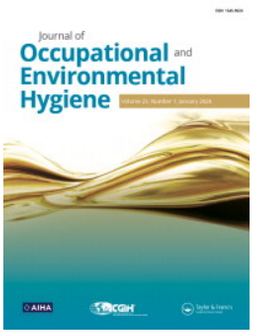

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Development of an animatronic headform test method for determining the efficacy of medical masks and barrier face coverings—part 1: total filtration efficacy

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ABSTRACT

The effectiveness of face coverings against respiratory viruses is crucial for public health but often lacks realistic performance assessments of protection and comfort. In this study, a system-level test method was developed using an animatronic headform to incorporate fit and dynamic wear into the assessment of total filtration efficacy of medical masks and barrier face coverings. Six commercially available products were evaluated, including an N95 respirator as the control. Total filtration efficacy was calculated from differential particle counts recorded inside and outside of face coverings each minute. The baseline method was able to statistically differentiate between products to a difference in means of 5% at a particle size of 0.3 μm optical diameter. The 16 and 28 L/min sinusoidal flow rates significantly impacted total filtration efficacy, as did the influence of headform movement and duration of wear for select products. There were statistical differences between operators at both flow rates for the KN95 and surgical style masks that were difficult to don consistently, highlighting the variability in performance due to fit. However, the product type remained the most significant cause of variance in the method at 66.10%, demonstrating that the headform test method was able to repeatedly and reproducibly evaluate the efficacy of various face coverings. Furthermore, there were significant decreases in filtration when the facepiece was not sealed properly due to poor fit. This highlights the importance of evaluating these source control devices, including barrier face coverings and public use of medical masks, as they are intended to be worn to incorporate their fit into the reported results.

KEYWORDS

Aerosols; COVID-19; inward leakage; public health; respiratory protection; source control

Introduction

The public is exposed to a wide array of respiratory hazards spanning from infectious agents to environmental pollution. During the COVID-19 pandemic, biological hazards became prominent with respiratory viruses transmitted predominantly as aerosols. Viral aerosols are defined as airborne solid or liquid particles of biological origin less than 5 μm in diameter, which are generated when individuals breathe, speak, cough, or sneeze (Kutter et al. 2018; Jayaweera et al. 2020). At the same time, environmental events such as wildfires, dust storms, volcanic eruptions, and industrial emissions continue to produce airborne particulate matter that contributes to respiratory and cardiovascular diseases, particularly among vulnerable populations (Burnett et al. 2018). Both biological and non-biological aerosols can penetrate the respiratory tract upon inhalation and have the potential to cause a variety of health impacts resulting from their deposition and translocation in the body (Racz et al. 2017). These overlapping threats underscore the importance of effective strategies and protective measures to reduce respiratory exposures across diverse hazardous environments in both occupational and public sectors.

Protecting the respiratory tract from hazardous and infectious substances is essential for safeguarding individual and population health and has historically been a cornerstone of occupational safety programs

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This article has been corrected with minor changes. These changes do not impact the academic content of the article.

(National Institute for Occupational Safety and Health 2023). Most respiratory protection standards and technologies have been developed primarily for regulated workplace settings, where comprehensive risk assessments and formal fit-testing are routine. However, the COVID-19 pandemic exposed a critical limitation of this occupationally focused paradigm: the general public, lacking access to certified respirators and fit-testing infrastructure, faced significant respiratory risks without widely applicable guidance or effective protective solutions. This experience highlighted the need to expand respiratory protection solutions, performance testing, and public guidance beyond traditional occupational standards to ensure that the broader population has access to practical and evidence-based information about the capabilities and limitations of accessible products during health emergencies.

During the pandemic and in the years following, individuals turned to products with varying levels of filtration performance. There are three basic categories of products that have been used in this capacity: traditional respiratory protection devices, medical masks, and barrier face coverings. The most common form of respiratory protection used by the public was Filtering Facepiece Respirators (FFRs), including N95s, which are disposable air-purifying respirators made from nonwovens. FFRs must be certified in the United States by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR Part 84 Approval of Respiratory Devices to filter at least 95% of airborne particles at a count median diameter (CMD) of $0.075 \pm 0.020\,\mu m$ with a geometric standard deviation of 1.86 (Department of Health and Human Services 2002).

While not considered respiratory protection devices, medical masks and barrier face coverings can provide a simple barrier to prevent transmission of respiratory droplets and act as a method of source control for the public in situations where FFRs may not be accessible (U.S. Centers for Disease Control and Prevention 2024). Medical masks are nonwoven, disposable masks with a liquid-repellent outer layer to protect the wearer from droplets. They are regulated by the U.S. Food and Drug Administration (FDA) and fit loosely to the face, typically utilizing simple ear loops for donning (U.S. Food and Drug Administration 2004). Barrier face coverings offer another comfortable and accessible option for the public that come in a variety of materials and designs. Barrier face coverings should cover the nose and mouth while simultaneously providing a reasonable degree of filtration and breathability. They are generally loose-fitting and have varying performance levels based on the inherent properties of their materials and the environment in which they are worn (Tcharkhtchi et al. 2021).

The rising demand for barrier face coverings in the consumer market during the pandemic inspired several studies to evaluate the efficacy of accessible materials. The fiber composition, shape, and diameter, along with the weight, thickness, and packing density, have been reported to influence the particulate filtration efficiency (PFE) of materials to different extents across studies (Konda et al. 2020; Zangmeister et al. 2020; Zhao et al. 2020; Drewnick et al. 2021; Hao et al. 2021; Joo et al. 2021; Kwong et al. 2021; Kiryaman et al. 2024). However, variations in literature and standard testing procedures have made it difficult to directly compare data since changes in particle size, charge, and flow rate can have a significant impact on the reported results (Rengasamy et al. 2017).

Additionally, different performance standards for evaluating respirators and medical masks designed to address their unique occupational functions across different populations may not be directly applicable to these new barrier face coverings intended for public use. NIOSH requirements for air-purifying respirators are designed to evaluate the worst-case scenario under a constant 85 L/min flow rate with neutralized 0.075 µm CMD NaCl particles to test the filter media. The FDA requires surgical masks to be tested for PFE following ASTM F2100-21 Standard specification for performance of materials used in medical face masks. This standard references ASTM F2299-17 Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres to test for PFE with unneutralized 0.1 μm latex spheres within a wide allowable range of face velocities ranging from 0.5 to 25 cm/sec (ASTM International 2017, 2021a). Bacterial and viral filtration efficiency procedures are also available; however, they use larger 3 μm particles, which tend to be filtered out more readily than smaller particles, leading to inherently high filtration efficiencies (Rengasamy et al. 2017).

As of March 2021, ASTM F3502-21 Standard Specification for Barrier Face Coverings formally defined barrier face coverings as products that are worn over the nose and mouth that do not qualify as surgical masks or respirators. It established minimum performance requirements for PFE and breathability using a modified version of the NIOSH test for air-purifying respirators referenced in 42 CFR Part 84

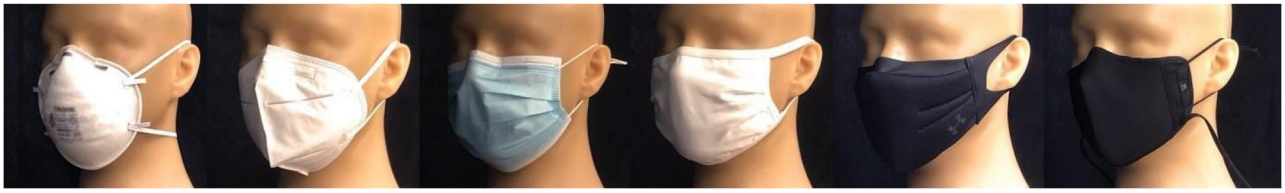

Figure 1. Products tested from left to right: N95 respirator, KN95 style mask, surgical style mask, cotton face covering, athletic face covering, and hybrid face covering.

(ASTM International 2021b). However, the ASTM F3502-21 method seals the products around the edges, which does not account for the curvatures of the face or the dynamic wear characteristics of fit. The standard references an optional quantitative fit assessment following the procedure in ASTM F3407-20 Standard Test Method for Respirator Fit Capability for Negative-pressure Half-facepiece Particulate Respirators, but human subject testing can prove challenging and costly (ASTM International 2020). Headforms are capable of simulating fit testing more repeatably than human wear trials while maintaining acceptable respirator fit factors (Bergman et al. 2014). Barrier face covering filtration performance has been shown to drop 60% or more when measured on a headform from leakage around the bridge of the nose, chin, and jawline due to poor fit (Hill et al. 2020). The design of a barrier face covering can play a significant role in improving filtration if it creates a seal to the face that requires particles to travel through the material by minimizing leakage through gaps at the interface with the skin (Fischer et al. 2020; Verma et al. 2020a).

The objective of this study was to develop a baseline test method to evaluate the efficacy of various medical masks and barrier face coverings by referencing and combining aspects from ASTM F3502-21 and the fit-test protocol from ASTM F3407-20 to adapt them for the animatronic headform. For this initial study, a select number of medical masks and barrier face coverings were tested alongside an N95 respirator high-performance benchmark that is certified to filter at least 95% when evaluated according to 42 CFR Part 84. The medical masks and barrier face coverings tested were chosen to represent a wide variety of source control devices available to the public during the COVID-19 pandemic. The scope of this paper will focus on evaluating specific test variables and factors that influence total filtration efficacy on the headform and those that can be optimized in a follow-on study. The current study's companion paper (Development of an animatronic headform test method for determining the efficacy of medical masks and barrier face coverings – part 2: validation study) refined this headform method, incorporated differential pressure measurements, evaluated a wider selection of barrier face coverings, and compared them to the ASTM F3502-21 standard method (Armistead et al. 2026).

Methods

Samples

Six commercially available products were evaluated as shown in Figure 1. They comprised a variety of material and design characteristics listed in Table S1. The first product used in this method was a certified N95 respirator, which served as a high-performance benchmark to ensure the system was working and capable of measuring filtration performance in the higher end of the range. Before testing, all samples were preconditioned at $20 \pm 2\,^{\circ}C$ and $65 \pm 5\%$ relative humidity for a minimum of 25 h. Each face covering was carefully donned on the headform to minimize gaps at the skin interface. The ear loops on the medical masks were tied to achieve a better fit, a common practice when wearing these products. One pre-conditioned sample was used per test cycle and tested as received from the manufacturer without laundering. Ten samples of each product type were used to replicate this test cycle. Testing was conducted over multiple days by three different operators.

Headform specifications

A medium animatronic headform sized according to ISO 16900-5:2016 Respiratory Protective devices—Methods of Test and Test Equipment was used to develop a system-level evaluation of face covering performance, as shown in Figure 2 (International Organization for Standardization 2016). The Fully Animatronic Respirator Testing Head Form (i-bodi Technology Ltd, Buckingham, UK) uses a digital breathing machine connected to the mouth cavity to simulate breathing. It performs four basic movements that include shaking the head side-to-side, nodding up and down, wobbling side-to-side, and opening and closing the jaw to simulate talking. The headform

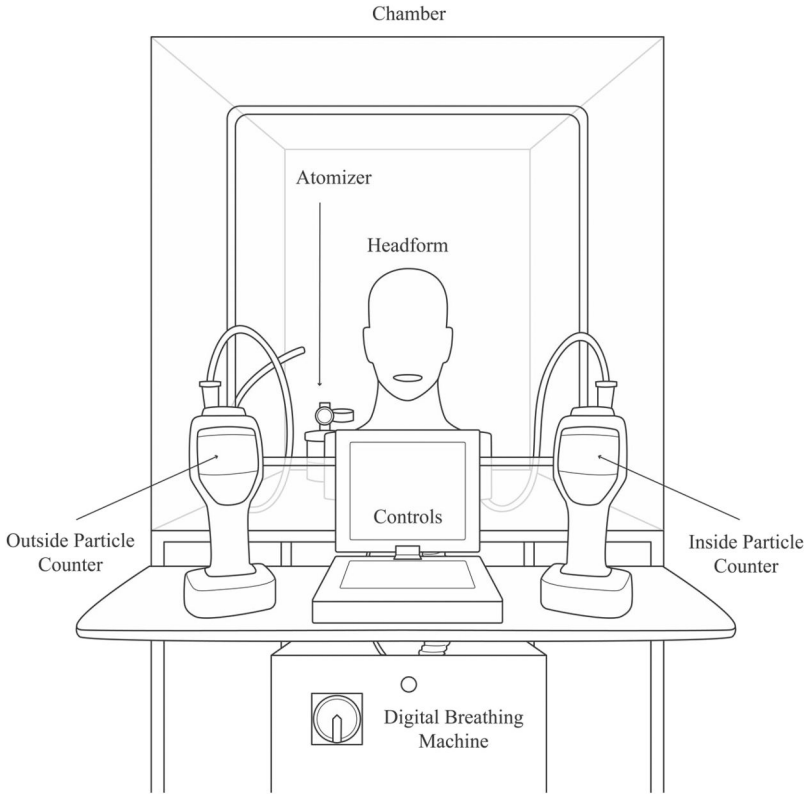

Figure 2. Diagram of the animatronic headform test apparatus.

software allows for customizable breathing and movement sequences. It has a compressible silicone skin to allow for the formation of a simulated seal to the face. The headform is enclosed in an acrylic chamber 3.43 x 10^5 cm^3 in volume, with a removable door that provides access to the headform and allows tubing to connect outside the system.

Measurements

Two six-channel Fluke 985 optical particle counters (Fluke Corporation, Everett, WA) capable of detecting particles down to 0.3 μm optical (geometric) diameter (D_{opt}) were used for the testing. Optical particle counters (OPCs) were selected for headform testing in this initial study due to their widespread availability and relatively low cost compared to specialized particle-sizing instruments such as scanning mobility particle sizers (SMPS). While devices like the SMPS can accurately measure particle sizes at the most penetrating particle size (MPPS) range used in the NIOSH certification (the count median diameter (CMD) of 0.075 μm and mass median aerodynamic diameter (MMAD) of 0.3 μm), these systems are more expensive and not commonly accessible in most research or applied laboratory settings. OPCs, in contrast, measure optical (geometric) diameter and are limited in reliably sizing and counting particles below 0.3 μm, which introduces well-recognized limitations for direct comparison to regulatory filtration test data. Nonetheless, their practicality allows for the development of a broadly replicable approach to system-level face covering evaluation, providing a useful basis for comparison and future method refinement as more advanced instrumentation becomes available.

In the headform setup, the "outside" count measured the chamber environment outside of the face covering, and the "inside" count measured inside the face covering through the mouth cavity and adjacent to the breathing tube. The average difference between the two particle counters was determined to be 4.52 ± 3.11% for 0.3 μm D_{opt}. Each measurement was taken via approximately 80 cm of tubing from each sampling location to the particle counters positioned outside the chamber. The differential particle count data was logged during the test at one-minute increments at a flow rate of 2.83 L/min. The corresponding inside and outside measurements were then used to calculate the filtration efficacy.

The term total filtration efficacy (TFE) was used to distinguish this system-level test from the material-based PFE methods. TFE considers particles that

penetrate the material as well as those that may leak around the barrier. This value encompasses the combined effects of materials, design, and fit of the sample being tested. The percent TFE was calculated for the cumulative and differential particle counts each minute using Equation 1:

$$\%\ TFE = 100 - \%\ P \quad (1)$$

where the percent penetration (%P), or total inward leakage (TIL), was determined by the ratio of particles measured inside to outside each sample. TFE is reported in this study to compare the measured filtration efficiencies more easily with those reported in the material-level PFE tests. However, this method can also be used to determine the reverse, TIL, in an effort to quantify inward leakage for these products that are not designed to seal to the face.

Procedure

Testing was conducted when ambient particle counts measured below 100,000 particles/min at 0.3 μm D_{opt} on the Fluke counters to ensure enough particles could be generated inside the chamber without oversaturating the instruments. Temperature and relative humidity were recorded daily, but the testing environment was not controlled. An unneutralized, polydisperse aerosol was generated with the Single-Jet Atomizer 9302 (TSI Inc, Shoreview, MN), using a 2% NaCl solution. During testing, the atomizer was turned on to 2.0 ± 0.5 psi and placed in the back left corner of the chamber. Each sample was donned, and then the chamber was filled with aerosol for approximately 15 s while the door was fitted in place before the test began.

Each test cycle consisted of one five-minute segment of static breathing and then a second five-minute segment of dynamic movement and breathing. During the static segment, the headform was breathing and remained stationary for the five-minute duration. In between tests, an air purifier was run inside the chamber to reset the environment. For the dynamic segment, the headform performed one minute of each of the four available movements at a rate of 24 reps/min, followed by one minute of stationary breathing. The dynamic protocol included head shaking, nodding, jaw biting, and head wobbling to mimic a respirator fit test on the headform. These protocols are listed in Table S2.

Testing was repeated at two different sinusoidal respiration patterns to approximate light and moderate workloads. The first breathing sequence was programmed at 16.26 breaths per minute (BPM) with a tidal volume of 0.98 L to generate a minute volume flow rate of 15.93 L/min. This equates to a peak inspiratory flow of approximately 50 L/min by multiplying the minute volume by pi. The second sequence was programmed at 28.23 BPM with the same tidal volume of 0.98 L for a flow rate of 27.67 L/min. Peak inspiratory flow at the higher setting was approximately 87 L/min to reach a similar penetration to the 85 L/min constant flow used in respirator testing (Zhu et al. 2018). After completing 10 replicates at each flow rate, the test products were sealed to the headform with 3 M Transpore tape around the perimeter of each sample to compare the material PFE to TFE on the headform. Five replicates were completed at both flow rates by a single operator. Sealed testing was otherwise completed in the same way as the original unsealed method.

Statistical analysis

Statistical analysis was performed using JMP Pro statistical software (16.0, SAS Institute Inc, Cary, NC). An assumption of normality was made due to the high number of observations in each data set and confirmed with an analysis of the residuals. The Analysis of Variance (ANOVA) test was used for the comparative analysis between each test variable and TFE at 0.3 μm D_{opt}. A P-value (P) of less than 0.05 was used to indicate significance. If $p < 0.05$, post hoc testing was completed using Tukey's Honest Significant Difference (HSD) test to further determine the significant differences between all pairs. Individual P-values are listed in supplemental material Tables S3 through S26. Clinically significant changes in TFE were considered to be statistically significant differences of 5% or more.

In this study, statistical analysis focused on the smallest particle size reliably measured by the OPCs, 0.3 μm D_{opt}. For NaCl aerosols, this optically measured particle size corresponded to approximately 0.44 µm MMAD and 0.139 µm CMD, which are about twice the diameters used in standard regulatory testing (0.237 µm MMAD and 0.075 µm CMD under 42 CFR Part 84). Although using particles of larger diameter limits direct comparability to NIOSH certification methods, this approach enables robust assessment of face covering performance on the headform and provides valuable data on the method's consistency and reproducibility across products.

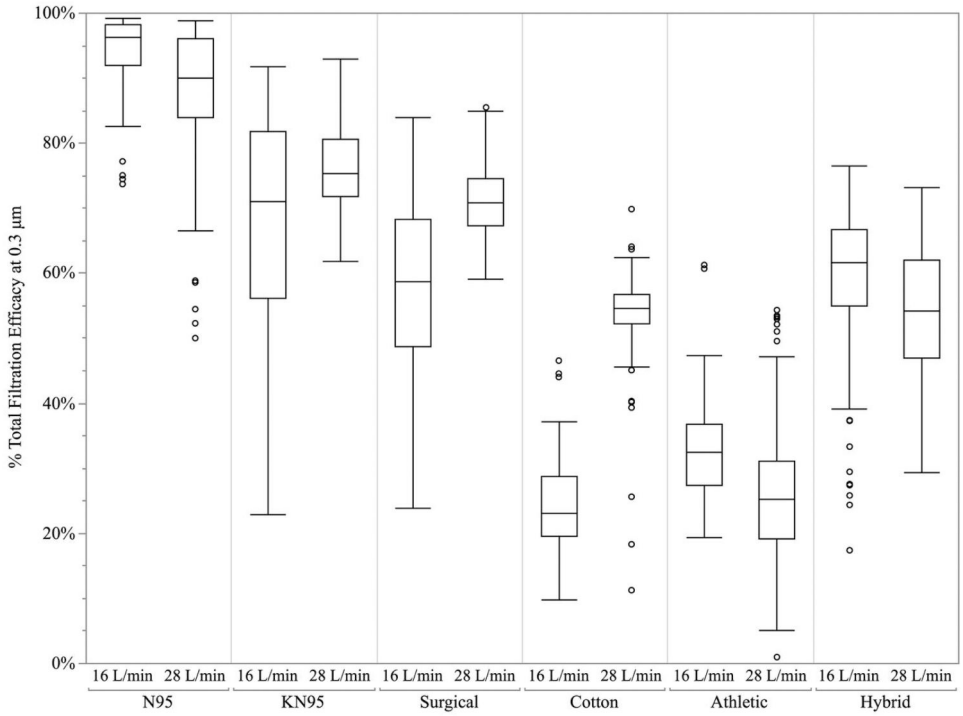

Figure 3. Box plot for TFE at 0.3 μm optical (geometric) diameter comparing breathing flow rates by product.

Results

Total filtration efficacy

The mean cumulative and differential TFE values were determined for each product along with their standard deviations at both light and moderate flow rates (approximately 16 and 28 L/min, respectively). The N95 respirator maintained a consistent TFE across all particle sizes with an average TFE of 88 to 94% at 0.3 μm D_{opt}. The KN95 and surgical style masks averaged between 58 and 76% TFE. These two had the highest standard deviations of TFE, which were approximately 13 to 18% across all six products at the lower flow rate. The hybrid face covering made with a layer of nanomaterial was also able to perform near this range, with a TFE between 54 and 59% at 0.3 μm D_{opt}. The cotton and athletic face coverings had the lowest TFE between 24 and 53%, which was expected due to their relatively loose-fit and open-knit structures. The barrier face coverings all had standard deviations $\geq$ 7% at either flow rate. All products increased TFE as particle size increased up to 2 μm D_{opt} at both flow rates.

TIL values are the inverse of the reported TFE, where higher leakage corresponds to lower TFE. The athletic face covering had the highest TIL, which ranged from 67 to 74% across both flow rates. Next, the cotton face covering ranged from 47 to 76%, followed by the hybrid face covering from 41 to 46%, the surgical style mask from 29 to 42%, and the KN95 style mask at 24 to 33%. As expected, the N95 respirator had the lowest TIL, which ranged from 6 to 12% depending on the achieved fit.

Flow rate

At 16 L/min, the product type was found to be statistically significant. The pairwise analysis determined that the only means that were not statistically different from each other were the hybrid face covering and the surgical style mask. The smallest significant difference detected was around 8% between the KN95-style mask and the hybrid face covering. The higher 28 L/min flow rate performed similarly, where all pairs were statistically different except for the hybrid and cotton face coverings. The smallest significant difference identified between means was around 5% from the KN95 and surgical style masks. This shows that the baseline test method was able to effectively differentiate between the TFE of most products.

The difference in TFE between the light and moderate flow rates illustrated in Figure 3 shows that the KN95, surgical style mask, and cotton face covering had higher TFE at 28 L/min, while the N95, athletic, and hybrid face coverings had a higher TFE at 16 L/min. From the pairwise analysis, the only product that did not show a significant change in TFE at different flow rates was the hybrid face covering. The cotton, surgical, and KN95 style masks all had significant differences in

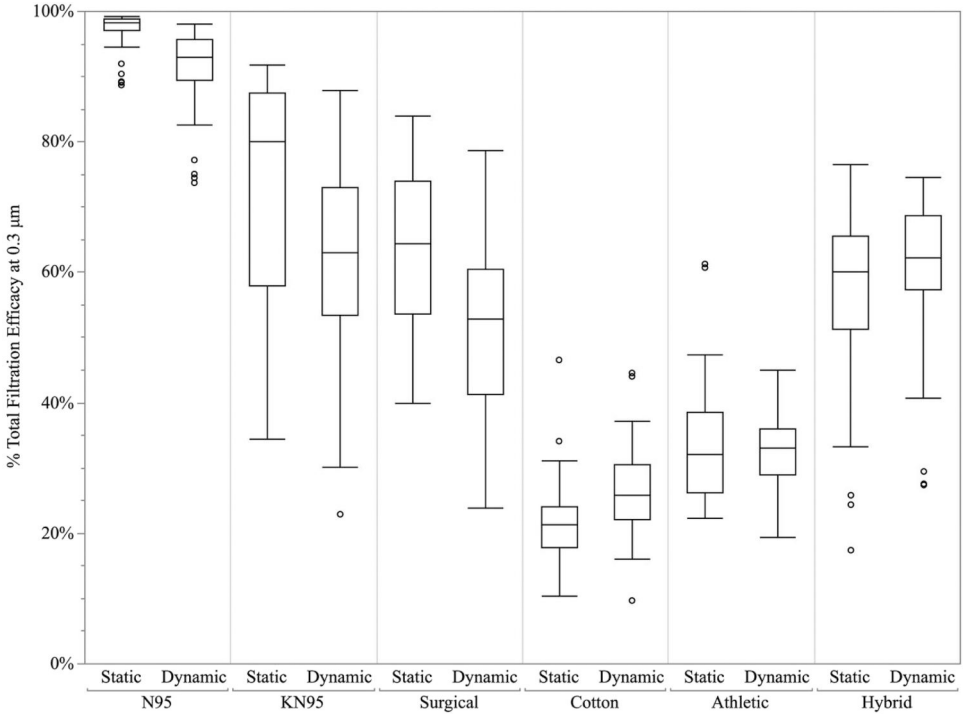

Figure 4. Box plot for TFE at 0.3 μm optical (geometric) diameter comparing the static and dynamic segments by product at 16 L/min.

TFE of 9 to 29%, while the N95 and athletic face coverings had changes of around 6%. Flow rate was shown to significantly influence performance, but whether it increased or decreased TFE depended on the product.

Movement

TFE during both test segments, where the headform was either static or dynamic were compared to identify if headform movement had a significant impact on face covering performance. At 16 L/min, product type, test segment, and their interaction on TFE at 0.3 μm D_{opt} were statistically significant. Looking across all the data, the average TFE was considerably lower during the dynamic segment. TFE was higher when the headform was static for four of the six products shown in Figure 4. TFE noticeably decreased when the headform was in motion during the dynamic segment for all three nonwoven products. Of the three, only the surgical and KN95 style masks were identified as statistically different across the two segments, with average differences in TFE between 11 and 12%. The cotton and hybrid face covering performed inversely, with slightly higher TFE during the dynamic segment. The design, fit, and material filtration are likely the reasons for this.

At 28 L/min, product type, test segment, and their interaction were all identified as significant as well. Average TFE across the data set remained lower during the dynamic segment at the higher flow rate. TFE at 0.3 μm D_{opt} decreased from the static to dynamic segments in all six face coverings shown in Figure 5. This decrease in TFE was only considered statistically significant for two of the six products. The N95 had the largest change in TFE, decreasing by 8% when the headform was moving, while the athletic face covering similarly decreased 6%. These two products also had the largest range of TFE during the dynamic segment, which may be attributed to higher variability in performance or fit.

Both test segments were further evaluated every minute to determine if the filtration changed significantly over the course of the static segment. At 16 L/min, the effects of product type and time were both found to be significant. Average TFE decreased over the duration of the test. A pairwise analysis showed significant differences between the first minute of testing and the last three minutes, decreasing TFE up to 6 to 8% as shown in Figure S1. The interaction between the product type and time was not found to be significant, but five of the six products decreased TFE by the end of the static segment. Only the N95 maintained consistent TFE over the five-minute test.

The analysis of TFE at 28 L/min showed a similar change over time in Figure S2, with significant differences between product types and the interaction of each product and time. The effect of time itself was not significant at the higher flow rate. The KN95 and

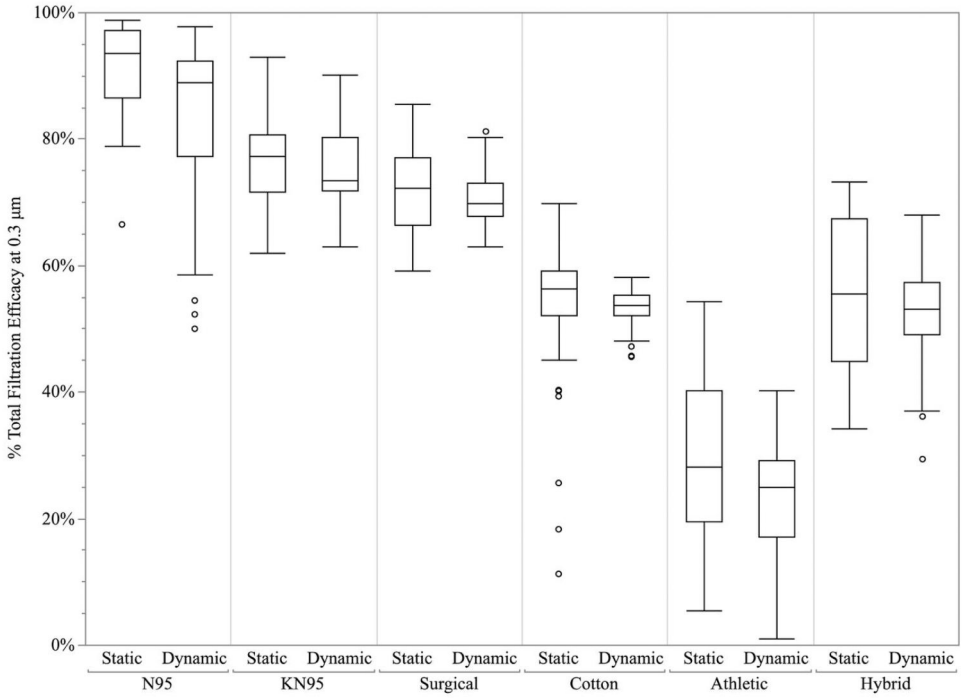

Figure 5. Box plot for TFE at 0.3 μm optical (geometric) diameter comparing the static and dynamic segments by product at 28 L/min.

cotton face covering had lower TFE in the first minute that substantially increased by the second minute. The other four products showed the same gradual decrease in TFE identified at the lower flow rate. The cotton face covering was the only product that had significant differences in TFE over time, between the first minute and the second, third, and fourth minutes, with an increase in TFE of 17 to 19%. This significant increase in TFE after the first minute may suggest residual particles in the breathing cavity or a sampling error.

The headform movements in the dynamic segment were also analyzed by their activity each minute at the 0.3 μm D_{opt}. Looking across the entire data set at 16 L/min, TFE decreased over the course of the five-minute test. The effect of headform movements was shown to be significant; however, the interaction between the product and activity was not. There was no clear pattern across the different products shown in Figure S3. A closer pairwise analysis of the five activities showed that the only notable difference was between the head shake and stationary breathing, with a 6% difference in TFE. These are the first and last movements in the test, which suggests that movement may contribute to the change in TFE over time.

The effects of headform activity and product type, along with their interaction, were significant at 28 L/min. However, the pairwise analysis found that none of the activities were significantly different from each other. The bite movement had the lowest TFE across the data set. The interaction between specific headform movements and the product type was significant; however, the N95 was the only product to have a statistically significant difference between the head nod and bite movements shown in Figure S4. This led to an average decrease in TFE of 17%, which increased again when the bite movement stopped. None of the other activities across the other face coverings had statistical differences. It remains unclear how much of an impact movement makes over time and if one type of movement has a significantly larger impact on TFE.

Operator

Three trained operators conducted the tests. Evaluating operators was important to determine the reproducibility of the method. At 16 L/min, Operators 1 and 2 conducted 31 and 29 test cycles, respectively. There were notable differences in mean TFE between operators, as shown in Figure 6. Product, operator, and their interaction were considered statistically significant. Operator 1 measured a higher TFE across the data set. Pairwise analysis determined that three of the six products tested had notable differences between operators, including the KN95, surgical style mask, and hybrid face covering, with differences in average TFE across operators from 11 to 17%.

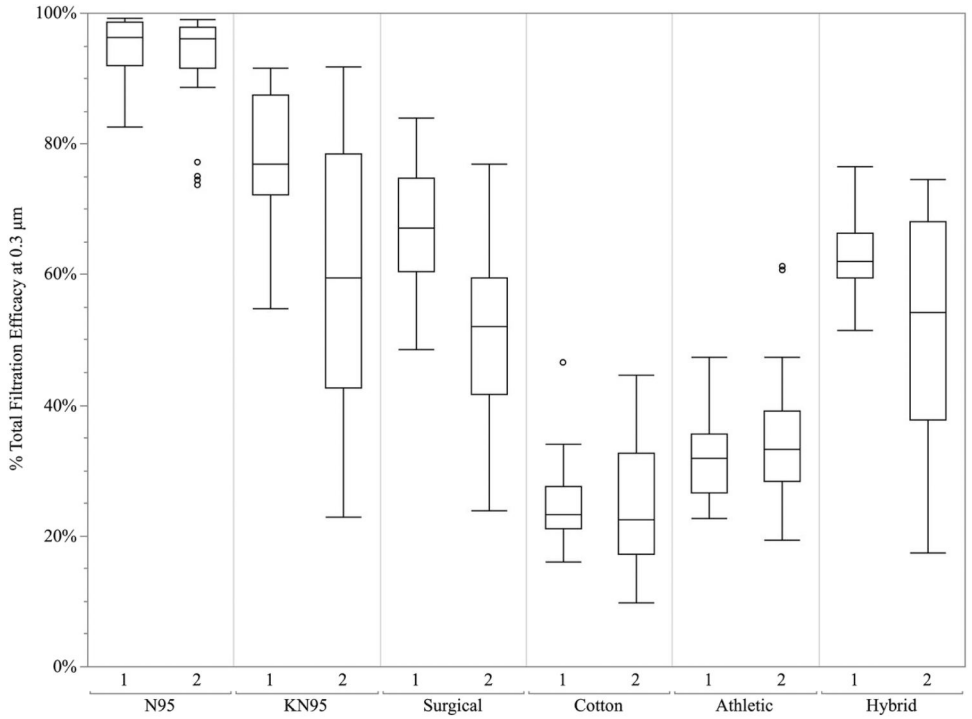

Figure 6. Box plot for TFE at 0.3 μm optical (geometric) diameter comparing the operator for each test cycle across products at 16 L/min.

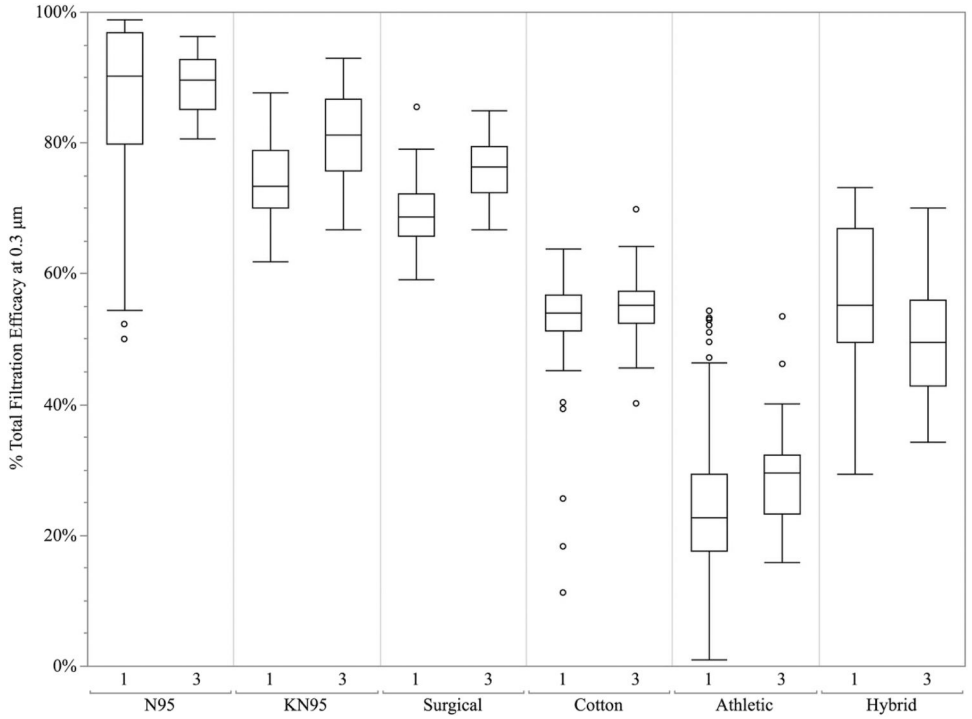

Figure 7. Box plot for TFE at 0.3 μm optical (geometric) diameter comparing the operator for each test cycle across products at 28 L/min.

Operators 1 and 3 were responsible for testing the products at 28 L/min. Operator 1 completed 42 test cycles, and Operator 3 completed 18. The differences in TFE between operators appeared smaller at the higher flow rate in Figure 7, although product type, operator, and the interaction between them remained statistically significant. Looking across the aggregate data set, Operator 3 measured higher TFE. Similarly,

when this was broken down by individual product, higher average TFEs were measured for five of the six products tested by Operator 3. The pairwise analysis identified that the difference between operators was only significant for the KN95 and surgical style masks, with a change of 6 to 7% TFE. These two products showed significant differences between operators at both flow rates, suggesting there may be a higher variability in fit for these styles.

Variability analysis

The coefficient of variation (CV) in TFE at 0.3 µm D_{opt} for each product at 16 and 28 L/min was computed to determine the measurement stability in the method. The N95 respirator showed the least variability relative to the mean, as expected. At 16 L/min, the N95 had a very good CV of 6.19% at 0.3 μm D_{opt} that increased slightly to 11.98% at 28 L/min. Most of the face coverings fell within the 10 to 30% range at 0.3 μm $D_{opt,}$ offering good or acceptable variation from the mean. The KN95, surgical style mask, cotton, and hybrid face coverings all had lower CVs at the higher flow rate. The only exception was the athletic face covering, which had a larger CV of 43.93% at 28 L/min.

An analysis was conducted on the different test variables using the variance component estimates. The analysis looked at the product, flow rate, movement, movement type, time, and operator to see which parameters caused the most variation in the baseline test method. This analysis revealed that the product type contributed 66.10% (out of 100%) to overall variability, as expected. The within value or inherent variability from unexplained error used to determine the repeatability was 11.40%, demonstrating that the test method variation was relatively low compared to the variation between products, which indicated good repeatability or method stability. The interaction between product and flow rate was similar at 11.20%. The reproducibility of the method was determined by looking at the effect of the operator and the interaction between operator and product, which contributed to 3.10% and 4.20% variability, respectively, indicating a reliable and repeatable method across operators. To total 100%, the remaining 4% variance was attributed to the summation of the other effects that did not significantly affect the method.

Sealed

Each of the samples was taped to the headform to measure the material PFE by eliminating leakage around the edges of the face coverings. Sealed PFE was measured at both flow rates in Figure S5. The N95 continued to filter around 94% at 0.3 μm D_{opt}. The other nonwoven products, the KN95 and surgical style masks, had PFEs between 84 and 90%. The hybrid face covering had the next highest PFE at both flow rates from 62 to 66%, while the cotton and athletic face coverings varied more significantly across rates from 40 to 78%. The sealed PFE increased as a function of particle size for all six products. Half of the products had lower standard deviations in PFE when they were sealed to the headform, except for the three barrier face coverings. This may be related to difficulty maintaining the taped seal throughout the duration of the test or higher variability in the product itself.

The five replicates of each product's sealed PFE were compared with the first five replicates' TFE from the original unsealed method to assess the impact of fit. As a result, the unsealed product means varied slightly from those reported in previous sections. At 16 L/min, the effects of fit, product type, and their interaction were shown to be statistically significant. Across the data set, the sealed PFE was significantly higher. Five of the six products had higher PFE sealed to the headform than their unsealed TFE, as shown in Figure 8. The N95 was the only exception, with a 1% decrease in PFE when taped. Pairwise analysis determined that four face coverings showed a significant difference in means between test methods. The KN95, surgical style mask, cotton, and athletic face coverings all had statistical differences between the sealed and unsealed tests, suggesting their performance was considerably impacted by fit. This equated to a drop in TFE of 13 to 32% when donned on the headform as worn (unsealed).

Testing at 28 L/min showed similar results. Sealed PFE remained significantly higher across the entire data set. Similarly, all six products had higher PFE when sealed to the headform shown in Figure 9. A pairwise analysis indicated five of the medical masks and barrier face coverings had significant differences between PFE and TFE when sealed or unsealed, respectively. The K95 and surgical style masks, hybrid, cotton, and athletic face coverings all had a statistical difference in performance when they were worn as intended (not sealed to the headform) with decreases in TFE between 8 and 25%. This illustrates a clear difference in product performance when evaluated as a sealed material (PFE) rather than a system that incorporates fit and leakage into the total filtration measurement (TFE).

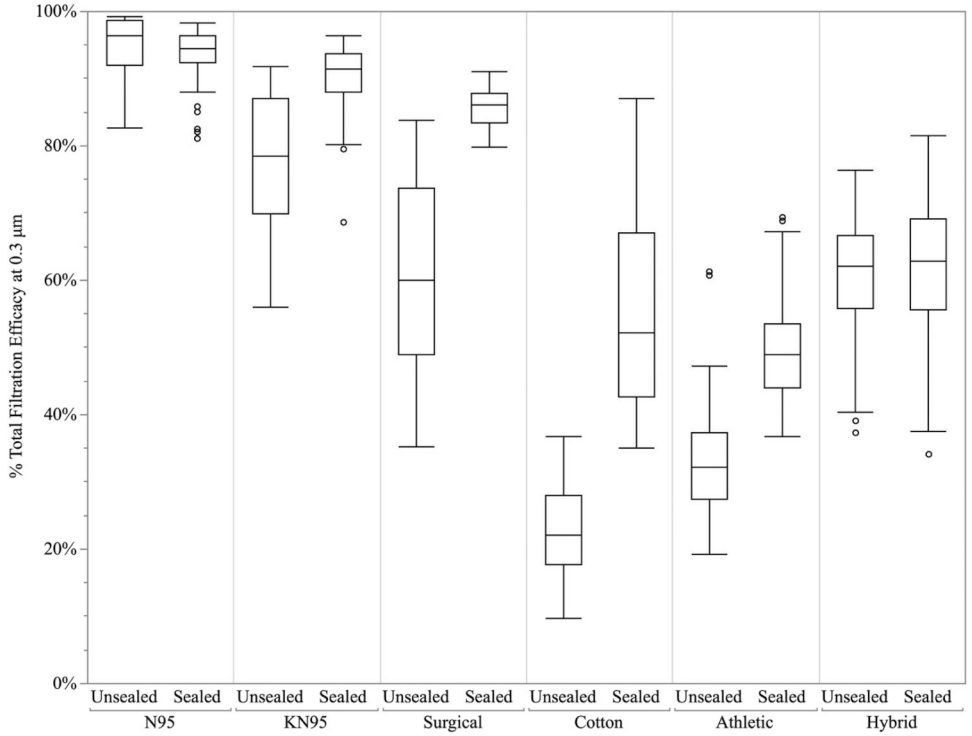

Figure 8. Box plot for TFE/PFE at 0.3 μm optical (geometric) diameter comparing the unsealed and sealed products on the headform at 16 L/min.

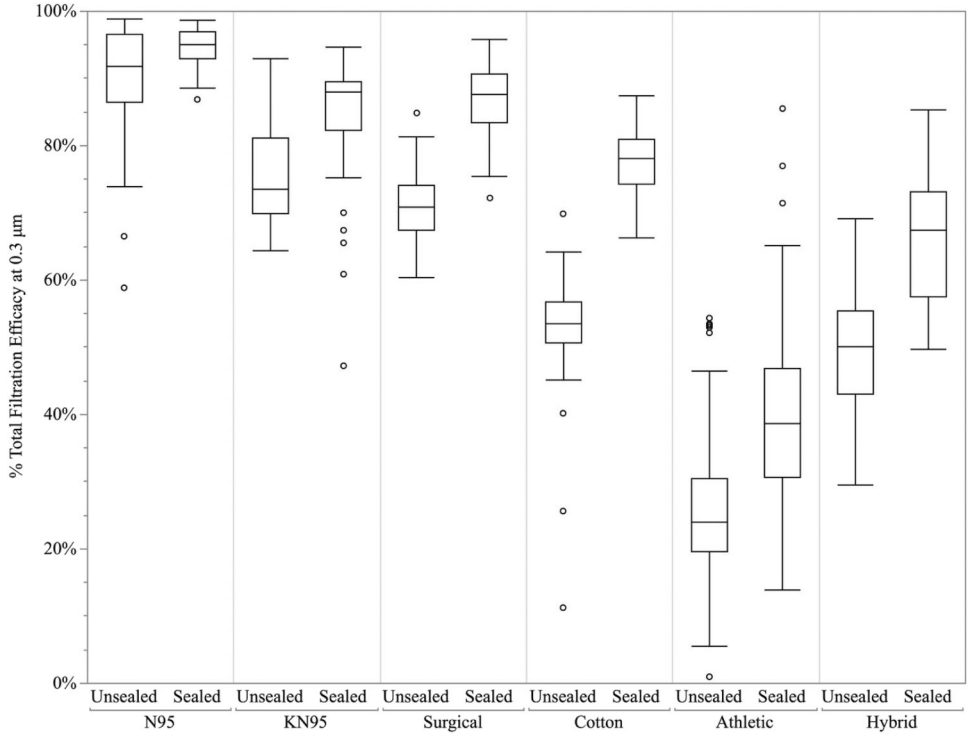

Figure 9. Box plot for TFE/PFE at 0.3 μm optical (geometric) diameter comparing the unsealed and sealed products on the headform at 28 L/min.

Discussion

The baseline headform test method is a system-level test capable of evaluating the efficacy of respirators, medical masks, and barrier face coverings. It is a reasonable inference that the test method's ten replicates, consisting of 100 observations, were capable of statistically distinguishing between products with a difference of means greater than 5% TFE at 0.3 μm D_{opt}. The N95 respirator control was used to determine if this test system could effectively measure TFE within its certified level of protection under 42 CFR Part 84, removing 95% of particles with a CMD of 0.075 ± 0.020 µm and a geometric standard deviation of 1.86 (Department of Health and Human Services 2002). The average TFE for the N95 was just below 95% at 16 L/min and around 88% at 28 L/min 0.3 µm D_{opt}. It maintained a consistently higher TFE than the other products, as expected due to the high filtration standard and required seal to the face. However, the values below 95% may be attributed to leakage due to fit challenges on the headform, which increased at the higher flow rate. It should also be noted that the OPCs used in this study detected higher geometric diameters than the more specialized SMPS used for certification, which suggests the N95s may have achieved lower filtration values at their MPPS.

Changing breathing flow rates was shown to significantly influence TFE depending on the product. Overall, the higher 28 L/min sinusoidal flow appeared to increase TFE, which is contrary to findings from other published studies in the literature. It was previously shown that increasing the flow rate reduced the PFE of smaller particles by shortening the resonance time through the material (Kwong et al. 2021; Tcharkhtchi et al. 2021). This increase in TFE at the higher breathing rate was seen in three of the six products (KN95, surgical style mask, and cotton face covering). The TFE during heavy breathing may depend more on the breathing resistance of the material. It may also be related to the breathing mechanism of the headform itself. Both the KN95 and surgical style masks, composed of nonwoven materials with high predicted PFEs, showed considerable variability in fit. At high volume flow rates, the masks were visibly sucked into the mouth cavity during inhalation. This may have created a vacuum around the opening, pulling particles through a smaller surface area, which could have increased particle loading and hence increased TFE. The three products that decreased TFE at the higher flow rate (N95, athletic, and hybrid face coverings) may have been able to maintain their shape and stand away from the face during the test.

There was a significant difference between static and dynamic TFE across the combined data sets. This behavior was expected since movement can shift the positioning of the medical mask or barrier face covering on the headform, which can break the seal to the face and allow additional inward leakage, thereby reducing TFE. Pairwise analysis showed that a significant decrease in TFE across the static and dynamic segments only occurred for select products, the surgical and KN95 style masks at 16 L/min, and the N95 and athletic face covering at 28 L/min. At the lower flow rate, the cotton and hybrid face coverings unexpectedly increased TFE during the dynamic segment. Movement may have caused the loose-fitting face coverings to shift and become seated better on the headform, reducing gaps at the skin interface. In general, variations in TFE during movement became more noticeable in loose-fitting face coverings where the product was unable to consistently create and maintain a seal to the face.

The TFE measured each minute during the static and dynamic segments was also evaluated to determine if certain activities had more impact. The headform remained stationary during the static segment, allowing the comparison of TFE over time. Most of the products showed a gradual decrease in TFE over the course of the five-minute test. This may be due to the loading of the filter surface. In the dynamic protocol, several products changed TFE during or after the bite movement. The bite movement was the closest measure to speaking or coughing on the headform and the only activity to engage the jaw. At 28 L/min, the bite movement appeared to impact the seal of the N95, decreasing TFE by an average of 17%, which partially recovered when the movement changed. Extending the jaw was also shown to shift the position of the medical mask or barrier face covering. This displacement was most noticeable with the surgical style mask. Despite these observations, the differences in TFE between individual activities were not considered clinically significant. They were too small to conclusively identify if one movement was more responsible for changes in TFE or if these differences were more closely related to testing duration.

TFE measurements allowed for the incorporation of fit into the filtration value. Poor fit has been shown to cause significant reductions in filtration performance due to leakage through gaps around the interface of the face covering and the skin (Hill et al. 2020; Konda et al. 2020; Verma et al. 2020b). The

importance of fit was observed in the statistical differences between the three operators. The KN95 and surgical style masks were difficult to consistently don in the same way. At 16 L/min, these two masks had the largest range in TFE of all the medical masks and barrier face coverings, so some variation in TFE may be attributed to the design and fit on the headform rather than the operator. The hybrid face covering appeared to fit better, but also showed notable differences between operators. This may be related to variability in the product or greater leakage pulling more particles around the barrier when a seal is not maintained. The variability analysis indicated that the operator may have contributed marginally to the variability, but most of the variability remained due to product type. This demonstrated that the developed method was reproducible.

The influence of fit can be quantified by comparing the sealed PFE to the unsealed TFE on the headform. Theoretically, the difference between the sealed and unsealed tests evaluated at the same testing conditions should be able to isolate the inward leakage that occurs around the perimeter of the product from poor fit. Almost all the samples had higher PFE as expected, except the N95 at 16 L/min that decreased PFE marginally when taped to the headform. The N95 still maintained the least variation between methods, as expected. The highest difference in means across flow rates was 25 to 32% in the cotton face covering. The large decrease in TFE due to leakage was consistent with previous literature, suggesting that the loose-fitting pleated design had difficulty creating a seal around the face (Hill et al. 2020; Konda et al. 2020). Similarly, the surgical style mask had a 16 to 25% decrease in TFE when worn, while the athletic face covering showed a change of between 14 and 17%. Taping the edges may not have been able to create a perfect seal for every product, but it clearly showed that reducing leakage can significantly increase the efficacy of the product.

Limitations

A standard-size headform was used to conduct all testing. This does not account for the possibility of variable fit across different facial shapes and sizes, which would be more representative of the public. The cup-shaped N95 was unable to maintain a perfect seal on this form, suggesting other models and designs should be considered for comparison in the future.

The generation of NaCl aerosol particles should also be investigated. The current method places the atomizer in the chamber at a low pressure to generate a continuous stream of particles. Controlling the atomizer outside the system could allow for a more consistent flow over the course of the test by increasing the pressure while diluting the aerosol so as not to overload the particle sensors. The current method does not neutralize the particles, which may contribute to overestimating filtration efficiency (Rengasamy et al. 2017). Neutralizing and stabilizing the NaCl particles may be considered in the future to more closely evaluate the worst-case scenario. As previously stated, the use of the OPCs instead of more robust and sensitive particle measurement devices results in the limitation of not being able to measure in the range of the MPPS often used for standard testing for respiratory protection products.

The experiment was conducted in an acrylic chamber, but the conditions inside the enclosure remained highly dependent on the external environment. Ambient particle counts fluctuated daily. There was no clear relationship between TFE and temperature, relative humidity, or ambient particle count across the data set. However, many of the trials were recorded at high relative humidity (above 40%), which had the potential to agglomerate the aerosol particles and may have impacted particle charge (Tcharkhtchi et al. 2021). The behavior of hydrophilic materials under humid conditions should also be considered. The preconditioning of cotton face coverings at 65% relative humidity in addition to the moisture in the air during testing may have impacted the filtration (Zangmeister et al. 2021). All these testing conditions and parameters should be considered when comparing TFE results.

Conclusions

This study evaluated six different medical masks and barrier face coverings at two breathing flow rates that were able to produce a wide range of TFE values ranging between 24 and 94% at 0.3 μm D_{opt}. The statistical analysis proved the headform test method could statistically differentiate between product types. The N95 control had the highest and most consistent TFE, followed by the KN95 and surgical style masks, the hybrid face covering, and finally the cotton and athletic face coverings. The experimental parameters were evaluated to determine the variability within the method and factors that influence TFE. Increasing the flow rate significantly impacted TFE, but whether TFE increased or decreased depended on the medical mask or barrier face covering selected. There were statistical

differences in TFE between the static and dynamic test segments depending on the product type and volume flow rate. TFE generally decreased over the course of testing during both static and dynamic protocols. The biggest contribution to the overall variability was the product type, suggesting that the current test method is repeatable and robust. Despite significant differences between operators, their low percentage of variance showed good reproducibility.

The headform assessment was able to effectively evaluate a range of products; however, the method still has room for development. Some of these changes may examine the effects of sizing, neutralizing, and stabilizing particles, particle size distribution, and controlling environmental conditions. The companion paper will incorporate measuring differential pressure on the headform to assess the breathability and comparing the optimized animatronic headform test method to current standards, including ASTM F3502-21 (Armistead et al. 2026).

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Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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