The HensNest: Mass Manufacturing a General Use Face Mask Here in Delaware

Catherine Fromen;¹ Whitney Sample;² Ajay Prasad;³ Jenni M. Buckley⁴

- 1. Assistant Professor, Chemical and Biomolecular Engineering, University of Delaware
- 2. Industrial Designer, Mechanical Engineering, University of Delaware
- 3. Chairperson, Mechanical Engineering, University of Delaware
- 4. Associate Professor, Mechanical Engineering, University of Delaware

Introduction

In the age of the COVID-19 pandemic, face masks have been universally touted by health care officials as the best practice in non-pharmaceutical intervention to stop the spread of airborne viral transfection.^{1–3} "Face masks" by definition are a transmission barrier that covers the mouth and nose to limit the number of exhaled particulates from the wearer. These are to be distinguished from "respirators," such as the clinically rated N95 respirator, which seals tightly to the face when properly fit tested and is designed to protect the wearer from inhaling airborne environmental particulates.⁴

Despite the distinction in intended utility between face masks and respirators, face masks can also provide protection to the user. How much protection depends on two interrelated factors: the face mask material and the fit to the face. Depending on the material composition, thickness, and layering options, cloth and do-it-yourself (DIY) face masks can demonstrate significant filtration efficiency.^{4,5} Recent reports have shown that layering materials with mechanical and electrostatic filtration mechanisms (i.e., cotton and silk) have filtering efficiencies equivalent to an N95 and that outperform standard disposable surgical face masks.⁴ While combinations of materials may combine to efficiently filter aerosols through the mask, they will not work if significant airflow bypasses the mask through leaks between the mask and the face.^{4,6,7} Materials with high mechanical filtration efficiency often have high internal resistance to airflow, leading to poor breathability and a higher likelihood of leakage around the face. Thus, these interrelated variables of filtration material and face fit are critical when considering what face mask options can simultaneously provide a high degree of comfort/wearabilty *and* personal protection against inhaled viral droplets.

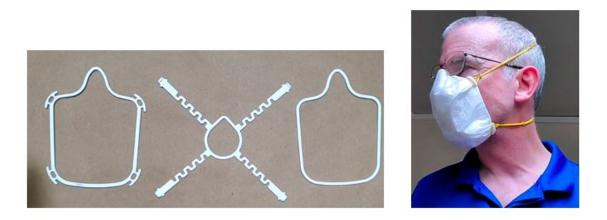
In line with Centers of Disease Control and Prevention (CDC) recommendations promoting the use of face masks for even brief excursions outside of the home, demand for face masks from the general public is expected to continue. Our team is driven to provide an answer to *"what is the best DIY face mask option?"* and provide practical solutions for personal face masks that afford protection to the wearer, without impacting the supply chain for clinically-rated N95 respirators.

The HensNest Face Mask Design

In response to these critical concerns surrounding mask availability and the need for good face fit, our team has developed an easy-to-manufacture face mask design, called The HensNest (Figure 1). The HensNest design consists of a simple plastic wireframe that can be quickly and cheaply manufactured through additive manufacturing (*i.e.*, 3D printing) and/or injection

molding. The plastic wireframe is dishwasher and disinfectant safe, can be packaged and shipped flat for self-assembly by the end user, and accepts a range of filter types, including common household materials such as HEPA furnace filters and shop towels. The most critical aspect of this design is that it lofts the mask away from the face while providing additional curvature to adequately cover the nose. In combination, this design was intended to improve face fit while increasing both comfort and wearer protection. The design has been released to open source platforms (GrabCAD and NIH 3D Print Exchange) and additional information about The HensNest design can be found on our website at: <u>https://me.udel.edu/hensnest-3d-printed-face-mask/</u>Our on-going research seeks to validate how the HensNest design compares to other DIY face masks, especially in regards to the two major variables: filter material and face fit.

Figure 1. The HensNest face mask consists of a plastic wireframe (left) that is assembled by the user and accepts one of several commonly available household filter media (right). The filter media shown in the image at right is from a household furnace filter. The design can be secured to the face with elastic bands.



Respiratory Fit Tests

Quantitative respirator fit tests have been performed on a single adult subject wearing multiple face masks using professionally rated and calibrated equipment (PortaCount Respirator Fit Tester 8038, TSI Incorporated).⁸ The Occupational Safety and Health Administration (OSHA) Fast Fit Test Protocol⁹ was repeatedly performed, which involves the subject performing multiple activities of daily living while wearing the mask, including normal breathing, bending over, turning head side-to-side, and jogging in place. The Fast Fit Test Protocol uses a known concentration of ultrafine salt particles 0.05 to 1.25 μ m in diameter (Particle Generator 8026 with Salt Tablets 80311, TSI Incorporated) dispersed into the ambient air to simultaneously quantify the particle concentration outside of and within the mask via a sampling tube. The primary output from fit testing is the "Fit Factor," defined as the ratio of ambient particulate concentration inside the mask, taken as an average across all activities prescribed by the test. A fit factor of five means that the face mask reduces particulate concentration by a factor of five.

Per OSHA protocol, calibration was performed immediately before mask testing. For each mask fit test, a small puncture hole was made at a single location approximately 1 cm lateral to the nostrils and widened sequentially to accommodate the ¹/₄" sampling tubing for the fit tester

equipment. The puncture hole was sealed on the interior and exterior side of the mask using provided fittings.

Our results shown in Table 1 demonstrate superior fit testing from the HensNest. Typical face masks with ear loops, whether medical-grade surgical masks, sewn cotton face masks, or nonsewn (e.g., bandana) masks, all demonstrated a fit factor of 1.0, which can be interpreted as offering no protection from airborne particles. When outfitted with a single ply of HEPA grade home furnace filter (Filtrete Ultra Allergen Air Filter, 3M Corp), the HensNest face mask demonstrated a fit factor of 8.0, meaning it reduced particle concentrations by 8x from ambient air conditions. Furthermore, the fit factor scaled with the number of material plies, and using 3-ply of the HEPA filter resulted in a fit factor of 23, although the subject did report more difficulty breathing through the mask with additional layers. The filtration protection of the HensNest does not yet match that of an N95 (fit factor 83 from our testing); however, we are continuously refining mask design and filter choice to compete with this benchmark. Additional studies on more individuals are on-going to further improve the HensNest protection.

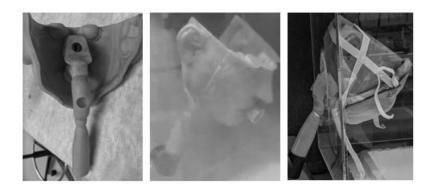
| Table 1. Results from Fit Testing | |
|-----------------------------------|--------|
| Mask Type | Fit |
| | Factor |
| Surgical Mask | 1 |
| HensNest (HEPA, 1 ply) | 8 |
| HensNest (HEPA, 3 ply) | 23 |
| N95 Respirator | 83 |

Table 1. Results from Fit Testing

Bench-top aerosol assessments

While quantitative respirator fit tests are the OSHA standard for filtration efficacy, they are destructive to the filter material of the mask⁹ and only expose the mask to limited environmental conditions. With the intention of accelerating our design iterations on mask geometry and filter media, our team has developed a benchtop model consisting of a single adult face profile attached to physiologically-accurate nasal and upper airway passages (Figure 2). This approach allows us to decouple mask efficiency during exhalation (to protect others) from mask efficiency during inhalation (to protect the wearer). Furthermore, we can assess downstream impacts to the wearer by approximating the location of aerosol deposition in the nose and lung. With this assay, we can expose the model to a controlled concentration of aerosols and evaluate potentially hazardous materials (including aerosols containing viral derivatives) to fully evaluate the mask efficacy, taking into consideration human breathing patterns and lung humidity. These benchtop studies will add a critical new dimension to face mask evaluations that can evaluate true face mask efficiency by combining both face fit and material filtration elements under realistic breathing simulation. Studies with the HensNest under varied environmental conditions are ongoing, with our current results supporting the superior personal protection reported in our human fit testing.

Figure 2. 3D printed airway model for face mask testing. From left to right: nasal and oropharyngeal airspaces with two aerosol sampling ports, mask generating aerosols through mouth outlet, model wearing the HensNest face mask.



HensNest Impact in Delaware

Given our promising findings to date, we believe the HensNest affords a superior DIY option in personal face masks that improves the fit on the wearer and provides upwards of four to eight times more protection compared to cloth masks.

We have begun to distribute our design to high risk individuals and frontline workers throughout the state. In addition to our open source design that is available globally, we have scaled local production to provide HensNest face masks throughout the State of Delaware. Through generous donations and essential organizational partners who have donated over \$100k in time and materials to the project, we have manufactured over 30,000 units. Stratasys Corp (Eden Praire, MN) and Negri Bossi North America, Inc, (New Castle, DE) have injection molded the plastic wireframes at no cost and have donated all time and materials necessary to do this. Donate Delaware (501c3 pending) has mobilized its volunteer force to package and distribute these mask kits, with The Newark Partnership and several local grocery store chains already requesting bulk orders. The University of Delaware College of Engineering and Department of Mechanical Engineering has generously covered all personnel costs associated with product development, testing, and project management, which at this point includes a team of approximately ten engineers and designers.

Our small volunteer team has assembled distribution packages of the facemask, filter material, elastic bands, and a brief set of assembly instructions. We are prioritizing donations in our local community to high risk individuals (elderly and immunocompromised individuals), home caretakers for high risk individuals, and those working in high exposure risk environments (grocery store workers, delivery persons). At the time of this publication, our masks are being used by frontline workers at Delaware Healthcare Facilities, City of Newark, VCA Animal Hospitals, and several local restaurant and grocery stores.

Conclusion

As face mask use remains our main weapon in fighting the spread of COVID19, continued efforts are needed to improve existing face mask options, develop testing tools to evaluate their efficacy, and introduce more effective face mask options for use by the general public. Our work in the design, testing, and distribution of the HensNest face mask is having an immediate public health in advancing these fundamental aspects of face mask utility and will continue to have impact throughout the state of Delaware.

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