entire size range. Masks that were tested on NIOSH head forms were: as printed, with the addition of foam strips, with heat form fitting, and with heat forming and foam strips. A TSI CPC 3775 and a TSI SMPS 3080 Classifier were used to quantify aerosol particles and pressure sensors (mm H2O) controlled by a Raspberry Pi recorded the pressure drop. Pediatric (PED) masks were tested under the same conditions as adult sized masks on a head form model of Dizzy from the FDA Virtual Family Project.

Washing: A Whirlpool dishwasher on High Temp with Heated Dry and "Cold"/regular wash cycles was used. Filtration and pressure drop were tested and visual analysis for warping was performed before and after each wash cycle.

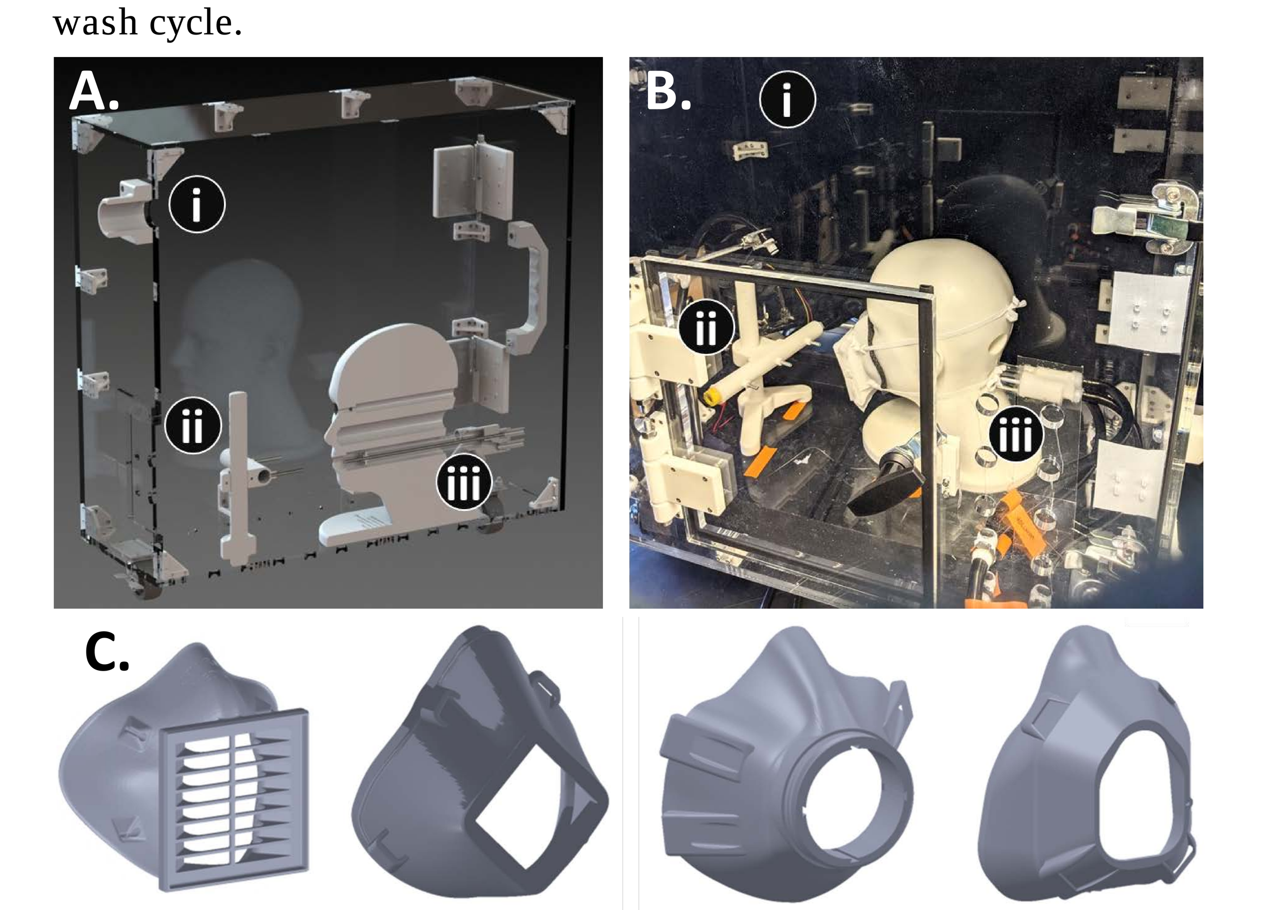

Figure 1. *(A) CAD rendering of the current testing chamber. (B) Testing chamber with NIOSH Medium Head wearing AM mask Frame A Size Medium. (i) Aerosol inlet to chamber (ii) Upstream Sampling port (iii) Downstream sampling port and vacuum line. (C) AM Mask Frames selected for the experiment taken from community 3D model repositories and freely available for download.*

Results and Discussion

- TIL increases with fit mismatch and decreased sealing efficacy. Frame modifications, such as: heat forming, adding foam strips, and utilizing flexible materials, appeared to reduce gapping between the face and mask frame and reduced TIL. Pressure drop data suggests that the frames with the higher filter cross sectional area allow for improved breathability.
- Hot wash cycles produced noticeable warping on some frames even with a high temperature tolerance AM filament (PETG). TIL appears to increase even under COLD wash settings without visible warping to AM mask frames suggesting a diminished sealing efficacy. It should be noted that washing cycles are not equivalent to sanitizing or sterilization and those effects were outside the scope of this project.
- While the TIL was comparable between the adult and PED sized masks, the pressure drop was noticeably higher for PED masks with values nearing the unacceptable range for adults. When tested at higher flow rates that mimic greater physical activity (data not shown) pressure drops rose higher than the acceptable range.

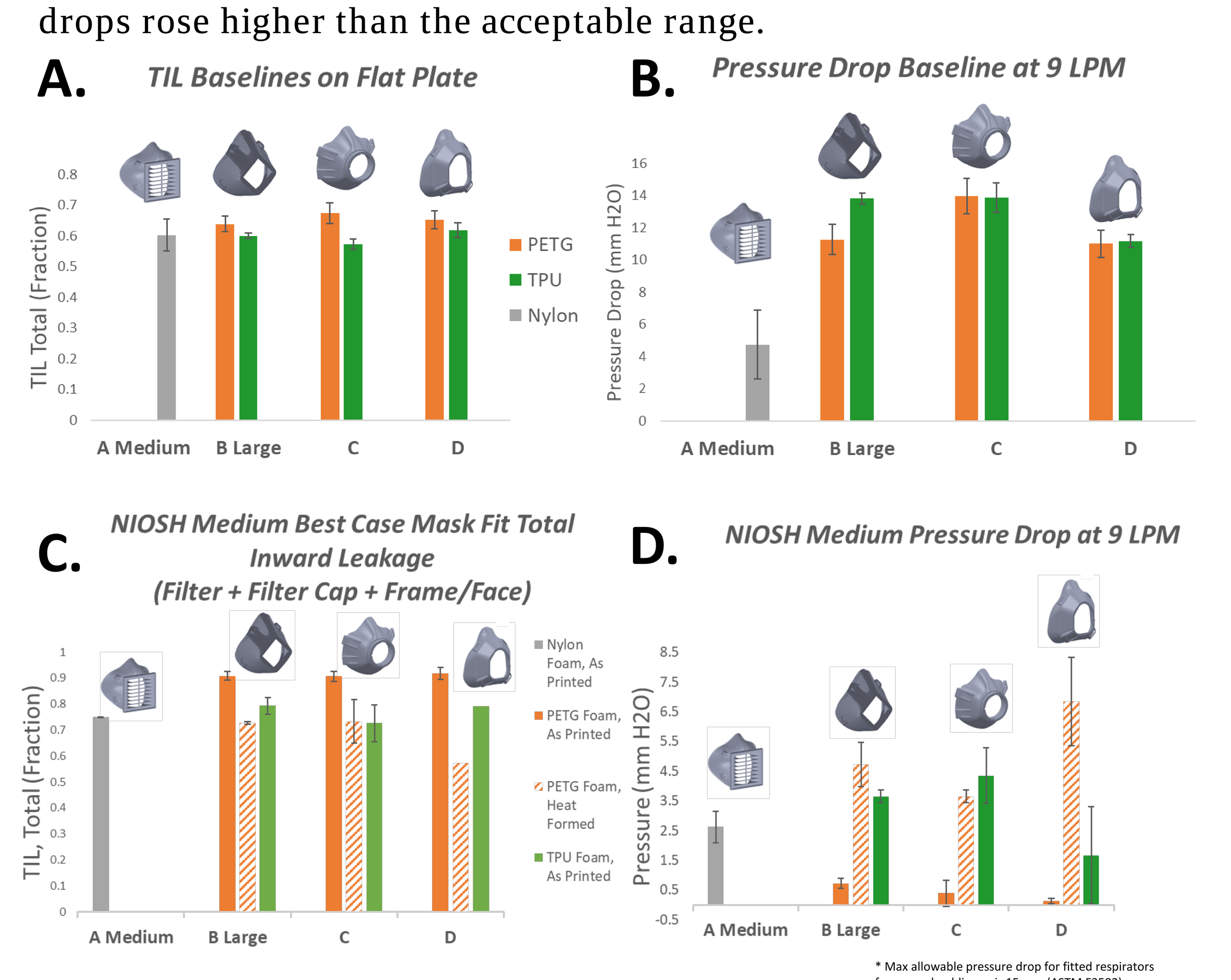

Figure 2. *(A) Total Inward Leakage for baselines (Filter + Filter Cap) at 9 LPM, error bars represent sd (n = 3). (B) Pressure drop recorded on baselines at 9 LPM, error bars represent sd (n = 3). PETG and Nylon are rigid materials, TPU is a flexible polymer. (C) Total Inward Leakage of full-sized AM mask frames on NIOSH Medium Rigid Nylon head form at 9 LPM for "best case" fit scenarios: heat formed (where possible) and with foam, error bars represent sd (n = 2). (D) Pressure drop across AM mask frames, error bars represent sd (n = 2). Filter material is 1 layer of 1000 thread count cotton and three layers of mask bandana.*

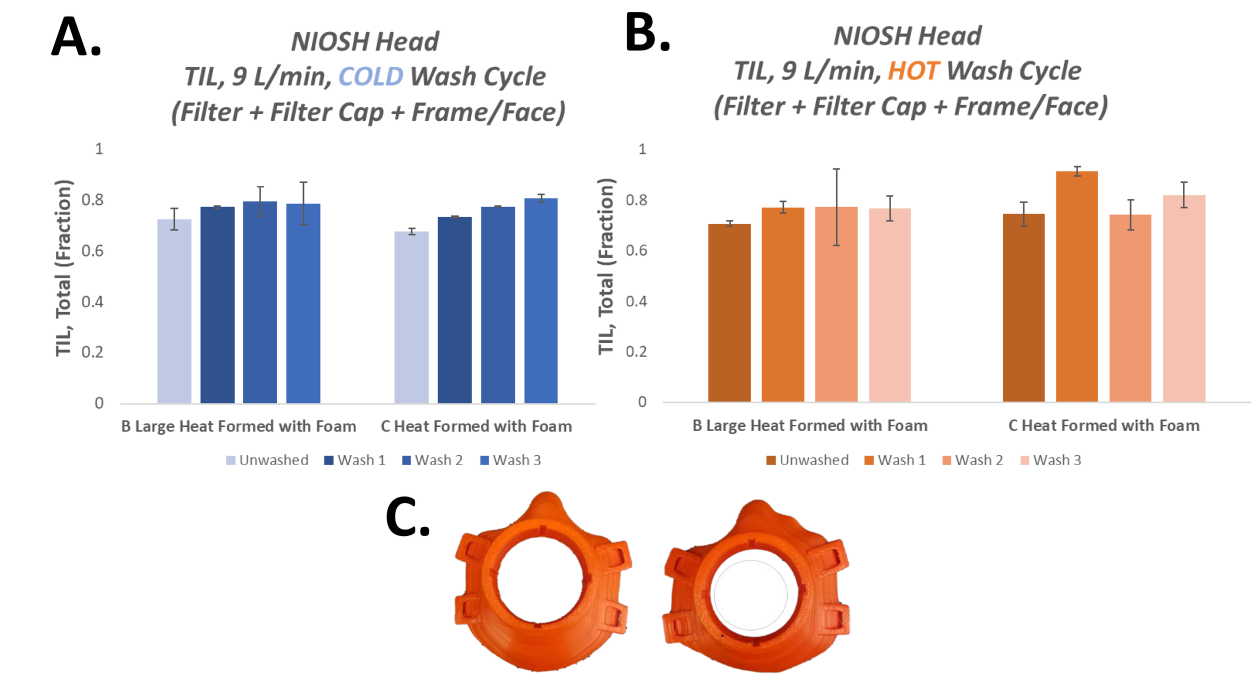

Figure 3. *Change in TIL of AM face mask frames B size Large and C over 3 wash cycles (A) COLD Cycle and (B) HOT Cycle. Error bars represent standard deviation (n = 2). Elastic ties and filter material (1 layer 1000 thread count cotton with 3 layers of mask bandana) were replaced between each wash cycle. Experimental set up was a dried aerosol run at 9 LPM from a 50 mg NaCl/ 100 mL water solution. (C) Frame warping occurring on Mask C printed in PETG before (left) and after (right) one HOT wash cycle.*

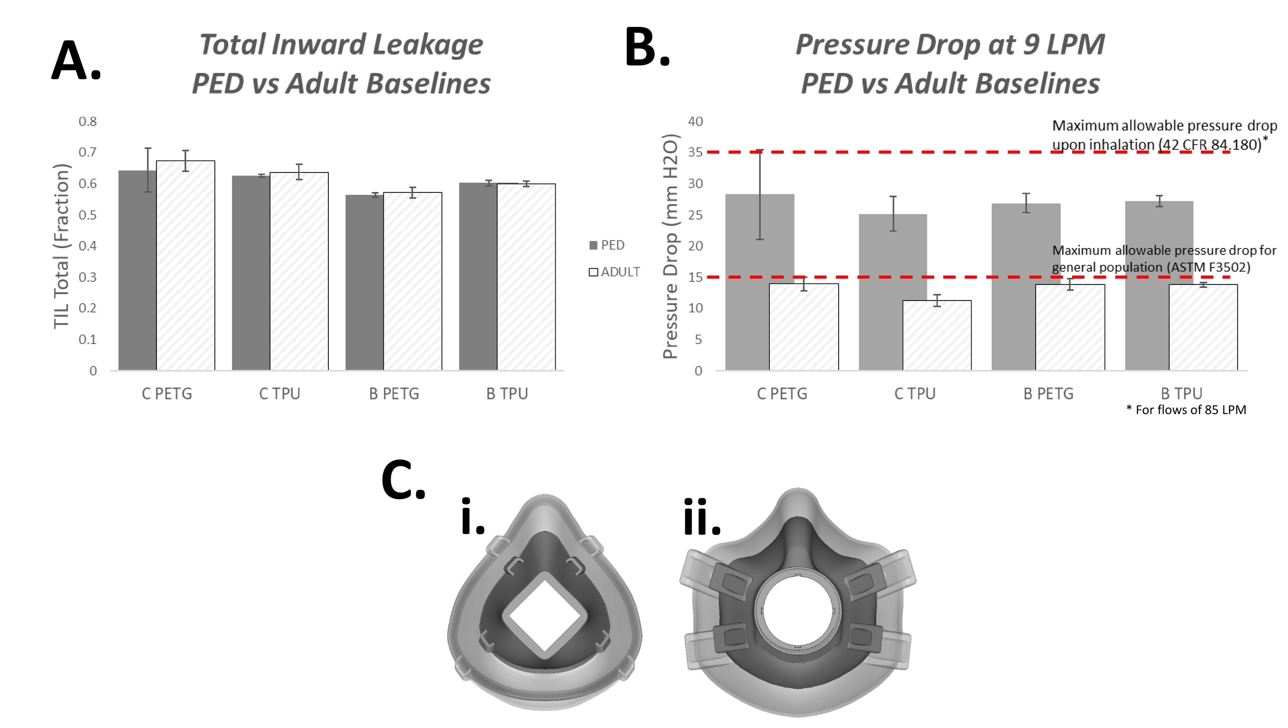

Figure 4. *(A)Total Inward Leakage (Filter + Filter Cap) of pediatric (PED) sized mask baselines versus adult sized frame, error bars represent sd (n=3) Cross sectional area of PED filtering region is 1.7 in² and 1.5 in² for PED Frames C and B, respectively. (B) Pressure Drop across mask filter and filter cap at 9 LPM, dashed line is maximal allowed pressure drop in certified N95s for adults in accordance with 42 CFR 84.180, error bars represent sd (n = 3). (C) Scaled PED mask frame superimposed over adult size (i) Frame B Large and (ii) Frame C, PED B is 80% scale of B Large and PED C is 75% scale of C.*

Conclusion

- Foam strips and heat forming can assist in improving fit on AM mask designs. Filter cross sectional area should also be noted when designing AM mask frames as a small filter cross sectional area can lead to unacceptable pressure drops.
- Performance of reprocessed masks depends on the AM manufacturing method and material chosen. Masks should be evaluated for leakage in between washing cycles to ensure structural integrity of the frame which may become compromised over time thus increasing leakage.
- When designing AM masks for pediatric use, cross sectional area of the filter should be maximized. The small filtration area used in this study increased the flow velocity (for the same flow rate compared to adult AM masks) which concomitantly increased pressure drop thus reducing breathability.