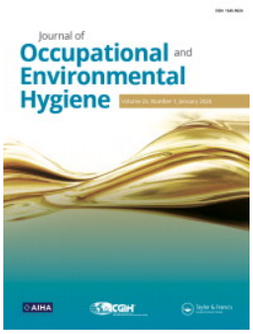

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Development of an animatronic headform test method for determining the efficacy of medical masks and barrier face coverings—part 2: validation study

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ABSTRACT

There is a need for a realistic method to evaluate the performance of barrier face coverings and medical masks in the wake of growing respiratory concerns among the general public. In this study, the previous animatronic headform test method was optimized to evaluate the total filtration efficacy and breathing resistance of 12 products during a 10-minute simulated fit test. These products included three respiratory devices, three medical masks, and six barrier face covering styles. The revised method was able to differentiate between products with total filtration efficacies ranging from 14% to 93%, down to a difference in means of 2% at 0.3 μm optical diameter. The impact of fit was illustrated by the increase in total filtration efficacy and breathing resistance across all three medical masks when the ear loops were tightened. The coefficient of variation for each product fell below 20% at 0.3 μm optical diameter, indicating good measurement stability. A second operator conducted an intra-lab validation to determine the method's reliability. This analysis confirmed the improved repeatability and reproducibility of the headform test method, which was shown to effectively evaluate the total filtration efficacy of respiratory products as a system in a controlled laboratory setting. However, more research is needed to improve the sensitivity of the breathing resistance measurements. Comparison to the ASTM F3502-21 Standard Specification for Barrier Face Coverings highlighted the differences between evaluating these products as a sealed system or as they are intended to be worn, with an overall decrease in total filtration efficiency and breathing resistance due to leakage when evaluated on the headform.

KEYWORDS

Aerosols; breathability; filtration; inward leakage; public health; source control

Introduction

There is an increasing demand for respiratory devices for the general public to protect against respiratory hazards; however, methods to quantify the performance of nontraditional devices vary widely across standards and studies. To address this gap, the previous study (Development of an animatronic headform test method for determining the efficacy of medical masks and barrier face coverings – part 1: total filtration efficacy) developed a baseline test method to determine the total filtration efficacy (TFE) of medical masks and barrier face coverings by evaluating each device as a system, incorporating both fit and material into the final filtration value. An animatronic headform with integrated breath and movement protocols was programmed to conduct a modified fit test to simulate wear. Measurements were made with optical particle counters (OPCs) inside and outside the headform under static and dynamic conditions at two breathing rates. Differences in breathing flow rates, duration, and movement were shown to have a statistically significant impact on TFE, dependent on product type. The efficacy of product fit was assessed by testing products as worn and sealed to the headform. These findings demonstrated that fit significantly impacted TFE, with leakage around poorly fitted medical masks and barrier face coverings reducing TFE by up to 32% (Armistead et al. 2026).

Literature has focused mainly on evaluating factors that influence the particle filtration efficiency (PFE)

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and breathing resistance of barrier face coverings at the material level, which does not account for leakage around the barrier due to poor fit when worn (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). The ASTM F3502-21 Standard Specification for Barrier Face Coverings includes an optional leakage component, utilizing a modified version of ASTM F3407-20 Standard Test Method for Respirator Fit Capability for Negative-pressure Half-facepiece Particulate Respirators to determine the leakage ratio of each face covering on a bivariate panel of participants. This requires the use of human subjects who have different facial dimensions. Respirators are required to seal to the face and must obtain a fit factor of 100 or more to pass (ASTM International 2020, 2021a). However, barrier face coverings are not sealed to the face, and their fit factors can be low, ranging from 1 to 4 for face coverings and between 3 and 7 for medical masks across subjects (Davies et al. 2013; Lindsley et al. 2021; O'Kelly et al. 2021). This makes it difficult to compare products and does not differentiate between low filtration efficiency and poor fit.

Other studies have modified stationary headforms to evaluate leakage in a more controlled setting. Headforms have been shown to achieve acceptable respirator fit factors by incorporating a silicone polymer skin to create a realistic fit (Bergman et al. 2014, 2015). Leakage can reduce the TFE of barrier face coverings by 60% or more when particles escape through gaps at the bridge of the nose, under the chin, and sides of the face (Hill et al. 2020; Verma et al. 2020). Barrier face coverings are primarily used as source control devices, therefore outward leakage is of considerable interest; however, there is currently no standard method to quantify it. Many of these studies focused on qualitative assessments of surgical masks and barrier face coverings on headforms and human subjects to visualize outward aerosol dispersion (Gupta et al. 2010; Arumuru et al. 2020; Verma et al. 2020). More recently, researchers have begun to measure the concentration of exhaled particles captured by the barrier during breathing and coughing by placing an aerosol generation system inside the headform (Lindsley et al. 2021; Pan et al. 2021). A comparison of inward and outward leakage showed similar results depending on the product fit and material (Pan et al. 2021). However, further research is needed to develop this comparison and adapt these methods into a standardized, accessible format.

This study developed an optimized headform test method to evaluate inward leakage and total filtration efficacy under the conditions tested by making small modifications to the previous method (Armistead et al. 2026). These modifications aimed to streamline the procedure, control the testing environment, and reduce the variability within each product. Additionally, differential pressure measurements were incorporated into the system to assess breathing resistance. A larger selection of products was chosen to incorporate a broad range of respirators, medical masks, and barrier face covering designs. The optimized method was evaluated for repeatability and compared to the baseline method to determine the effectiveness of these changes. These results were then validated for reproducibility by a second operator and evaluated according to ASTM F3502-21 to quantify the differences across methods. A comparison of the testing parameters used in each method can be found in Table S1.

Methods

Samples

Twelve commercially available products were selected, including the three respiratory devices, three medical masks, and six barrier face coverings shown in Figure 1. These products were chosen to represent a mixture of designs and materials available to the public. The three respiratory devices included a NIOSH-certified N95 respirator as the controlled reference to confirm

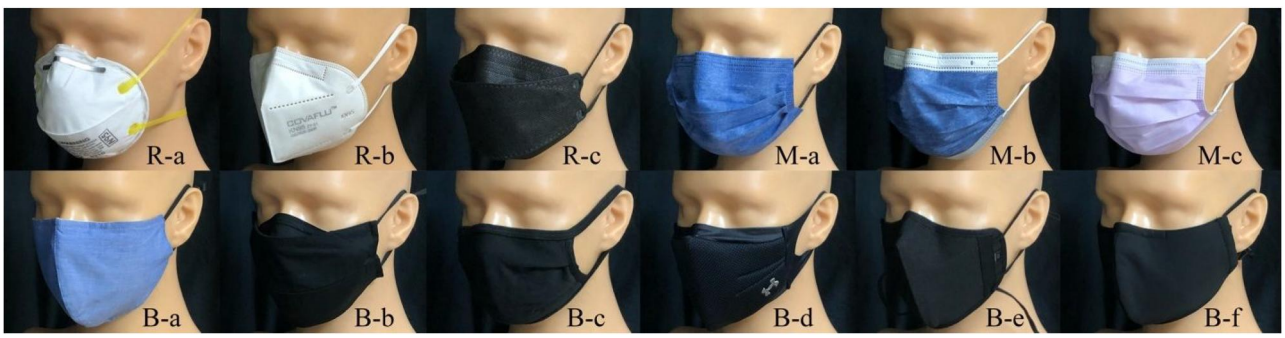

Figure 1. Selected products included three respiratory devices (R-), three medical masks (M-), and six barrier face coverings (B-).

the system was working, along with two styles of KN95s. N95s have been able to achieve passing fit factors on silicone headforms dependent on their shape and size (Bergman et al. 2014). Therefore, it was reasonable to assume that the system was working as intended with TFE >90% for the cup-shaped N95 under the given conditions. The three medical masks were certified to different performance levels under ASTM F2100-21 Standard Specification for Performance of Materials Used in Medical Face Masks and ASTM F3502-21 (ASTM International 2021a, 2021b). The six barrier face coverings were made from a variety of materials and included two woven fabric designs, two knit fabric designs, and two hybrid systems that incorporated nanomaterials into their construction, as listed in Table S2.

Respiratory devices, medical masks, and barrier face coverings were preconditioned for at least 25 h and tested in an environmental chamber under standard conditions of 20 ± 2 °C and 65 ± 5% relative humidity (International Organization for Standardization 2005). To reduce the variability of fit within each style, adjustable straps were fitted on the headform and then measured to adjust the remaining samples accordingly. The three medical masks were tested twice, once with regular elastic ear loops and then again adjusted with a cord lock to tighten each loop. For all other products, a new sample was used for each of the 10 replicates tested as received. These 12 products were compared to their TFE measured using the baseline headform test method. However, there were some differences in the newer products. A similar cup-shaped N95 (R-a) from the same brand was selected based on availability. The surgical style mask (M-a) appeared to have changed ear loops, while the knit cotton face covering (B-c) had a smaller surface area than the original.

Optimized headform test method

The Fully Animatronic Respirator Testing Headform (i-bodi Technology Ltd, Buckingham, UK) was previously used to develop a baseline method to evaluate the TFE of products like medical masks and barrier face coverings that are not intended to seal to the face. The term TFE is used to describe the systemic measurement of filtration efficacy that incorporates both fit and material performance into the final filtration value (Armistead et al. 2026). This method has been revised to reduce testing variability and incorporate differential pressure measurements. The headform was moved to an environmental chamber to control temperature and relative humidity. Testing was carried out under the same standard conditions that the samples were preconditioned to at 20 ± 2 °C and 65 ± 5% relative humidity (International Organization for Standardization 2005). The 300 square-foot chamber was equipped with several temperature and humidity probes to continuously monitor the environment. Additionally, wind speed, temperature, and relative humidity were measured next to the headform using a Kestrel 5000 anemometer (Nielsen-Kellerman Company, Boothwyn, PA). A wind speed of approximately 0.75 m/s was recorded throughout the trial.

The headform apparatus shown in Figure 2 was positioned in the middle of the chamber, facing away from the wind. A Particle Generator 8026 (TSI Inc, Shoreview, MN) was placed 6 feet directly behind it and ran continuously to generate an unneutralized

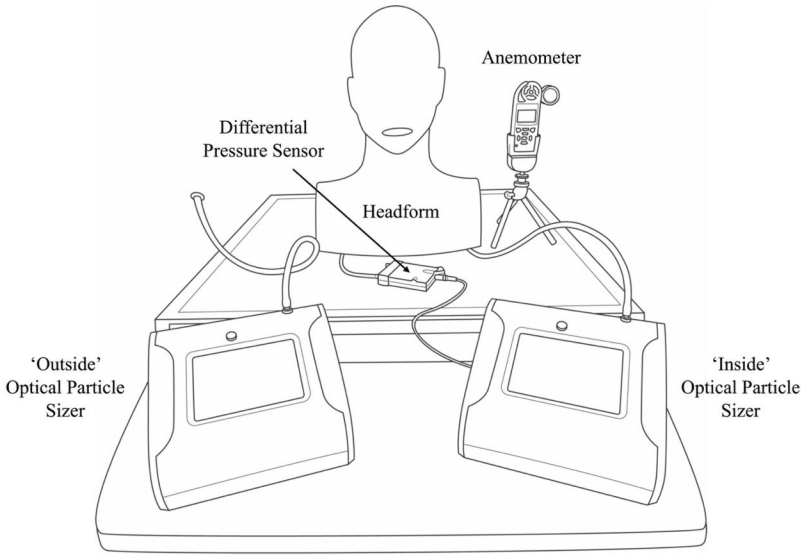

Figure 2. Diagram of the final animatronic headform apparatus.

polydisperse NaCl aerosol. Testing was conducted between 50,000 and 150,000 particles/min or 18-53 particles/cm^3 measured at 0.3 μm optical (geometric) diameter (D_{opt}) from the combined ambient and salt particles. Two six-channel Fluke 985 optical particle counters (Fluke Corporation, Everett, WA) were connected inside the chamber and mouth cavity of the headform through two pieces of tubing to measure the cumulative and differential particle counts upstream and downstream. The ratio between particle counters varied approximately 4.52 ± 3.11% at 0.3 μm (D_{opt}). The particle counts at 0.3, 0.5, 1, 2, 5, and 10 μm (D_{opt}) inside and outside the sample were recorded each minute at a flow rate of 2.83 L/min. These values were used to calculate the TFE percentage every minute by subtracting the percent penetration from 100.

OPCs were selected for this method because they are significantly more accessible and cost-effective than alternatives such as scanning mobility particle sizers (SMPS), which can be used to measure particles with mass median aerodynamic diameter (MMAD) in the lower 0.2 to 0.3 µm range or count median diameter (CMD) at 0.075 µm used in respirator certification protocols. While OPCs report optical (geometric) diameter and have limitations in accurately counting and sizing particles close to the most penetrating particle size (MPPS) range below 0.3 µm MMAD, their availability allows for widespread, practical adoption of system-level performance testing in research and industry settings. Even with the limitations of the OPC measurement, this work provides both a replicable methodology and a basis for comparison with more specialized and costly particle-sizing technologies.

A Model DL7 Differential Pressure Data Logger (Dwyer Instruments Inc, Michigan City, IN) was connected to the other side of the mouth cavity via tubing to measure the differential pressure across each product. The pressure drop was recorded every 5 seconds to determine the breathing resistance during wear. A 20-second background reading before and after each test was averaged together to determine the correction factor for the instrument. Corrected inhalation resistance was determined from the maximum pressure drop detected each minute.

A combined protocol was designed to replace the two static and dynamic segments in the baseline method. The new 10-minute test consisted of 2 minutes of stationary breathing followed by 1 minute of each of the bite, head nod, and head shake movements at 24 repetitions per minute. These movements were repeated for another 3 minutes before ending the test with 2 more minutes of stationary breathing. An additional 2 minutes of stationary breathing were added to the beginning of the protocol to clear out any residual particles in the mouth cavity before measurements began.

The breathing protocol was also adjusted based on the reported respiratory rates from ISO 16976-1:2015 Respiratory Protective Devices—Human Factors. A sinusoidal breathing rate of 15.12 breaths per minute (BPM) with the same 0.98 L tidal volume was programmed to achieve a volume flow rate of approximately 15 L/min based on the calculated minute volume to perform light work for a healthy medium-sized adult to correspond to the anticipated activity level during fit testing (International Organization for Standardization 2015; Zhu et al. 2018). This produced a peak inspiratory flow of around 46 L/min. An open 3D-printed mold was added inside the mouth cavity of the headform to prevent the silicone lips from being pulled into the mouth while breathing. A single operator conducted all 10 replicates for each product to match the ASTM F3502-21 requirements.

This method was validated by having a second operator run through the same protocol with 10 of the products, including the N95 control, both KN95s, one medical mask, and all six barrier face coverings. The only difference during the validation study was the use of two Optical Particle Sizers (OPS) Model 3330 (TSI Inc, Shoreview, MN) to measure the differential particle counts each minute. The transition to the OPS from the Fluke 985 optical particle counters was made to provide better accuracy and resolution in the collected data. Both work on the same light-scattering particle counting principle and therefore have the same limitations in measuring smaller aerodynamic diameters. The OPS were programmed to measure particles through six channels using the same particle size ranges of 0.3, 0.5, 1, 2, 5, and 10 µm D_{opt} sampled at 1.0 L/min. The same breathing and movement protocols were used, with 10 replicates completed per product.

ASTM F3502-21

All 12 products were sent to Intertek Testing Services in Cortland, NY, for ASTM F3502-21 testing. Only five of the 10 replicates required under the standard were completed for each product due to cost considerations. All samples were preconditioned at 38 ± 2.5 °C and 85 ± 5% relative humidity before testing in accordance with the standard (ASTM International 2021a). The entire product was mounted on a printed adult medium face form, sized according to ISO 16900-

Figure 3. ASTM F3502-21 testing with the printed adult medium face form, mounted sample, and test setup from Intertek.

5:2016 Respiratory Protective Devices—Methods of Test and Test Equipment, and sealed around the edges to prevent leakage, as shown in Figure 3 (International Organization for Standardization 2016). Testing was conducted on the 8130A Filter Tester (TSI Inc, Shoreview, MN). Each sample was tested at a face velocity of 10 ± 0.5 cm/s with flow rates between 36 and 71 L/min, depending on its surface area. PFE was evaluated using a neutralized NaCl aerosol with 0.075 ± 0.020 µm CMD and a geometric standard deviation of 1.86, while the differential pressure across the surface was measured simultaneously. All five PFE and airflow (breathing) resistance results were averaged together for this study. The optional quantitative leakage assessment and laundering considerations were not evaluated at this time.

Statistical analysis

The data was analyzed using JMP Pro statistical software (16.0, SAS Institute Inc, Cary, NC) to determine the repeatability of the optimized test method. Data was analyzed by its residuals to confirm normality. An Analysis of Variance (ANOVA) test was used to compare TFE at 0.3 μm D_{opt} across the different products and methods. This size was chosen as the smallest detectable bin on both OPCs. The optical particle diameter of 0.3 µm NaCl particles corresponds to a MMAD of approximately 0.44 µm and a CMD of approximately 0.139 µm. These values are roughly two times larger than those used in respirator certification testing, and as such, it is expected that higher filtration performance would be measured based on the filtration mechanisms employed.

A P-value (P) below 0.05 was considered significant. In addition to statistical significance, clinical or practical significance was defined as a change in TFE of 5% or more to exclude any potential differences between particle counters. If $p < 0.05$, Tukey's Honest Significant Difference (HSD) test was used for post-hoc testing to comparatively analyze differences between pairs. These individual P-values are listed in supplemental material Tables S4 through S17.

Results

Total filtration efficacy

The mean TFE and standard deviation for each product were compared. The N95 respirator control (R-a) maintained TFE between 93 and 97% across particle sizes. The two KN95s (R-b and R-c) ranged from 46 to 53% TFE at 0.3 μm D_{opt}. The three medical masks were tested as received and then adjusted to improve their fit. Unadjusted, the three products (M-a, M-b, and M-c) had TFEs between 37 and 45% at 0.3 μm D_{opt}. When the ear loops were tightened, all three medical masks increased TFE to values between 44 and 53%, falling into the same range as the KN95s. These moderately filtering products showed the highest standard deviation in TFE but remained below 10% variability at 0.3 μm D_{opt}. The hybrid face coverings (B-e and B-f) were next, ranging from 28 to 57% TFE. B-e was notably higher than the other

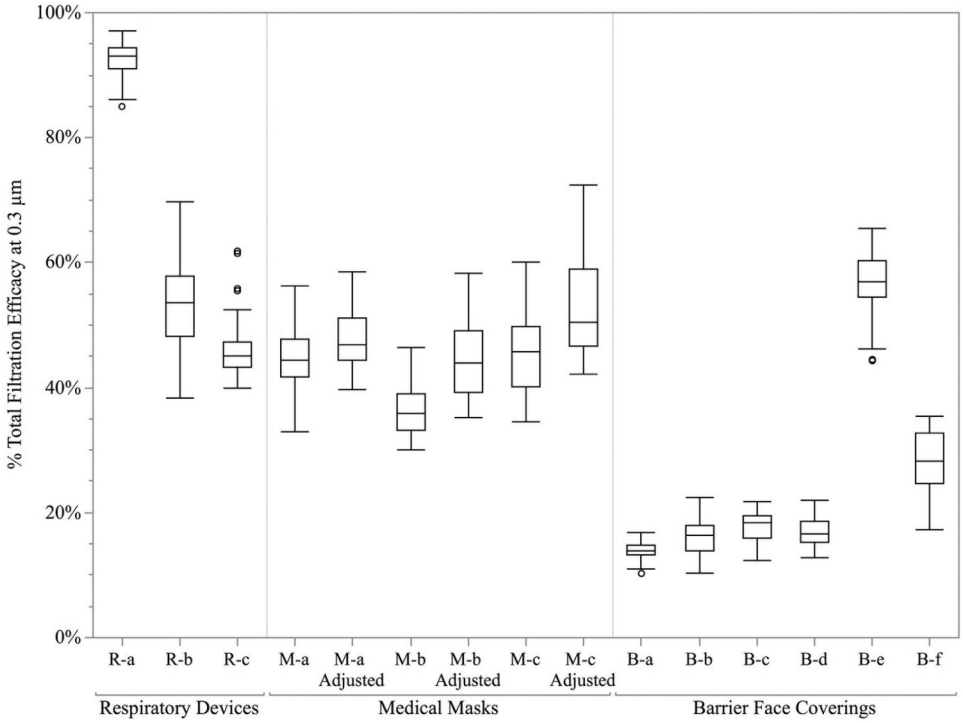

Figure 4. TFE across products at 0.3 μm optical (geometric) particle diameter measured using the optimized headform test method.

nonwovens. Lastly, barrier face coverings made from knit and woven fabrics (B-a, B-b, B-c, and B-d) had TFEs from 14 to 18% at 0.3 μm D_{opt}. Almost all products increased TFE across particle sizes shown in Table S3, except two barrier face coverings (B-b and B-f) that decreased at 2 μm. This may be due to a poor fit or possible material shedding.

TFE distributions for each product at 0.3 μm D_{opt} are shown in Figure 4. The average TFE for each of the three product categories (respiratory devices, medical masks, and barrier face coverings) was found to be statistically significant. Pairwise analysis indicated that the overall TFE for respiratory devices, medical masks, and barrier face coverings was each significantly different from one another, varying TFE by 19 to 39%. This demonstrated that the optimized method was able to differentiate between the three product categories.

Comparing individual products across categories was also found to be significant. Pairwise analysis identified that the majority of product TFEs were statistically different from each other, while only around 10% of the pairs showed no difference. Most of these indistinguishable differences in means were between barrier face coverings in the same product category. The test also had difficulty differentiating between the KN95s and medical masks. The lowest measurable significant difference in TFE reported at 0.3 μm D_{opt} was around 2% between R-c and adjusted M-a. This value demonstrated the improved sensitivity of the method below the previously defined clinical significance level. All three of the adjusted medical masks were also statistically different from their unadjusted means, with a 3 to 8% increase in TFE. This showed that tightening the ear loops improved performance, reiterating the importance of fit in the TFE measurement.

Previous headform test method comparison

The data from this optimized method was compared to the previous study's baseline headform test method in Figure 5. The previous medical masks had their ear loops tied to improve their fit and were therefore analyzed alongside the adjusted medical masks from the current study. The effects of product type, method, and their interaction were identified as statistically significant. Across the data set, the optimized method had an average decrease of 9% TFE from the baseline method. All 12 products saw a decrease in TFE and narrower standard deviations using the optimized method. However, these lower TFE values generally overlapped or fell within the wider data spread of the baseline measurements. The pairwise comparison showed nine of the products had statistically significant differences across the two methods. The lowest detectable change in TFE was around 7% in one of

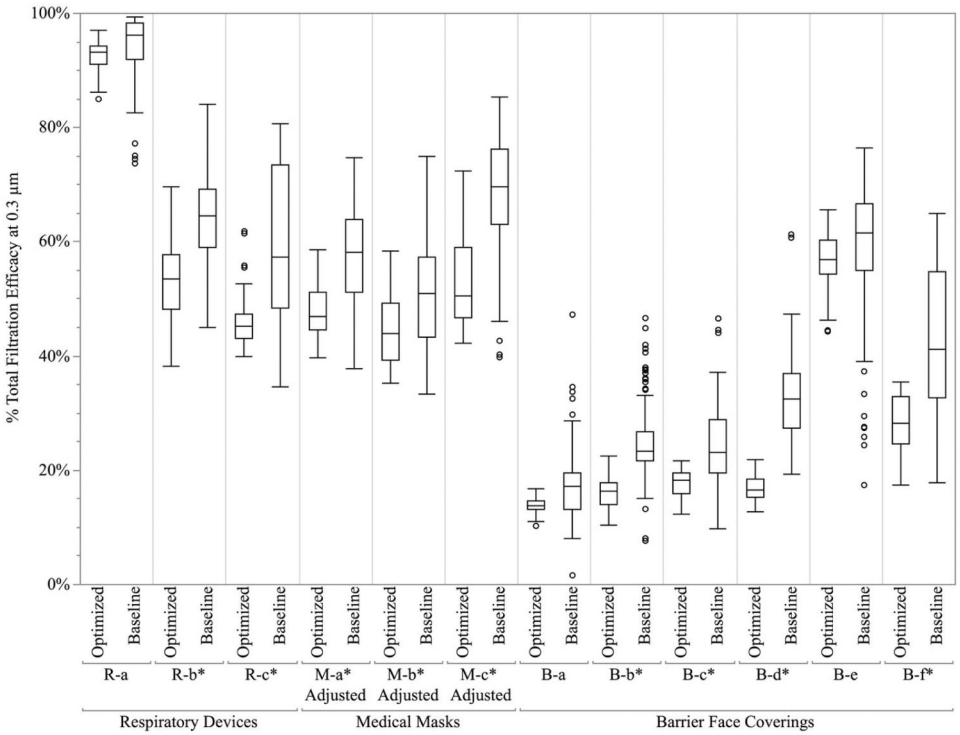

Figure 5. TFE at 0.3 μm optical (geometric) particle diameter comparing the optimized and baseline headform test methods across products (*indicates statistically significant difference across methods).

the knit face coverings (B-c). Only the N95 respirator control (R-a) and two of the barrier face coverings (B-e and B-a) showed no notable differences in mean TFE at 0.3 μm D_{opt} across tests.

Optimized method validation

TFE measurements were used to determine the coefficient of variation (CV) for each product across particle sizes. Each product's CV had good variation from the mean ($<$ 20%) at 0.3 μm D_{opt}. Five fell below 10%, including the N95 control with the lowest CV of 3.04% at 0.3 μm D_{opt}. This showed that the optimized test method could obtain stable measurements across products. The CV typically decreased as particle size increased. The majority of samples had very good CVs ($<$ 10%) at 0.5, 1, and 2 μm D_{opt}. There were a few notable exceptions among the barrier face coverings at the 2 μm optical particle size, most notably B-b and B-f. More research is needed to determine the reason for this large variation in select products.

Variance component estimates were used to determine which effects and interactions contributed to variability in the optimized method. The analysis examined the effect of product, movement, movement type, and change over time on TFE at 0.3 μm D_{opt}. Product type continued to make up the majority of the overall variability at 95.10% (out of 100%). The within-component or unexplained error was minimal at only 3.70%, indicating that the method was highly repeatable. The remaining effects of time and the interaction between time and sample made up the other 1.20%, while movement and movement type did not appear to influence the test. These results were an improvement over the baseline method.

To determine the intra-lab reproducibility of the method, a second operator evaluated 10 of the products following the same procedure. The comparison of TFE at 0.3 μm D_{opt} measured by both operators is shown in Figure 6. The difference in mean TFE across operators was around 6%, which was just above the level of clinical significance. Pairwise analysis showed all products except the cotton knit face covering (B-c) had statistically significant differences in TFE between operators. However, the difference between means across operators was only clinically significant for the two KN95s and the medical mask, with a difference in TFE ranging from 13 to 25%. The rest of the products all had differences between operators below 5%.

Variance components were analyzed again with the validation study data for all 10 products run by both operators. Product type made up the majority at 90.3% (out of 100%) of the total variance.

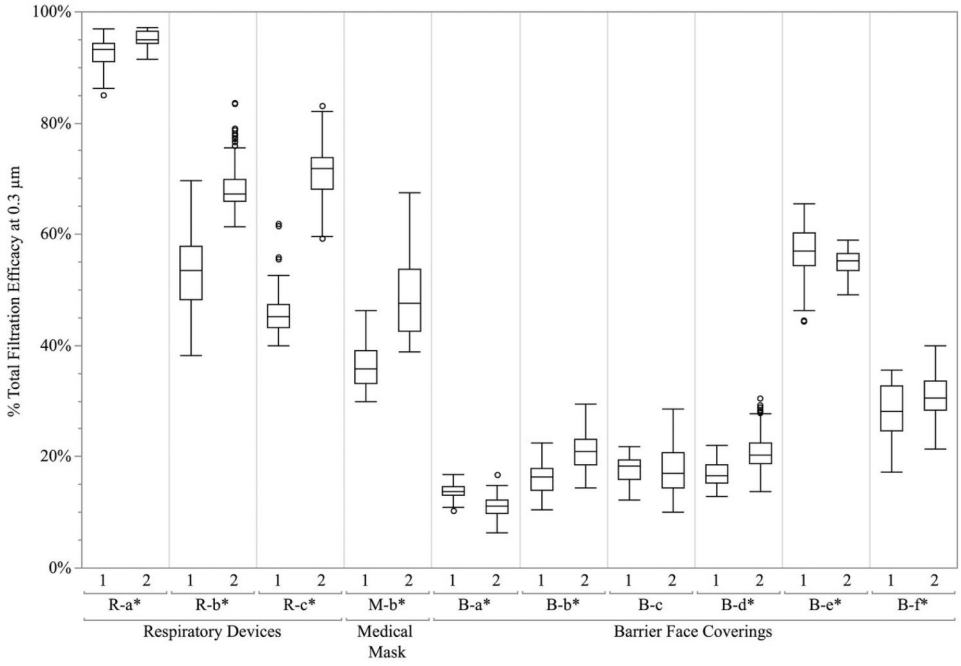

Figure 6. TFE at 0.3 μm optical (geometric) particle diameter comparing operators across 10 of the 12 products (*indicates statistically significant difference across operators).

Unexplained error represented by the within component was even smaller at only 1.9%, showing high repeatability. The operator and interaction between sample and operator accounted for 2.1% and 5.4%, respectively, totaling 7.5% of the variance to confirm good reproducibility. The remaining 0.3% came from different interactions between sample, operator, time, and movement. These estimates show that the optimized headform method is a consistent and robust test that can effectively evaluate the TFE of medical masks, barrier face coverings, and other respiratory devices.

Breathing resistance

The optimized method incorporated breathing resistance into the system by connecting a differential pressure sensor to the other side of the mouth cavity. Inhalation resistance was determined from the highest differential pressure measurement, while exhalation resistance was determined by the absolute value of the lowest differential pressure recorded each minute. The mean inhalation and exhalation resistances for each product are shown in Figure 7. The N95 respirator (R-a) maintained an average inhalation resistance of around 13 Pa, while the two KN95s (R-b and R-c) ranged from 15 to 17 Pa. The medical masks (M-a, M-b, and M-c) had inhalation resistances of 6 to 26 Pa that increased up to 8 to 75 Pa when the ear loops were tightened. Barrier face coverings (B-a, B-b, B-c, B-d, B-e, and B-f) saw an even wider range of inhalation resistances between 20 and 125 Pa with no clear relationship across fabric structures.

Average maximum inhalation resistance was compared across operators for the 10 products in the validation study, shown in Figure 8. The settings on the differential pressure sensor were adjusted for the second operator to increase measurement frequency to every second to more accurately capture the inhalation and exhalation peaks. Across the data, the influence of operator and/or pressure sensor settings had statistical significance with a difference of 86 Pa across methods. All breathing resistance measurements collected by the first operator, who sampled every 5 seconds, were significantly lower than those detected by the second operator during the validation. Pairwise analysis found that all products were statistically different across operators and measurement methods, with the lowest detected difference in inhalation resistance of 27 Pa for a woven barrier face covering (B-a). These differences were all clinically significant, unlike the comparison between TFEs. More research is needed to isolate the impacts of operator and sampling frequency to improve breathing resistance measurements.

ASTM F3502-21 comparison

All products were sent to a third-party laboratory for testing in accordance with ASTM F3502-21. The N95

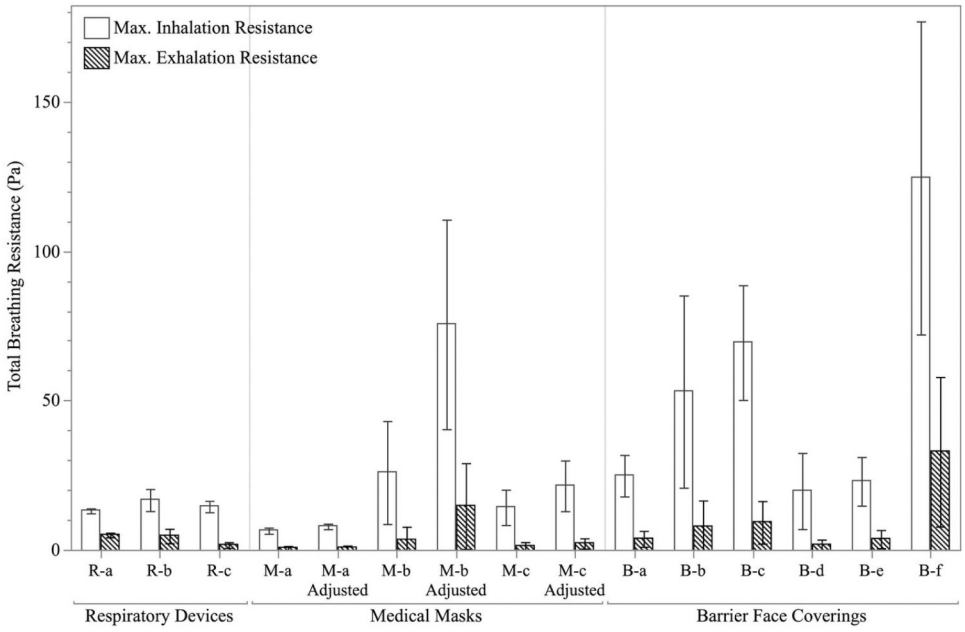

Figure 7. Mean maximum inhalation and exhalation resistance across products (error bars represent one standard deviation from the mean).

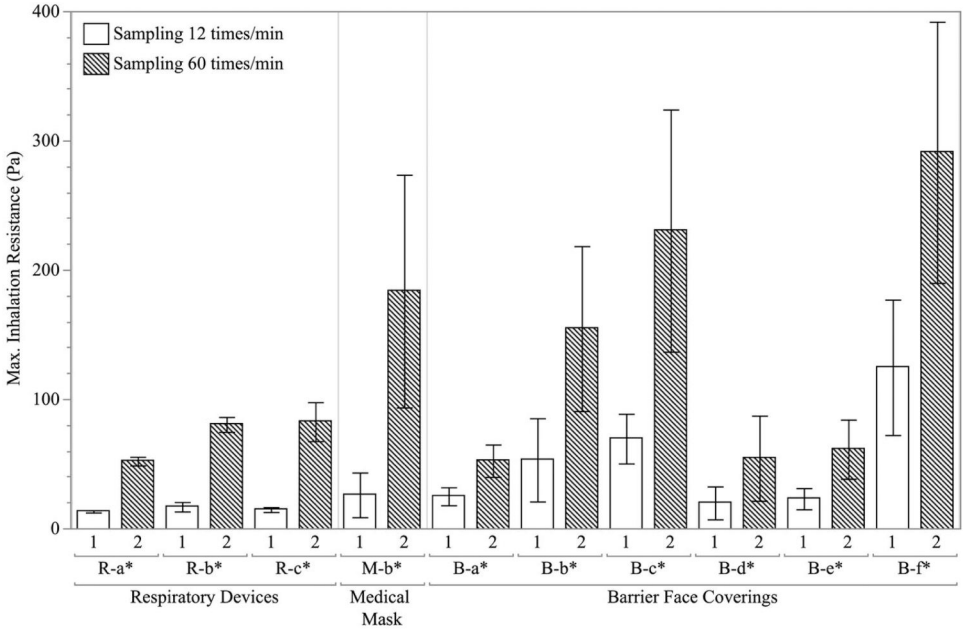

Figure 8. Mean maximum inhalation resistance by operator and sampling frequency across 10 of the 12 products (error bars represent one standard deviation from the mean; *indicates statistically significant difference across operators).

(R-a) measured above 99% PFE in the sealed face form, along with one of the KN95s (R-c), with breathing resistances of 73 and 139 Pa, respectively. The other KN95 had a PFE of around 93% with a breathing resistance of 117 Pa. The three medical masks (M-a, M-b, and M-c) ranged from 72 to 89% PFE with breathing resistances from 19 to 68 Pa. Barrier face covering performance varied widely across materials and designs, with PFEs between 7 and 46% and breathing resistances ranging from 14 to 111 Pa. Only the hybrid systems (B-e and B-f) and one of the woven face coverings (B-b) were able to achieve PFEs above the 20% performance threshold.

The standard was able to statistically differentiate across all three product categories based on their PFE, but there was no significant difference between the breathing resistance of medical masks and barrier face coverings. Pairwise analysis found the ASTM

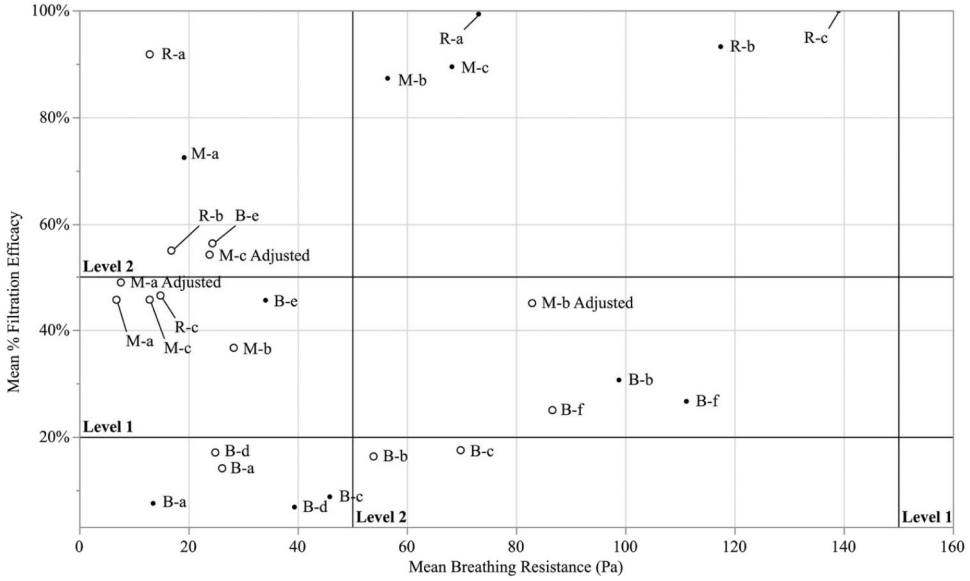

Figure 9. Comparison of the mean filtration efficacy and breathing resistance measurements from the optimized headform method (open circle) to the products tested under different conditions according to ASTM F3502-21 (solid circle). TFE results were reported at the 0.3 μm optical diameter size (0.139 μm CMD) while the F3502-21 results were measured at 0.075 μm CMD.

F3502-21 method was able to differentiate between the PFE of 86% of all product pairs down to a difference in means of 7%, with a few exceptions between some respiratory devices, barrier face coverings, and products made from nonwoven materials. The breathing resistance measurements were able to statistically differentiate between 91% of all possible pairs with a difference in means of 12 Pa. However, it was still difficult to distinguish between some of the medical masks and barrier face coverings.

To compare across methods, the first five replicates from each product evaluated with the optimized method were used. These values on the headform are shown alongside the ASTM F3502-21 testing in Figure 9, with the indication that the headform TFE measurements were reported at 0.3 μm D_{opt} or 0.139 μm CMD compared to the ASTM F3502-21 PFE measurements reported at 0.075 μm CMD. Product type, test method, and the interaction of product and method were statistically significant. Across this data set, there was a 17% decrease in TFE when donned as they are intended to be worn on the headform, even though the headform method measured larger particle sizes. All of the products, with the exception of one of the hybrid face coverings (B-f), were considered statistically different across methods. These differences in filtration ranged from 7 to 14% across the barrier face coverings (B-a, B-b, B-c, B-d, and B-e), 27 to 51% among the medical masks (M-a, M-b, and M-c), and 38 to 53% across the two KN95s (R-b and R-c). The N95 decreased TFE 8% on the headform, reinforcing one of the limitations of using a single-sized headform. TFE significantly decreased for all of the nonwovens when tested with the optimized headform method; however, some barrier face coverings (B-a, B-c, B-d, and B-e) increased TFE on the headform. This is likely due to differences in flow rate, aerosol properties, and measurement instruments across methods.

The breathing resistance measurements on the headform were representative of the maximum inhalation resistance detected. Similarly, the optimized method showed a decrease in breathing resistance of 36% across the data set. Only three respiratory devices (R-a, R-b, and R-c), one medical mask (M-c), and one barrier face covering (B-b) had significant differences in breathing resistance across methods. The respiratory devices saw the largest change in breathing resistance when sealed, increasing from 60 to 124 Pa. Similarly, M-c increased by 55 Pa sealed, and B-b increased by 45 Pa. The majority of products tested had higher resistance when sealed according to ASTM F3502-21. However, two of the face coverings that had higher TFE on the headform (B-a and B-c) maintained higher breathing resistances.

Discussion

Several changes were made to the baseline test method in an effort to reduce the variability of the measurements. A single 15 L/min sinusoidal breathing rate was selected to represent a medium-sized adult

performing at a light workload (International Organization for Standardization 2015; Zhu et al. 2018). A combined test protocol was created to consolidate the static and dynamic segments. Most significantly, the headform was moved into an environmental chamber, allowing test conditions to be controlled at 20 °C and 65% relative humidity (International Organization for Standardization 2005). These changes considerably reduced the standard deviation in TFE measurements. However, high humidity has been shown to influence the PFE of hydrophilic materials (Zangmeister et al. 2021). It can also agglomerate particles and impact their charge, which can affect how they interact with the filter (Tcharkhtchi et al. 2021). There did not appear to be any improvement in the TFE of barrier face coverings made from hydrophilic fabrics. Moreover, the higher humidity in the chamber may have reduced particle charge, making the nonwoven products that rely on electrostatic filtration less effective and ultimately contributing to the lower TFE values. More research is needed to determine the full effects of humidity on TFE, both in the environment and in the microclimate between the face and the barrier.

The optimized headform test method was able to differentiate between a wide range of products from three different categories (respiratory devices, medical masks, and barrier face coverings) with a difference in means of 2% TFE or more at 0.3 μm D_{opt}. The N95 respirator control was able to maintain TFE between 93 and 97% across particle sizes, as expected of a certified respirator designed to seal to the face. The lower TFE at 0.3 μm D_{opt} may have been the result of poor fit or high humidity conditions impacting the electrostatic filtration. However, TFE remained consistent over the course of the test with a standard deviation below 3% at all particle sizes. This demonstrated that the method was able to reliably measure TFE on the headform and maintain a reasonable seal to the face.

Similar to the baseline results, TFE increased as a function of particle size for almost all products with a few notable exceptions. The hybrid barrier face covering (B-f) saw a significant decrease in TFE at the 2 μm D_{opt} range, along with another barrier face covering (B-b) to a lesser extent. Typically, lower TFEs at higher particle sizes can be attributed to leakage due to poor fit since these particles are more easily captured by filtration mechanisms (Hutten 2016). There were also some negative TFE values at 2 μm D_{opt}, indicating that more particles were measured inside the facepiece than there were in the environment. This could suggest something was coming off the material or fabric was shedding over the course of the test, which might be harmful if inhaled. More research is needed to confirm that there was no instrumental or experimental error. However, the consistent performance of the remaining products suggests this may be related to specific properties of these face coverings.

The method was able to statistically differentiate between TFEs for 90% of all possible product pairs at 0.3 µm D_{opt}. There were statistically and clinically significant increases in TFE at 0.3 μm D_{opt} for all three medical masks that were tested as received and then adjusted by tightening the ear loops. This demonstrated that improving the fit of these pleated masks has the potential to enhance their TFE by up to 8%, in good agreement with other literature (Lindsley et al. 2021; Chiera et al. 2023; Pennington et al. 2025). The two styles of KN95s were also considered statistically and clinically different, with the flat fold KN95 (R-b) able to achieve a better fit on the current headform. The difficulty in statistically differentiating between medical masks and KN95s may have further implications. Although KN95s are certified to GB 2626-2019 and often classified as respiratory protection devices, they performed similarly to medical masks. It may be more reasonable to group them in the future if they cannot create and maintain a seal to the face. It was also difficult to differentiate between a few of the barrier face coverings. There were marginal differences between the four knit and woven face coverings, while the two hybrid face coverings made with nanomaterials were able to achieve higher TFEs. This emphasizes the importance of material selection in addition to fit.

A comparison of the two headform methods showed improvements in the TFE measurement during the optimized test with CVs $<$ 20% at 0.3 μm D_{opt}. The variability analysis also gave a strong indicator that the new method was able to evaluate different products more repeatably. Product type made up 95.10% of the method variability with a marginal unexplained error of 3.70%, demonstrating that the optimized method successfully reduced both method variability and inherent error. This test was initially performed by a single operator and could not yet determine reproducibility. However, the validation study run by a second operator following the same procedure only found clinically and statistically significant differences for the two KN95s and the medical mask that were previously shown to have more variable fit across operators (Armistead et al. 2026). The new variance component estimates found product type to be 90.3% of the variation in the method, while operator and the interaction of operator and product

totaled 7.5%, demonstrating good reproducibility. The inherent variability in the method was low at 1.9%, indicative of its improved stability.

The breathing resistance measurements were less robust. The optimized method sampled at a frequency of one measurement every 5 seconds to identify the maximum pressure differential from the 12 data points collected each minute. However, due to the nature of sinusoidal breathing, this may not have been able to capture the true inhalation and exhalation peaks, but rather a lesser point along the curve. Measurement frequency was increased to sample each second during the validation study with the second operator, allowing this maximum value to be determined from 60 data points collected each minute. Higher differential pressure values were reported, but more research is needed to confirm if this is due to sampling frequency or operator differences. Furthermore, more frequent sampling should be evaluated to ensure these values can reliably capture the full breathing cycle.

The headform results were compared to the current method for evaluating barrier face coverings (ASTM F3502-21), which tests the full product mounted and sealed and does not account for potential leakage around the perimeter that can occur on a three-dimensional form. However, it is important to note that particle generation and detection instruments were different across methods, with the OPCs in the headform method measuring particles approximately two times larger than the ASTM F3502-21 method. Under this standard, the performance levels for PFE and breathing resistance are defined as $\geq$ 20 and 50% and $\leq$ 50 and 150 Pa, respectively (ASTM International 2021a). Products that obtained both the higher Level 2 TFE and breathing resistance on the headform included the N95 control (R-a), one of the KN95s (R-b), one of the hybrid face coverings (B-e), and the adjusted medical mask (M-c). Only M-a was able to achieve this performance following the ASTM F3502-21.

The TFE of all respiratory devices and medical masks decreased when they were measured on the headform, as expected due to the impact of leakage around the facepiece that can occur when worn. However, some of the barrier face coverings had higher TFE than PFE. This may be related to differences in flow rates between the lower sinusoidal breathing on the headform and the high 36 to 71 L/min constant flow on the filter tester. The 10 cm/s face velocity required in the standard is achieved by adjusting the flow rate according to the surface area of the facepiece. This leads to variable airflow rates across products within the same method, which can also impact their performance (Rengasamy et al. 2017). Despite these differences, overall, there was a 17% decrease in TFE and a 36% decrease in breathing resistance measured on the headform. This demonstrates the importance of incorporating leakage into the measurement of these products that do not seal to the face.

Limitations

The headform is a single size, which does not factor in different facial structures and sizes that can impact fit. The current test used unneutralized, polydisperse NaCl particles, but neutralizing the particles and controlling their size distribution may allow closer testing of the worst-case scenario. Additionally, the current approach of using OPCs limits the ability to assess particles in the smaller MPPS range, so direct comparison or correlation with the respirator certification protocols or ASTM F3502-21 is limited. The 15 L/min minute volume flow rate was also relatively low. Evaluating each sample at multiple flow rates may be an important consideration in the future to better understand their performance at different activity levels. These flow rates were programmed using the accompanying headform software but may need to be validated for future inter-lab comparisons on different systems.

Completing 10 replicates of the current 10-minute protocol was a long test to run. The differential pressure sensor has limited data storage that would not allow for continuous monitoring throughout the entire test duration. To increase measurement frequency, the method or sensor may need to be changed. Based on the statistical analysis, reducing the test duration and the number of replicates could be considered to improve testing efficiency for method standardization without impacting the reliability of the measurements.

Conclusions

The optimized headform test method was able to differentiate between 12 different products across three categories with a range of TFEs between 14 and 93% at 0.3 μm D_{opt}, influenced by a combination of material, fit, and design. This was evident in the KN95s that had moderate TFEs despite their high material filtration due to difficulty maintaining a seal to the face. The performance of medical masks significantly improved by tightening the ear loops with cord locks. Consequently, their breathing resistance similarly increased. Meanwhile, the hybrid barrier face coverings appeared to improve TFE by incorporating

nanomaterials into their products with variable breathing resistances.

The most significant change in the optimized method was the controlled environmental conditions. The comparison between the baseline and optimized methods found that the optimized method had lower TFE and smaller standard deviations across all 12 products. Product type was responsible for the majority of the variance, with low unexplained error in the method. Further validation through an intra-lab study with a second operator confirmed good measurement stability and reproducibility across operators.

A comparison to the current ASTM F3502-21 standard highlighted the limitations of evaluating these products as a sealed system. Testing on the headform decreased TFE and breathing resistance across the data set due to inward leakage, with a few exceptions among the barrier face coverings. Overall, the optimized method is a repeatable and reproducible test that can more realistically evaluate the TFE and breathing resistance of products that are not designed to seal to the face. However, there is room for further development of the differential pressure measurements to more accurately capture the inhalation and exhalation resistance peaks. The current method is designed to evaluate inward leakage, but the reverse (generating particles from inside) remains an important consideration for source control devices. The differences between inward and outward leakage should be compared under this test system to determine if an additional outward leakage component should be added. Future studies could also explore TFE across different facial dimensions.

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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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