

ABSTRACT

ARMISTEAD, MELISSA KAYE. Development of an Animatronic Headform Test Method for the Evaluation of Fit and Total Filtration Efficiency of Barrier Face Coverings. (Under the direction of Dr. R. Bryan Ormond).

The COVID-19 pandemic has had widespread implications. Early supply shortages made it difficult to obtain traditional respiratory protection. The general public was advised to instead wear medical masks or barrier face coverings as a method of source control. These products offer variable efficacy depending on their material, fit to the face, and the environment in which they are worn. Recent studies and standards tend to evaluate these products at the material level or as a sealed product which does not account for leakage around the perimeter of the barrier due to poor fit when worn. This research focused on developing a system-level method to realistically assess the performance of these products that are not designed to seal to the face. An advanced animatronic headform with breathing and movement capabilities was used to evaluate the total filtration efficiency of several respiratory devices, medical masks, and barrier face coverings.

The baseline headform method was able to clinically and statistically differentiate between samples. The respiratory flow rate, testing duration, and operator were shown to significantly impact filtration while the influence of movement was less conclusive. The variance component estimates confirmed that the method had good repeatability and reproducibility. A closer analysis across particle sizes was able to compare the fit to the headform. The filtration efficiency measured with the baseline method was compared to the recent ASTM F3502-21 Standard Specification for Barrier Face Coverings. This standard evaluated the samples as a sealed product which eliminated leakage from the measurement. There was a notable decrease in filtration efficiency on the headform compared to the ASTM method due to the incorporation of fit into the measurement that offered a more realistic assessment of daily wear. However, both

methods generally agreed on the product classification levels for a large percentage of the samples suggesting similarities between the two measurements.

From this analysis, an optimized headform method was developed to reduce the variability within samples. The animatronic headform was moved into an environmental chamber that allowed for temperature and humidity control. The condensed protocol was still able to statistically differentiate between samples across the three product groups. The measured total filtration efficiency was significantly lower with the optimized method for each sample along with their coefficient of variation from the mean. The variance component estimates demonstrated that the new method improved repeatability. This study offered an alternative method to traditional material and system-level evaluations that was able to realistically evaluate the performance of barrier face coverings and other products on a headform.

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Development of an Animatronic Headform Test Method for the Evaluation of Fit and Total
Filtration Efficiency of Barrier Face Coverings

by
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DEDICATION

I would like to dedicate this work to my parents for their endless encouragement and support, and to Zach, who got me through every step of the way. Thank you.

BIOGRAPHY

Melissa Armistead was born and raised in Northern Virginia. She received a B.F.A. in Fashion Design and B.S. in Fashion Merchandising from Marist College in Poughkeepsie, New York, in the Spring of 2018 before transitioning into the science and engineering field. She plans to continue her education at North Carolina State University in the Fiber and Polymer Science Ph.D. program after the completion of her M.S. in Textile Engineering in 2022. Her research focuses on developing and evaluating personal protective equipment for CBRN applications.

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CHAPTER 1: Introduction

1.1 Background

Viruses and disease have left a significant impact on history. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) first surfaced in December of 2019 and rapidly grew into a global pandemic. Two years later, there have been over 94.9 million reported cases and over 1.0 million deaths in the United States alone [1]. Coronaviruses are a group of RNA viruses that attack the respiratory track. They are transmitted through contact, aerosol, and droplets. Droplets and aerosols are airborne particles carrying a viral load that are released during breathing, speaking, and coughing [2]. Wearing a barrier face covering can reduce aerosol and droplet transmission by providing a physical barrier. Social distancing, hand hygiene, vaccinations, and boosters have also been recommended by the Centers for Disease Control and Prevention (CDC) to reduce transmission.

There are several classifications of respiratory protection and source control devices. Respirators are designed to protect the wearer from inhaling hazardous substances. N95 respirators are disposable filtering facepiece respirators (FFRs) that filter particulates under negative pressure. KN95s and KF94s, the Chinese and South Korean equivalents to the U.S. N95, have recently been sought out due the shortage of available N95s. Source control devices, on the other hand, are intended to contain the wearer's respiratory droplets in order to prevent transmission to others. Medical masks, including surgical and procedural masks, are primarily designed to protect the wearer from contact with bodily fluids during procedures but can additionally contain the wearer's respiratory fluids. Barrier face coverings are defined as products worn over the nose and mouth that may provide a degree of filtration for the wearer but are primarily used to provide source control [3].

Barrier face coverings provide variable efficacy depending on the material properties, fit to the face, and environment in which they are worn. The mechanisms of filtration play a significant role in capturing respiratory particles as they pass through the filter media. Larger and smaller particles are more easily captured by traditional filtration mechanisms [4]. Several studies have investigated the influence of fiber characteristics, fabric structure, surface properties, and additional layers on the filtration efficiency and breathability of household materials. Overall, higher density materials like cotton with a tight weave and low porosity performed comparatively well. Multiple layers of material increased filtration efficiency and consequently reduced breathability [5] [6] [7]. Hydrophobic fabrics with an inherent or applied electrostatic charge also increased filtration [6] [7]. Several studies used variations of different standard methods for particulate filtration efficiency which made it difficult to directly compare.

The American Society for Testing and Standards (ASTM) along with the International Organization for Standardization (ISO) and other international standards organizations are responsible for creating technical testing standards. In the United States, N95s are federally regulated by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR Part 84 to filter at least 95% of airborne particles. The U.S. Food and Drug Administration (FDA) temporarily authorized emergency use of certain international respirators manufactured in China until July 2021. KN95s are tested under the Chinese standard GB2626-2006 for a 95% minimum filtration efficiency. KF94s are evaluated under the South Korean standard KMOEL-2017-64 that requires similar quality controls to NIOSH and a 94% or higher particulate filtration. Medical masks are classified by the FDA as level 1, 2, or 3 based on their particulate and bacterial filtration efficiency, differential pressure, blood penetration, and flammability using ASTM F2100-21. In response to the rising demand for accessible respiratory protection, barrier

face coverings can now be evaluated using ASTM F3502-21 for particulate filtration efficiency and airflow resistance.

Conflicting performance standards used to evaluate respirators, medical masks, and now barrier face coverings may confuse manufacturers and end users. Testing parameters including the flow rate, particle charge, and particle size vary significantly between methods which can affect the reported performance [8]. The ASTM standards for particulate and bacterial filtration efficiency used to evaluate medical masks are significantly different from the NIOSH certification process for N95 respirators which is designed to evaluate the worst-case scenario. The new ASTM standard for barrier face coverings more closely aligns with the NIOSH NaCl testing procedure. However, unlike respirators, these products are not designed to seal to face even though they are sealed to a plate during testing. Current testing and standards evaluate these products at the material level, or as a sealed product, which does not account for leakage due to poor fit or movement when worn.

There has been limited research on the performance of these products as a system. Restrictions during COVID-19 made it difficult to conduct traditional wear trials or fit testing to evaluate their efficacy when worn. Advanced headforms offer an alternative method of assessing performance on a three-dimensional model. Technology has enabled animatronic headforms with programmable breathing and movement sequences that are capable of more realistically measuring performance. These are important considerations because these products are not designed to fit to the face. Leakage around the barrier due to poor fit has been shown to significantly reduce the filtration efficiency [6], [9]. System-level evaluations offer an important perspective in evaluating the efficacy of medical masks and barrier face coverings.

1.2 Purpose

The purpose of this experimental study is to comparatively analyze material and system-level test methods that evaluate the efficacy of different barrier face covering and medical mask styles in order to statistically determine the precision and accuracy of the methods. The proposed system-level test method, using an animatronic headform, will additionally assess the impacts of fit and movement on the barrier performance. A range of commercially available products including certified N95 respirators, KN95s, medical masks, and barrier face coverings will be analyzed using the ASTM F3502-21 Standard Specification and the animatronic headform test method. Filtration efficiency and breathing resistance will be compared.

This study will aim to address the following research questions:

1. What are the measurable and statistical differences between some of the current material and system-level evaluations?
2. Can headform testing offer a reliable alternative to current standards and fit testing across a broad range of product designs?
3. How do fit and movement affect the performance of respirators, medical masks, and barrier face coverings?

This research will help to understand the factors that influence the efficacy of barrier face coverings and how they can be incorporated into standardized testing to provide a more realistic measure of performance. This has applications beyond the COVID-19 pandemic. The principles of barrier face coverings can be applied to other respiratory threats faced by first responders and the general public.

CHAPTER 2: Literature Review

2.1 Biological Hazards

Bacteria, fungi, viruses, and other living organisms that threaten the health of humans or other living things are considered biological hazards. They can enter the body through inhalation, ingestion, or the skin and cause local and systemic reactions. These threats are often invisible and difficult to detect [10]. The World Health Organization (WHO) has assigned risk groups to these microorganisms based on their pathogenicity, route of exposure, and available treatment. They go from levels one to four, increasing with their perceived risk to individuals and the community. The risk groups correspond with Biosafety Levels (BSL) for laboratory work. BSL-1 agents are typically microbes that are not known to cause disease and pose minimal risk in the lab. BSL-2 agents may be moderate threat diseases like *Staphylococcus aureus* and will require labs to have some additional protective procedures. BSL-3 agents pose a significant threat if inhaled like *Mycobacterium tuberculosis*. Labs that deal with these agents or toxins must have controlled air flow and higher protective clothing. The highest level BSL-4 agents pose a high risk via aerosol transmission with no known treatment available like the Ebola virus. These agents require maximum containment facilities [11] [12].

Biological hazards pose a significant threat if outbreaks of an infectious disease are able to spread throughout a community causing an epidemic, and in some cases can expand across international borders into a pandemic. Diseases have always plagued humanity, though they have continued to spread exponentially as civilization developed. The highest death toll was in seen in 1347 during the Bubonic Plague, or Black Death, that rapidly spread across Europe killing over a quarter of the population. Plagues are transmitted from the bacteria *Yersinia pestis* via rats and fleas to humans, or human-to-human contact depending on the form. Bubonic plagues infect the

lymphatic system. There are also septicemic and pneumonic plagues that have routes of transmission through the blood and lungs, respectively. The Justinian Plague of 541 transmitted through bubonic and septicemic routes which lead to large fatalities in Constantinople [13]. More recently, the influenza pandemic of 1918, also called the Spanish Flu, was a virus that spread from person-to-person through airborne transmission and infected at least a third of the population, causing at least 50 million fatalities [14]. These infections have been mapped by fatalities alongside the most recent global pandemic, COVID-19, in Figure 1.

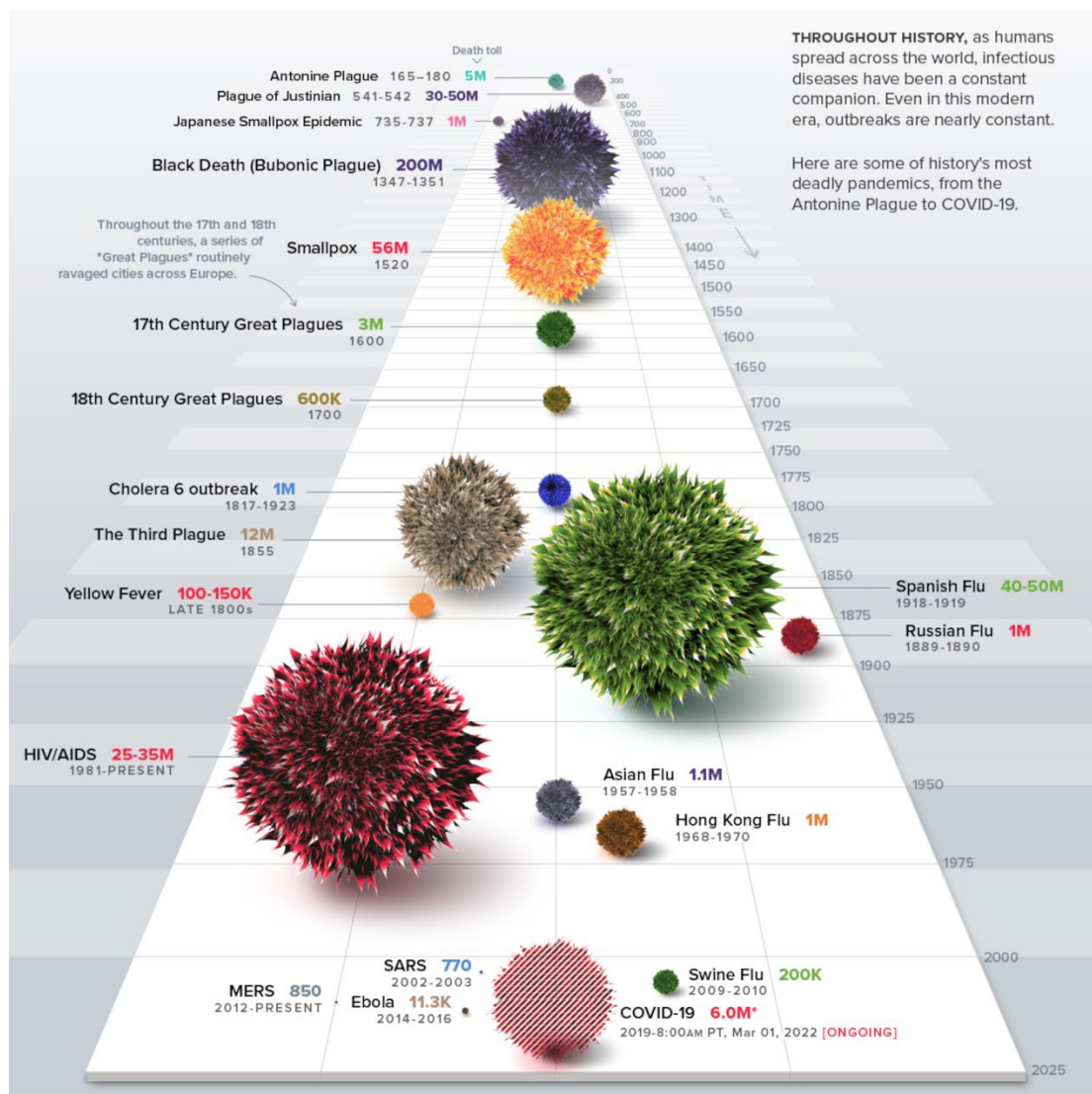


Figure 1. The world's most deadly pandemics throughout history [15]

2.1.1 SARS-CoV-2

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus responsible for COVID-19, first surfaced in Wuhan, China in December of 2019 when clusters of pneumonia cases with an unknown origin were identified [16]. It rapidly spread across borders and was declared a global pandemic by March of 2020. Coronaviruses are a family of RNA virus that can cause respiratory and other illness. SARS-CoV-2 is the seventh known variant to effect humans. It was identified as a risk group level three biological agent that poses a significant threat to the community through airborne transmission [17]. SARS-CoV and MERS-CoV, identified in 2002 and 2012, respectively, share similar characteristics and mechanisms of action to SARS-CoV-2 by infecting the lower respiratory track. The spike protein on the coronaviruses shown in Figure 2 allows them to bind and fuse with the host cells. These host cell receptors are distributed across the body which can lead to a wide range of symptoms [18]. These symptoms may include but are not limited to fever, cough, shortness of breath, fatigue, body aches, headache, nausea, and diarrhea. COVID-19 can also be spread by asymptomatic individuals. One study suggested at least 50% of infections were transmitted from individuals who showed no symptoms [19]. This has made it more difficult to control the spread.

Several variants have emerged over the course of the pandemic caused by mutations in the genetic code. These mutations are more likely to occur when transmission remains high, providing more opportunities to multiply and evolve. These variants become a concern when there are changes to the structure and characteristics of the virus. These structural changes can impact infectiousness and may inhibit antibodies from binding to the virus [20]. The Delta variant (B.1.617.2) was first identified in India in October 2020 and quickly became the dominant variant globally. It is more infectious than the original strain and cases have generally

been more severe. This variant has higher viral loads and more mutations to the spike protein which increases the likelihood of infection. Omicron (B.1.1.529) surfaced in South Africa in November of 2021 and spread to the U.S. the following month. This variant is significantly more contagious than Delta with significantly higher mutation of the spike protein that allow it to evade immune system response. Most cases are generally milder although the rapid spread raises significant concerns for healthcare systems. Breakthrough infections have been seen with both variants, but vaccinations and booster doses continue to help reduce the risk of hospitalization. As of September 2022, Omicron remains the only classified variant of concern [1]. Time will tell how the virus may continue to evolve.

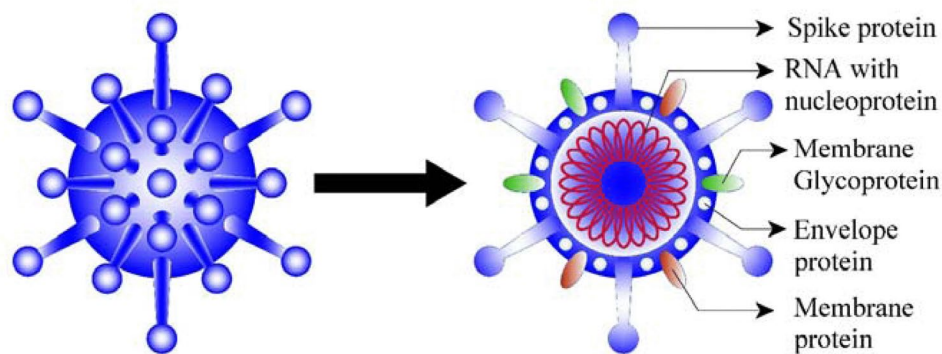


Figure 2. Structure of SARS-CoV-2 [20]

2.1.2 Virus Transmission

There are three routes of transmission for respiratory viruses. Contact transmission occurs through direct or indirect contact with an infected person or object contaminated with the virus. There has been some debate on the definitions of droplets and aerosols. Droplet transmission typically involves airborne particles with a diameter greater than 5 μm . Droplets can be dispersed short distances before settling on surfaces. Aerosol transmission is also airborne, but it involves smaller particle sizes with a diameter less than 5 μm . Aerosols, sometimes referred to as droplet nuclei, remain suspended in the air for longer periods of time and are capable of traveling farther

distances. These forms of transmission are dependent on the environment, crowding, and the host [21]. COVID-19 is primarily transmitted from person-to-person during breathing, talking, sneezing, or coughing. A distribution of particles generated from a cough can travel 2-4.5 m, while a sneeze can go as far as 7-8 m from the infected individual shown in Figure 3 [2]. Wearing a face covering can help reduce this particle trajectory, however the efficacy of the barrier will vary by design and filtration.

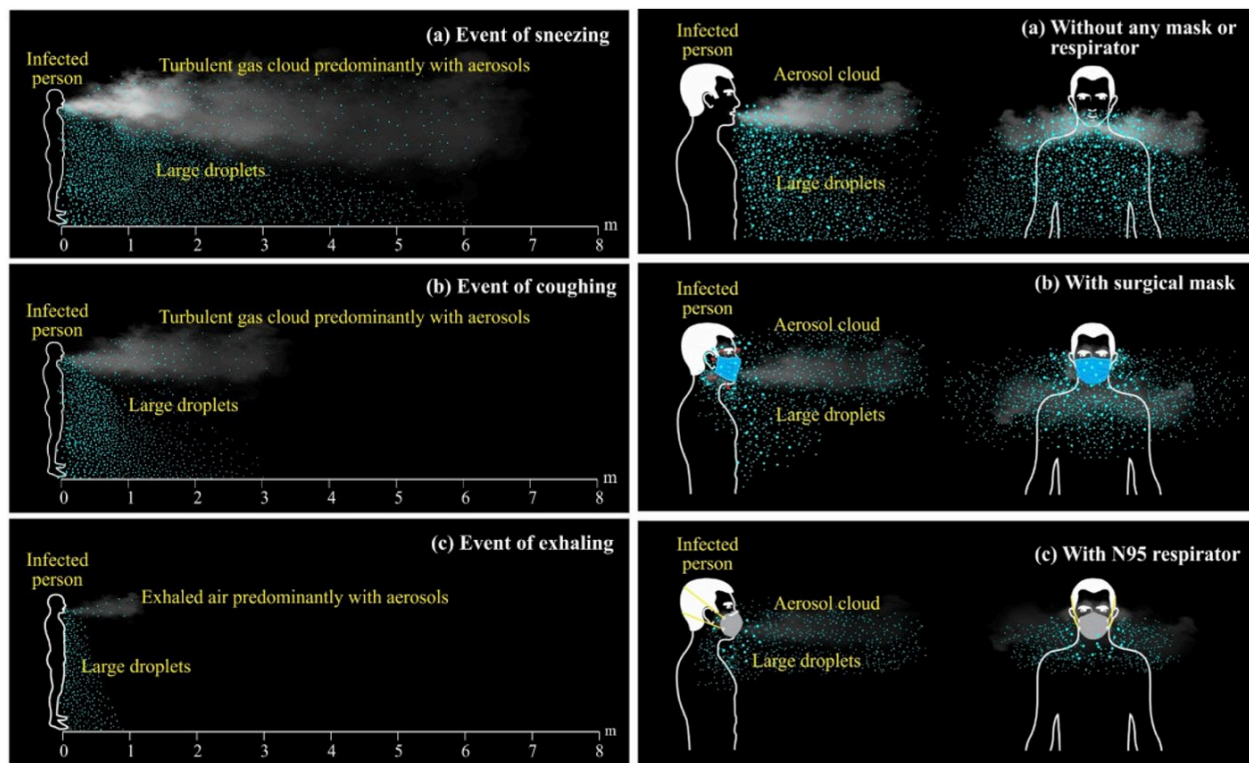


Figure 3. Droplet and aerosol transmission during sneezing, coughing, and exhaling (left) and transmission with different barriers (right) [2]

The basic reproductive number, R_0 , has been used to define the contagiousness of infectious diseases. The numerical values represent the average number of people infected from contact with a sick individual. It can be derived with statistical or theoretical models that factor in the duration of the infection, likelihood of transmission, and contact rate. The original coronavirus strain has an R_0 value of 2.4-2.6. Some studies found a wider range of 1.5-6.68

depending on the sample group and modeling methods [22]. This can be compared to other infectious diseases in Figure 4. The Delta variant has an R_0 value of 5-8, making it more than twice as transmissible as the original strain. This Delta variant is also significantly more infectious than smallpox, which was reported to have an R_0 value of 3.5-4.6 [20]. Omicron has an average R_0 value of 8.2, within a range of 1.9-24 across different countries data and has been reported as at least three times more transmissible than Delta [23]. A virus with an R_0 value greater than one will spread quickly across a population. The only controllable variable is human-to-human contact, which can be mitigated through social distancing measures.

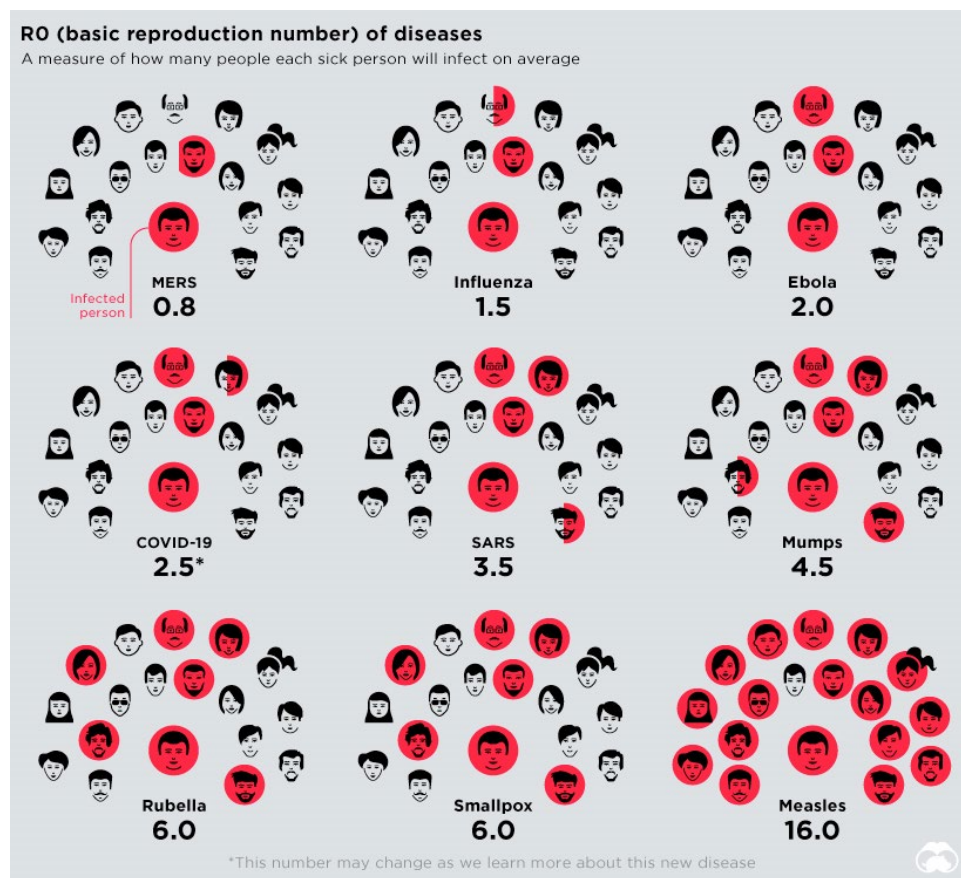


Figure 4. Comparing R_0 values of several infectious diseases [15]

There have been over 94.9 million reported cases and over 1.0 million deaths in the United States alone since the pandemic began, and these numbers have continued to rise [1]. The

Centers for Disease Control and Prevention (CDC) recommended a number of measures throughout the pandemic to help reduce transmission. These included social distancing, wearing a mask, hand hygiene, and getting vaccinated. The Pfizer-BioNTech vaccine was granted emergency use authorization by the U.S. Food and Drug Administration (FDA) in December of 2020, quickly followed by the Moderna and Johnson & Johnson vaccines. As of September 2022, 83.8% of people over the age of five have at least one dose of the vaccine. 34.9% of this same group have received their first booster dose [1]. Even with infection and hospitalization rates declining, it remains important to continue to follow these evolving public health guidelines to curb the spread of the virus and subsequent mutations [1], [2], [19], [20], [22].

2.2 Principles of Protection

The practice of wearing a face mask is not a new concept. Masks that cover the nose and mouth have been around since the early plagues. The notorious bird-beak masks worn by doctors during the Bubonic Plague were filled with herbs in an effort to neutralize the suspected airborne transmission of the illness. The first surgical mask was created by Mikulicz-Radecki in 1897 to protect patients in surgery from respiratory germs. It was made up of a layer of gauze that tied behind the head [24]. In the Manchurian Plague of 1910-1911, large cotton rectangles secured around the head with gauze were worn in an effort to protect medical workers. This resurfaced during the Influenza Pandemic of 1918-1919, where face masks became mandatory for health professionals. By this time, the masks were reusable and composed of several layers of gauze held together by a metal frame. These were replaced by disposable masks in the 1930s and disposable nonwovens in the 1960s [25]. Respirators were designed around this time for the mining industry in order to protect workers against particulate inhalation. The N95 respirator was

finally approved in 1972, but it was not introduced in the healthcare field until the 1990s during treatments of tuberculosis [24].

These concepts continue to be applied today. However, it is important to note that personal protective equipment (PPE) is often the last line of defense. According to the hierarchy of controls for addressing hazards in the workplace, elimination, substitution, engineering, and administrative controls should all be considered before PPE [26]. The COVID-19 pandemic provides a challenging threat to address in both healthcare settings and among the general public. The biological hazard cannot be easily removed or replaced. Engineering and administrative controls like physical barriers and ventilation systems, social distancing, sanitation practices, contact tracing, and quarantine measures have been encouraged and/or mandated. Lastly, respiratory protection and source control devices can be worn to help reduce transmission.

2.2.1 The Respiratory System

It is important to understand the functions of the respiratory system before discussing the mechanisms of protection in more detail. The respiratory system is a complex network primarily responsible for the ventilation and gas exchange in the body. These processes distribute oxygen across the body and remove carbon dioxide from the bloodstream. The respiratory system can be divided into the upper and lower respiratory tract shown in Figure 5. The upper respiratory tract consists of the mouth, nose, pharynx, and larynx. The lower respiratory tract is primarily made up of the trachea and the lungs. This is also where the conducting and respiratory zones responsible for ventilation and gas exchange reside [27].

Ventilation, or simply breathing, is the process that moves air in and out of the lungs through inspiration and expiration. This movement of air occurs due to the pressure differences

that result from muscle contractions in the diaphragm. These contractions primarily occur during inspiration and relax during expiration. The breathing rate can be defined by the number of inspirations that occur each minute. For an average healthy adult, this equates to 12-16 breaths per minute (BPM). The minute ventilation, or total volume expired each minute, for the same group of adults typically ranges from 5-7 L/min. Lung volume varies person to person based on a number of demographics including age, gender, and ethnicity. The average tidal volume, the air being moved each breath in a person at rest, is around 0.5 L for an adult. All of these values can change considerably during exercise or other strenuous activities [27], [28].

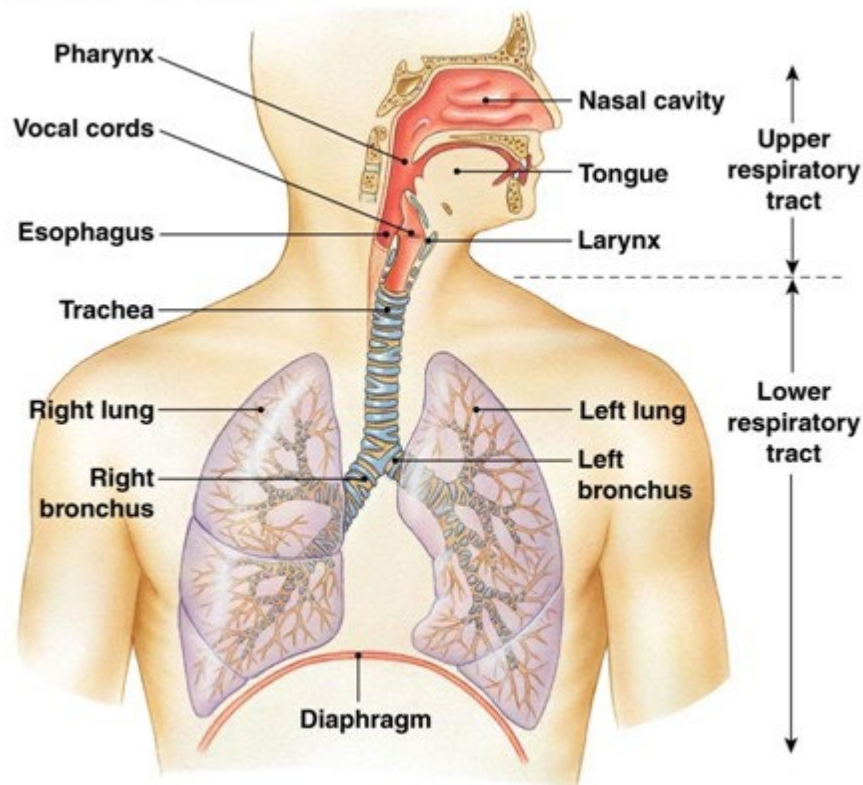


Figure 5. The respiratory system [28]

Gas exchange is the diffusion process that occurs across the lung membrane. After ventilation, gas is exchanged between the air and blood in a process called external respiration.

This exchange occurs across alveoli sites in the lungs. The pressure gradient between the alveoli and blood leads to the diffusion of oxygen into the blood and the subsequent release of carbon dioxide to be expelled during exhalation. The blood then transports oxygen across the body and exchanges this air with other tissue during internal respiration. Here, the pressure difference between the blood and surrounding fluid leads to the diffusion of oxygen from the blood into the cellular membrane to be used by the body [27], [29], [28].

The respiratory system has its own defenses to maintain homeostasis. The upper respiratory tract can typically filter larger particles while the smaller particles that can travel farther down the system may be countered with mucus, coughing, and bronchoconstriction [27]. In some cases, these internal defenses may not be enough. The lungs are uniquely vulnerable because they are directly exposed to the outside environment. Biological hazards can enter the body during inhalation where they may be absorbed into the bloodstream and rapidly transported across the body. This can lead to a wide range of complications in addition to inflammation and damage to the lungs. It is important to protect the respiratory system and take appropriate measures to reduce risks in hazardous environments.

2.2.2 Respiratory Protection and Source Control

There are several forms of respiratory protection and source control that have been employed throughout the pandemic to meet the increased demand in healthcare settings and among the general public. Filtering facepiece respirators (FFRs), including the N95, are disposable air-purifying respirators that remove contaminants from the air under negative pressure. N95s are generally made up of four layers of nonwoven material consisting of an inner and outer layer of polypropylene, a melt-blown filter, and a modacrylic support [4]. These

respiratory protection devices are capable of filtering particles both in and out of the filter media. N95s must be certified by the National Institute for Occupational Safety and Health (NIOSH) to filter at least 95% of airborne particles and fit to an individual before use to ensure a seal to the face. This seal must be created and maintained throughout wear to prevent leakage [30]. Surgical N95s have additional clearance from the Food and Drug Administration (FDA). Some N95s have exhalation valves which reduce the physiological burden on the wearer. This only protects the wearer since the exhaled air is not filtered and are not recommended for use against biological hazards.

N95 respirators are commonly used in healthcare settings, however the sharp rise in cases at the onset of the pandemic created severe shortages. The CDC advised the public to instead wear surgical masks or cloth/barrier face coverings primarily to provide a barrier for respiratory droplets. Respirators certified in other countries were temporarily approved for emergency use authorization in workplace settings when NIOSH certified respirators were unavailable. This included certain KN95s and KF94s that were approved by the FDA. A comparison of these products can be found in Table 1. Based on material performance, these alternatives should offer similar protection to N95s if a good seal is created and maintained. KN95s are Chinese respirators that are certified by the Standardization Administration of China (SAC) under GB2626-2006 or GB 2626-2019 to have a 95% or greater filtration efficiency. They are typically designed as a flat fold style that sticks out from the face when worn. KN95s are generally made up of four layers of nonwoven material, an inner layer, cotton layer, filter layer, and outer layer. The melt-blown filter layer is largely responsible for the mechanical and electret filtration [31].

Table 1. Different filtering facepiece respirators [31], [32], [33]

	N95	KN95	KF94
Country of Regulation	United States	China	South Korea
Certification/ Standard	NIOSH-42 CFR Part 84	GB2626-2006, GB2626-2019	KMOEL-2017-64
Material ^A	Nonwoven Polypropylene	Nonwoven Polypropylene	Nonwoven Polypropylene
Style	Varies	Flat Fold	Tri-Fold
Retention	Head Straps	Ear Loops	Ear Loops

Example



^A Most commonly used materials.

Another type of respirator that became largely popular in the U.S. is the Korean respirators, KF94s. These products are generally made up of three to four layers of nonwoven polypropylene material in a tri-fold shape that allows the respirator to sit off of the face while maintaining a close fit around the perimeter. They are designed primarily for the general public to filter dust and pollution, and as such come in both adult and children's sizes. KF94s are closely regulated by the South Korean Ministry of Food and Drug Safety (MFDS). This process is significantly more involved than KN95 certification and allows better quality control of the product. These respirators must filter at least 94% of particulates under KMOEL-2017-64 [32]. Counterfeit respirators have become a growing concern during the pandemic due to the continued demand and widespread use of alternative products. It is important to check that the

respirators are certified and sourced from a known manufacturer. If that is not an option, the product labeling should be carefully inspected and checked against the FDA Appendix A [34].

Surgical masks and barrier face coverings are primarily designed as methods of source control to reduce the wearer's viral shedding to limit transmission from an infected individual. These are compared to respiratory protection devices in Table 2. Surgical masks are pleated, disposable masks with a liquid-repellent outer layer to protect the wearer from droplets. They are generally composed of three layers of nonwoven material, an outer liquid barrier, a filter, and an inner absorptive layer [4]. They are cleared by the U.S. Food and Drug Administration (FDA) for fluid resistance, filtration, differential pressure, and flammability. Surgical masks are not intended to provide respiratory protection for the wearer [30]. The level of filtration can vary significantly based on the test method and conditions in which they were evaluated. The pleated design fits loosely to the face which allows for leakage around the perimeter of the mask.

Cloth or barrier face coverings offer another comfortable and accessible option for the public that come in a variety of materials and designs. The CDC recommends using a non-valved face covering made of multiple layers of tightly woven fabric. These face coverings must cover the nose and mouth while providing a reasonable degree of filtration and breathability [1]. They are generally loose-fitting and have varying performance based on the inherent properties of the face covering materials and the environment in which it is worn. As of March 2021, barrier face coverings can submit for compliance to ASTM F3502-21. However, the market remains largely unregulated and the performance of these cloth or barrier face coverings can vary significantly.

Table 2. Comparison of respiratory protection and source control devices [4], [30]

	N95 Respirator	Surgical Mask	Barrier Face Covering
Purpose	To provide respiratory protection from airborne particles	To provide fluid protection and minimize respiratory emission	To act as source control and provide some degree of filtration
Certification/Conformance	NIOSH	FDA	ASTM (Optional)
Standard	42 CFR Part 84	ASTM F2100-21	ASTM F3502-21
Filtration	High	Moderate	Low-Moderate
Fit	Tight seal to the face	Loose-fitting	Loose-fitting
Material	Nonwoven	Nonwoven	Varies
Reuse	No	No	Yes
Example			

2.2.3 Mechanisms of Filtration

The filtration performance of these products is dependent on the chemical and physical properties of the filter material in addition to the particle size, charge, and airflow in the environment. There are several mechanisms of filtration responsible for capturing particles as they interact with the filter media. Gravity sedimentation occurs when larger respiratory droplets between 1-10 μm interact with the filter due to downward gravitational forces. Inertial impaction is effective with particles 1 μm and above that are too heavy to follow the flow streamlines and

collide with the fiber. Interception behaves similarly, capturing particles up to $0.6\ \mu\text{m}$ that are intercepted by the filter following normal airflow patterns. Diffusion captures smaller aerosol particles less than $0.2\ \mu\text{m}$ that interact with the fiber due to random Brownian motion. Lastly, electrostatic attraction occurs between oppositely charged particles and fibers. It is generally used to help capture smaller particle sizes [4], [35]. These mechanisms of filtration with respect to the flow around a single fiber are all shown in Figure 6.

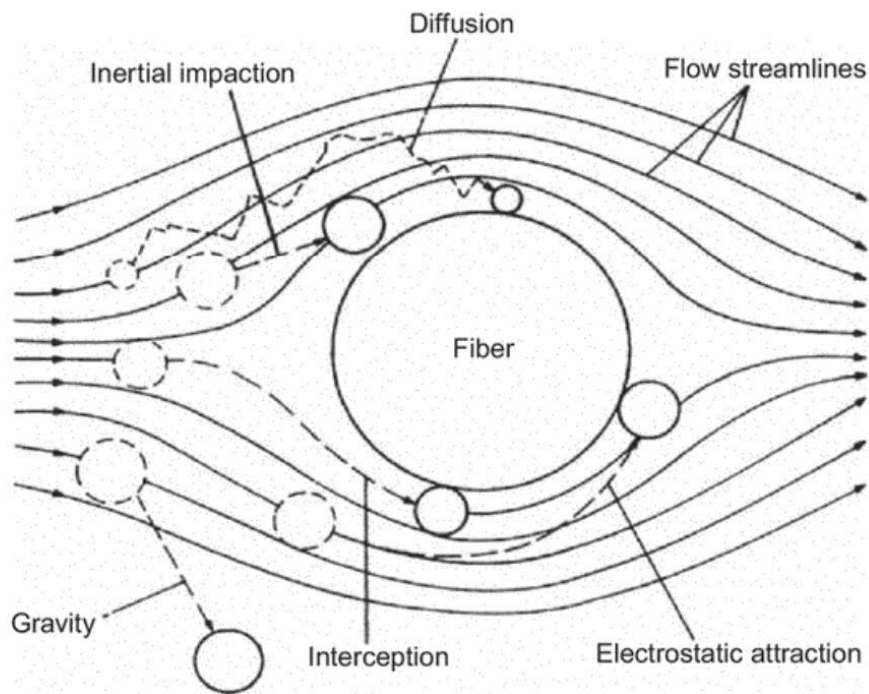


Figure 6. Mechanisms of filtration [35]

The dominant filtration mechanism is largely dependent on the particle size. Gravity sedimentation, inertial impaction, and interception are the primary mechanisms for filtering larger particles sizes while diffusion and electrostatic attraction are more effective at capturing smaller aerosol particles. The most penetrating particle size (MPPS) is the most difficult particle size to capture across these mechanisms. Several reports in literature have determined the MPPS can range between $0.04\text{-}0.4\ \mu\text{m}$ [35]. The MPPS varies with the filter media and velocity,

however, for testing purposes it is largely accepted as 0.1-0.3 μm [36]. This particle size is an important measure used to evaluate filter performance under maximum penetration.

2.3 Testing and Standards

Face masks and respirators have become a daily requirement in the COVID-19 environment. The demand for respiratory protection in workplace and healthcare settings has encouraged the rapid development of a number of homemade and commercial products with little to no regulation on their performance. In the face of a versatile and ever-increasing product inventory, it is important to find standard methods of evaluation to determine the efficacy of products that are being made readily available to the public. ASTM International is an international standards organization located in the United States that develops and releases standard methods across a wide range of technical fields. The International Organization for Standardization (ISO) is largely responsible for developing and distributing standards internationally. Other national standards including European (EN) Standards and China's Guobiao (GB) Standards are also used. The existing standards have different test procedures that can result in widely varied performance [8]. Prior to ASTM F3502-21, none of these standard test methods were designed to test barrier face coverings, which are now widely worn by the public. These conflicting performance standards may confuse manufacturers and end-users trying to evaluate the efficacy of these different products.

2.3.1 Filtration

Respirators are regulated under NIOSH 42 CFR Part 84. Air-purifying respirators, including FFRs, are classified by the series and filter efficiency level. The N-, R-, and P-series

designations are dependent on their resistance to oil. N-series are not oil resistant whereas P-series are completely oil resistant. The filter efficiency levels are determined by the minimum level of filtration capacity between 95-100% at 0.3 μm . N95s are tested by NIOSH for filter efficiency, airflow resistance, and fit along with individual components as needed. Filtration efficiency is measured using a 2% NaCl aerosol at a high flow rate of 85 L/min. The particles are neutralized with a count median diameter of 0.075 μm , equivalent to a mass median diameter of 0.3 μm , the MPPS. The total load concentration should not exceed 200 mg/m^3 . These tests are designed to achieve maximum penetration and airflow to evaluate the worst-case scenario [37].

International respirators follow similar performance requirements to certified N95s. KN95s are the most widely available international respirators, certified by SAC under GB2626-2006. This standard was updated in GB2626-2019 and has stricter performance requirements for breathing resistance. KN95s could be certified to either standard until July 1st, 2021. Similar to N95s, the KN products are not oil resistant and are classified by their level of filtration from 90-100% at 0.3 μm . KN95s are tested for filtration efficiency, inhalation and exhalation resistance, total inward leakage, and carbon dioxide (CO_2) clearance. Filter performance is evaluated at an 85 L/min flow rate using NaCl aerosol like the NIOSH testing [33], [38]. South Korean KF94s are another comparable product. KF94s are classified as Korea 1st class respirators by MFDS. The “KF” stands for Korean filter which is evaluated under the KMOEL-2017-64 for filtration, inhalation and exhalation resistance, total inward leakage, and CO_2 similar to KN95s. They are classified by their level of filtration at or above 94% efficiency at a flow rate of 95 L/min. This is slightly higher than the other standards. KF94s are also tested with both NaCl and paraffin oil with an average particle size from 0.4-0.6 μm depending on the test agent [33], [39].

Table 3. Comparison of international standards for filtering facepiece respirators [33]

	N95	KN95	KF94
Country of Regulation	United States	China	South Korea
Certification/ Standard	NIOSH 42 CFR Part 84	GB2626-2006	KMOEL-2017-64
Test Agent	NaCl	NaCl	NaCl and Paraffin Oil
Flow Rate	85 L/min	85 L/min	95 L/min
Filtration	$\geq 95\%$	$\geq 95\%$	$\geq 94\%$
Inhalation Resistance	≤ 343 Pa (at 85 L/min)	≤ 350 Pa (at 85 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)
Exhalation Resistance	≤ 245 Pa (at 85 L/min)	≤ 250 Pa (at 85 L/min)	≤ 300 Pa (at 160 L/min)
Total Inward Leakage	N/A	$\leq 8\%$	$\leq 8\%$

A comparison of these three respirator standards can be found in Table 3. While the performance of these products should be similar, NIOSH found that only select products were able to pass the NIOSH respirator test standard for approved use in the workplace. KN95s are loosely regulated and have poor quality control compared to N95s and KF94s. A substantial number of KN95s being used throughout the U.S. did not pass the filtration efficiency standards [34], [40], [41]. Several devices have been removed from Appendix A due to fraudulent claims and the emergency use authorization has been lifted. It is important to be careful of counterfeit products that may not offer the same level of protection.

There are a number of standards and documents referenced in the evaluation of medical and surgical masks. ASTM F2100-21 details the requirements for medical masks that must be

evaluated for sub-micron particulate filtration efficiency, bacterial filtration efficiency, differential pressure, blood penetration, and flammability. Medical masks can be classified as Level 1, Level 2, or Level 3 depending on these results. Level 1 requires a particulate and bacteria filtration efficiency at or above 95% whereas Levels 2 and 3 must have filtration at or above 98%. The difference between Level 2 and 3 classifications is an increased resistance to synthetic blood penetration [42]. Particulate filtration efficiency is tested in accordance with ASTM F2299-17. This tests the material with an aerosol of neutralized, monodisperse latex spheres between 0.1-5.0 μm . The concentration should remain less than 102 particles/ cm^3 . The face velocity can fall within a range of 0.5-25 cm/s. Particulate filtration efficiency can then be determined at 0.1 μm from the concentration ratio of particles using Equation 1, given $P(D_p)$ is penetration defined as the downstream particle concentration over the upstream particle concentration [43].

Equation 1. Particulate filtration efficiency [43]

$$\text{Efficiency} = 1 - \text{Penetration}$$

$$\eta(D_p) = [1 - P(D_p)]100$$

Bacterial filtration efficiency results are also required. Following ASTM F2101-19, *Staphylococcus aureus* is prepared and distributed with a nebulizer. Monodisperse 3.0 μm particles are directed through the cascade impactor at a 28.3 L/min flow rate. The agar plates are incubated for 48 hours before the six plates can be counted. Bacterial filtration efficiency is determined using Equation 2, where C is the plate count for the test controls and T is the total plate count for the sample [44]. All testing is conducted by third party labs before the results can be sent to the FDA for medical clearance. There are some differences between the FDA guidance document and ASTM F2100-21 [45]. The ASTM standards test the material while the guidance

document recommended evaluating the whole mask. The guidance document also requests unneutralized particles as opposed to neutralized in the particle filtration efficiency test which may overestimate efficiency depending on the environment. These changes between documents may be a source of confusions for manufacturers and labs.

Equation 2. Bacterial filtration efficiency [44]

$$\% \text{ BFE} = \frac{C - T}{C} \times 100$$

Barrier face coverings can be evaluated under ASTM F3502-21 for particulate filtration efficiency and airflow resistance. The standard establishes minimum conformance requirements at two levels of protection and comfort. Level 1 must have a filtration efficiency greater than or equal to 20%, and the higher protection Level 2 requires a filtration efficiency of greater than or equal to 50%. Ten trials are conducted on the entire product using a modified version of the NIOSH N95 test. The concentration and charge of the aerosol are the same. A 0.3 µm mass median diameter NaCl aerosol is generated inside the chamber at a 10 cm/s face velocity with a flow rate not exceeding 85 L/min. Since barrier face coverings are reusable, the testing must be conducted before and after the maximum number of laundering cycles. The calculation for particulate filtration efficiency is the same as ASTM F2299-17, using the ratio of particles that penetrate the sample [3].

Table 4. Comparison of standard test methods evaluating filtration efficiency in the U.S. [3], [8]

	NIOSH 42 CFR Part 84	ASTM F2299-17	ASTM F2101-19	ASTM F3502-21
Test	PFE	PFE	BFE	PFE
Test Agent	NaCl	Latex Spheres	<i>Staphylococcus aureus</i>	NaCl
Particle Distribution	Polydisperse	Monodisperse	Monodisperse	Polydisperse
Particle Size	0.3 μm	0.1-5.0 μm (0.1 μm) ^A	3.0 μm	0.3 μm
Particle Charge	Neutralized	Neutralized (Unneutralized)	Undefined	Neutralized
Concentration/ Load	200 mg/m ³	10 ⁷ -10 ⁸ particles/m ³	2200 particles/test	200 mg/m ³
Flow Rate	85 L/min	0.5-25 cm/s face velocity	28.3 L/min	10 cm/s face velocity
Duration of Exposure	Max penetration	1-5 min	1 min	4-15 s
Samples	Entire Product	Material (Entire Product)	Material (Entire Product)	Entire Product
Preconditioning	85% RH, 38°C	30-50% RH, 21°C	85% RH, 21°C	85% RH, 38°C

^A Different requirement from FDA guidance document noted in parenthesis.

The differences between standard testing procedures for filtration efficiency have made it difficult to directly compare data. These test methods are compared in Table 4. The NIOSH requirements for air-purifying respirators are designed to evaluate the worst-case scenario by using a high 85 L/min flow rate and 0.3 μm neutralized NaCl particles to test the filter media. Surgical masks are tested for PFE according to ASTM F2299-17 that requires testing with unneutralized 0.1 μm latex spheres within a wide range of face velocities from 0.5-25 cm/sec. These two test setups are shown in Figure 7. Bacterial and viral filtration efficiency procedures are also available; however, they use significantly larger 3.0 μm particles. The new barrier face

covering standard uses a modified version of the NIOSH respirator test with NaCl and a high 10 cm/s face velocity. These different methods are confusing for consumers and manufacturers alike. Changes in the test particle size, charge, and flow rate have been shown to have a significant impact on filter performance that suggests a wide variability in reported results [8]. Additionally, these tests are largely conducted at the material-level and the products are sealed down around the edges when they are tested intact. These results may be reduced when fit is a factor.

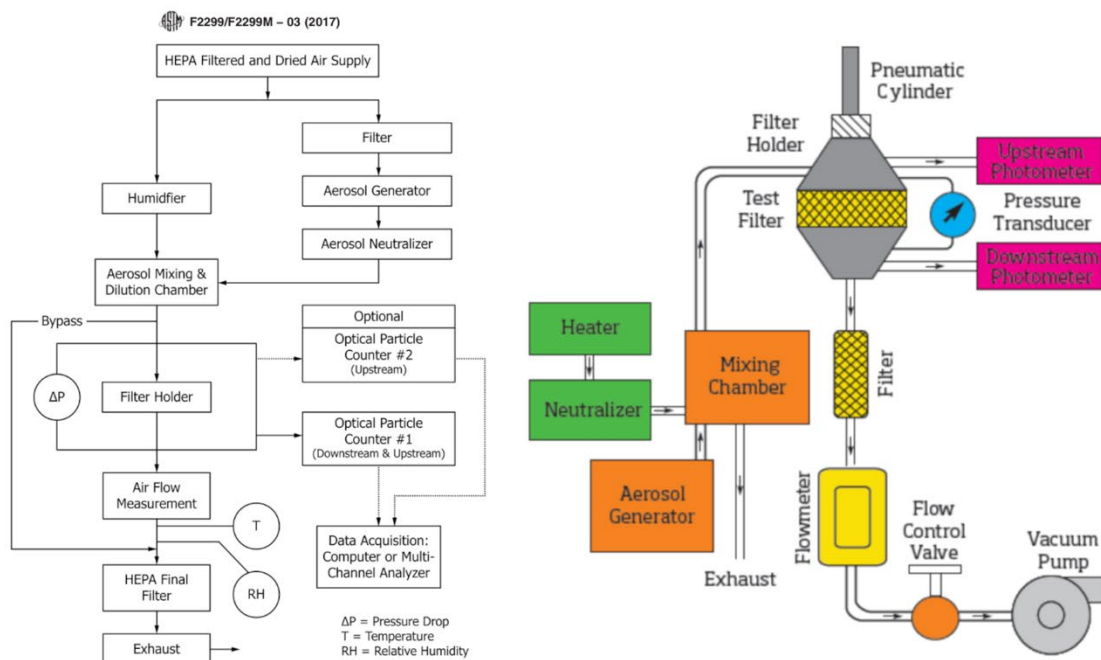


Figure 7. ASTM F2299-17 (left) and NIOSH 42 CFR Part 84 (right) filtration efficiency test setups [43], [46]

2.3.2 Breathability

There is always a balance between protection and comfort to consider when evaluating personal protective equipment. Respirators, surgical masks, and barrier face coverings are no different, whether their purpose is respiratory protection or source control. Increasing the

protection level or filtration efficiency often comes at the cost of breathability. Breathing or airflow resistance is typically measured as the pressure differential across the filter using a differential pressure sensor or manometer. This resistance must fall below a certain level depending on the product and performance standard to ensure safety and comfort for the wearer.

NIOSH 42 CFR Part 84 evaluates the airflow resistance of FFRs at a continuous 85 L/min flow rate that must achieve an inhalation resistance at or below 35 mm H₂O and an exhalation resistance at or below 25 mm H₂O. Breathing resistance measurements are the largest discrepancy among international respirator standards. Flow rates range from 30 L/min to 160 L/min depending on the airflow direction and standard. The requirements for certification also vary respectively. KN95s can have a maximum inhalation resistance of 350 Pa or 35.7 mm H₂O and a maximum exhalation resistance of 250 Pa or 25.5 mm H₂O at 85 L/min under GB2626-2006. KF94s are evaluated at different flow rates for inhalation and exhalation. They can have inhalation resistances at or below 70 and 240 Pa, 7.1 and 24.5 mm H₂O, at 30 L/min and 95 L/min, respectively using KMOEL-2017-64. Exhalation resistance is measured at a significantly higher flow rate of 160 L/min with resistance at or below 300 Pa or 30.6 mm H₂O. These comparisons can be found in Table 3. N95s have the lowest exhalation resistance and moderate inhalation resistance making them a bit more breathable than their counterparts [33].

Source control devices that are not designed to seal to the face must also have acceptable levels of breathability. Medical masks in compliance with ASTM F2100-21 must have a differential pressure at or below 5 mm H₂O for Level 1 classification or 6 mm H₂O for Levels 2 and 3. These materials are tested at a flow rate of 8 L/min under EN 14683. ASTM F3502-21 offers barrier face covering compliance for Level 1 airflow resistance no more than 15 mm H₂O and Level 2 at or below 5 mm H₂O. These barrier face coverings are evaluated at a flow rate of

85 L/min or a face velocity of 10 cm/s if the sample is tested flat. Lastly, air permeability of textile fabrics can also be evaluated under ASTM D737-18 using a small sample of the material with a minimum pressure drop of 125 Pa or 12.7 mm H₂O. Air permeability, measured in cm³/s/cm², is inversely related in the breathing resistance [47]. The requirements for breathability vary by the product and standard method which require different samples and flow rates, although the pressure drop compared to the airflow demonstrates these methods are relatively similar [33].

Breathability can be related to filtration efficiency with the filter quality factor, Q. It can be calculated with Equation 3, where 1 - FE/100 refers to the penetration and ΔP is the pressure drop in kPa. It has also been calculated logarithmically by replacing the natural log in the same equation. According to the WHO, a Q-factor of three or higher is recommended using the natural log relationship [48]. However, this metric is rather abstract and may be less reliable to compare filter performance across studies. Depending on the equation, these values will change. Filter quality is also dependent on the flow rate which can vary significantly. Higher filtration efficiency and lower breathability will increase the Q-factor. This also means that an extreme value for either parameter can significantly impact the value. For example, a lower filtering material with very low breathing resistance may reflect a higher Q-factor despite offering lower protection. This may not be the most effective measurement of material performance, but it does illustrate the important balance between protection and comfort.

Equation 3. Filter quality factor [49]

$$Q = -\frac{\ln(1 - FE/100)}{\Delta P}$$

2.3.3 Fit

Fit is an integral factor in filtration performance. Leakage due to poor fit can significantly reduce filtration efficiency by providing a path for particles to move freely around the filter material [5], [6]. Total inward leakage (TIL) refers to the concentration of particles that get inside a barrier through the filter and around the perimeter. Among the international respirator standards, NIOSH is also the only organization to not require a test for total inward leakage for certification, however fit testing in the workplace is required before use [33]. The new ASTM F3502-21 standard for barrier face coverings has made fit testing optional. As of September 2022, only three of the 27 face coverings currently listed in the CDC conformance page have reported the optional leakage ratio [50]. The difficulty in evaluating fit for barrier and medical masks is that these products are not intended to seal to the face. Barrier face covering designs have evolved since the beginning of the pandemic, where many of them are now able to achieve a better fit than the pleated surgical style. However, neither one creates the seal required by N95s and other respiratory protective devices. It is important to understand that the purpose of these face coverings is primarily as a method of source control when evaluating their lower fit factors.

Recently, NIOSH has added workplace performance recommendations in addition to the ASTM F3502-21 requirements for filtration and breathing resistance. These add minimum requirements for leakage and new labeling instructions. Products that conform to these recommendations should be able to provide a certain level of source control when worn in the workplace. Masks can be compliant with “Workplace Performance” or “Workplace Performance Plus” if they meet the criteria. Workplace Performance products must have a filtration efficiency at or above 50%, breathing resistance at or below 15 mm H₂O, and a leakage ratio of greater than or equal to five. Similarly, Workplace Performance Plus products have a filtration efficiency at

or above 80%, breathing resistance at or below 15 mm H₂O, and a leakage ratio of greater than or equal to 10 [51]. This required leakage ratio is measured by fit testing with human subjects following ASTM F3407-20. The three ASTM conforming products that list a leakage ratio are listed as workplace performance plus [50].

ASTM F3407-20 is the respirator fit testing standard used to establish minimum performance requirements for FFRs and elastomeric respirators in the workplace. As written, the standard offers a pass-fail criterion where 13 of the 25 participants in the bivariate panel must obtain a respirator fit capability (RFC) above 100. This value is determined by the concentration ratio outside to inside the respirator. During the test, 2% NaCl aerosol is used to generate neutralized particles in a large chamber with a concentration between 2000-8000 particles/cm³ throughout the test. Participants don the respirator and perform a series of activities including normal and deep breathing, side-to-side and up-and-down head movements, talking, reading, and bending over. The RFC values for each activity can be calculated and averaged together to determine the overall performance [52]. An adapted version of this test can be used to determine the total inward leakage of barrier face coverings. It is imperative to consider the relationship between fit and filtration when evaluating the efficacy of these products.

2.4 Material-Level Evaluations

The rising demand for barrier face coverings has inspired a number of studies to evaluate the efficacy of common household materials. Material-level evaluations are designed to examine the physical properties of the fabric in a controlled environment. It is important to consider that material filtration efficiency and airflow resistance measurements are generally conducted in a sealed test apparatus, which does not account for potential leakage around the perimeter due to

poor fit when worn. The procedures used in these material-level evaluations varied significantly from one study to the next making it difficult to directly compare results. Aerosol, particle size, charge, and face velocity introduced variances that resulted in a wide data distribution. Despite these variabilities in testing, material characteristics have been shown to play a significant role in the performance of barrier face coverings. Filtration and breathability are related to the characteristics of the fibers, fabric structure, density, inherent charge, and other properties. Literature on this topic is continuing to develop alongside the progression of the pandemic.

2.4.1 Fiber Composition

Fiber composition can have a significant influence on filter performance. Fibers have distinctive properties based on their structure, shape, and composition [53]. Cellulose fibers are natural, plant-based fibers that are primarily made up of cellulose molecules, which have a rigid backbone of connected glucose rings shown in Figure 8. The hydroxyl groups allow them to form hydrogen bonds. Cotton is the most widely used cellulose fiber that has a twisted shape with a high crystallinity, density, and moisture regain. Cotton is hydrophilic and will absorb moisture from the air which swells the fibers and can change their properties. Similar effects are observed in other cellulosic fibers such as jute, hemp, and flax [53].

Since the beginning of the COVID-19 stay-at-home order, cotton fabrics were widely used in homemade face coverings. Recent literature has reported a wide range of efficiencies in cotton. Bagheri et al. tested seven cotton fabrics with different structures that ranged from 4-60% filtration when tested as single layers against particles ranging from 0.3-10 μm [54]. O'Kelly et al. also tested several cotton materials and found jersey knit had the lowest efficiency around 25% from 0.02-0.1 μm , while a single layer of denim was able to get up to 46% [55].

Zangmeister et al. reported three of their highest performing materials were made up of 100% cotton sourced from lightweight flannel, a hand towel, and a pillowcase. These materials were tested as two layers, with minimum filtration efficiencies between 20-32% from 0.05-0.825 μm and breathing resistances between 62-129 Pa. The lowest performing cotton material filtered around 7% [49]. Joo et al. found cotton had one of the lowest filtration efficiencies of the materials evaluated measuring 12% from 0.017- 0.7 μm with a pressure drop of 62 Pa [56]. Unlike the other studies, Konda et al. saw unusually high filtration efficiencies up to 96% for cotton quilting above and below 0.3 μm with a 2.7 Pa pressure difference. Similar results were reported for their high thread count and hybrid cotton systems. They later made a correction that the experimental flow rate was lower than the one presented, which may account for some of this difference [6]. Filtration efficiencies ranging from 4-96% across cotton fabrics suggest that the material structure and properties may play a more significant role in filtration performance.

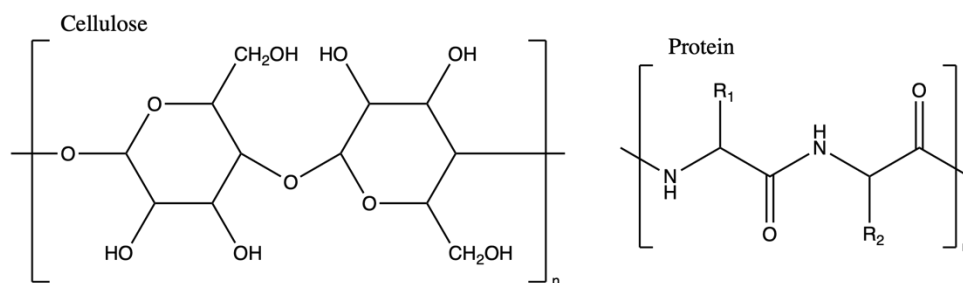


Figure 8. Base chemical structures of natural fibers

Protein fibers are another group of natural fibers. They are made up of polypeptide protein links shown in Figure 8. The order and composition of the proteins vary based on the source. Wool and silk are the most commonly used protein fibers in textiles. Wool comes from a number of sources including sheep, rabbits, and goats. Keratin, the primary protein in wool, has two different possible crystal structures that give the fiber unique properties. It has hydrogen bonding like cotton, but a lower crystallinity due to the presence of bulky side groups. Wool has

a helical structure responsible for its extensibility and crimp. It has directional friction properties due to the scales on the fiber surface. Silk is made up of the protein fibroin that comes from the silkworm. The molecules are well oriented and hydrogen-bonded, which gives it higher crystallinity. Silk has a triangular cross-section that contributes to its unique hand and sheen. Like the other natural fibers, silk and wool have good moisture regain [53].

Some studies have included wools and silks in their evaluation of accessible materials. Silk has been of particular interest due to its inherent ability to hold a charge. However, on its own, silk appears to have a lower filtration efficiency than cotton. Hao et al. found that silk had a filtration efficiency around 10% at 0.3 μm and around 13% across the 0.03-0.6 μm particle range. The low breathing resistance around 20 Pa gave the sample a high quality factor of 5.35 kPa^{-1} despite the low protection [57]. Zhao et al. found an initial filtration efficiency for a silk napkin even lower at around 5% at 0.3 μm with a pressure drop around 7 Pa and a logarithmic Q-factor of 2.8 kPa^{-1} [7]. Despite the lower value, this Q-factor is actually higher than Hao et al. when recalculated with the natural log in Equation 3. Meanwhile, Konda et al. found significantly higher performance for a single layer of silk with filtration efficiencies between 54-56% and 2.5 Pa pressure drop that both increased with additional layers [6]. Overall, silk was shown to filter between 5-56% across a range of particle sizes. The impact of fabric weave and the triboelectric effect will be explored in more detail later.

Synthetic, man-made fibers are also widely used in the textile industry. Their properties are largely dependent on polymer processing and treatment. Polyamide fibers like Nylon 6 and Nylon 6,6 have flexible chains linked by amide groups that can hydrogen bond. Nylons are often characterized by their high toughness and tenacity. One of the most common synthetic fibers used in textiles and apparel is polyester. Polyester fibers, typically polyethylene terephthalate

(PET), are characterized by the presence of a benzene ring and an ester linkage in the backbone. Polyesters have good dimensional stability, strength, resistance to chemicals, and have very low moisture regains [53]. Both structures are shown in Figure 9.

Polyester is another accessible fabric used in homemade face coverings. Zangmeister et al. evaluated two layers of six 100% polyester materials and measured filtration efficiencies from 1-21% and breathing resistances from 13-217 Pa. This placed two of the polyester fabrics in their top five at 20-21% filtration alongside the three earlier cotton samples. Four two-layer cotton and polyester blended fabrics had around 5-19% filtration and resistances of 58-168 Pa [49]. Joo et al. had similar results with a single layer of fabric, where 100% woven polyester fabrics filtered between 19-22% from 0.017-0.7 μm with differential pressure between 120-150 Pa. This performed slightly better than their 100% cotton sample. Cotton/polyester blends offered a wider range of filtration efficiency between 11-48% at the same particle size with pressure drops between 62-77 Pa [56]. Rengasamy et al. evaluated several cotton/polyester blends from sweatshirts and t-shirts. The highest performing blend was the Hanes sweatshirt with filtration efficiencies of 43-60% from 0.02-1 μm , while the remaining sweatshirts measured 18-30% and the t-shirt materials measured 14% across two different face velocities. Breathing resistances ranged from approximately 4-20 Pa [58]. From these studies, polyester filtered from 1-22%, while cotton/polyester blends were able to filter more from 5-60%.

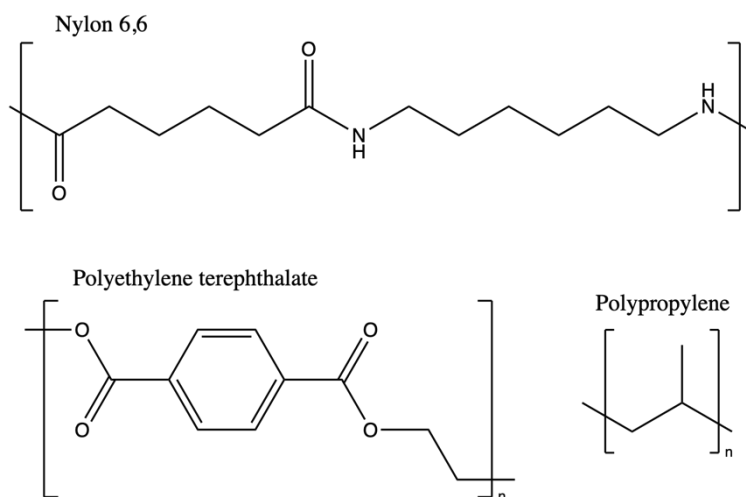


Figure 9. Chemical structures of common synthetic fibers used in textiles

Another group of important synthetic fibers in the textile industry are polyolefins. These thermoplastic polymers are linear chain molecules with a hydrocarbon backbone [53].

Polyethylene and polypropylene are the two most produced polyolefins. In textiles, polypropylene is used in nonwoven materials for filtration and medical applications due to its hydrophobicity, light weight, durability, and resistance to microorganisms, chemicals, and mildew. Melt-blown polypropylene undergoes a charging process to be used as an electret filter layer in N95s and surgical masks to capture smaller particles through electrostatic attraction. Spunbond polypropylene is used in the multi-layered filtration system and can be found in medical materials and everyday fabrics like interfacing.

Accessible medical and filter materials were evaluated alongside cloth fabrics for potential applications in homemade face coverings. Sterilization wraps, wipes, vacuum bags, coffee, and other filter materials were tested. Overall, the nonwovens did comparatively well. Bagheri et al. found that HVAC filters had the highest performance from 94-99% but may not be recommended to wear over the nose and mouth due to the risk of fiberglass inhalation. Sterilization wraps, typically made from nonwoven polypropylene, had higher filtration ranging

from 36-96% for a single layer of material against 0.3-10 μm particulates and around 80% filtration from 2-5 μm . The wrap could be layered with cotton to improve its properties, while increasing the pressure difference across the fabric [54]. Joo et al. also found sterilization wraps performed well across particle sizes, from 20-63% at 0.017-0.7 μm and differential pressures of 77-150 Pa depending on brand. The coffee filter had a filtration efficiency of 40% across the particle range and a differential pressure of 220 Pa. The HEPA filter had the highest filtration of 96% across particle sizes and a pressure difference of 75 Pa, however health concerns remain an important consideration in its application [56]. Zangmeister et al. measured single layers of sterilization wraps at 70-81% filtration at 0.05-0.825 μm and around 91-141 Pa based on the fabric density. The coffee filter performed around 34% with a pressure difference of 239 Pa, while the HEPA filter maintained 94.4% filtration and 59 Pa [49]. The product brand was shown to impact performance and may account for the differences between studies. Overall, sterilization wraps ranged from 20-96% filtration with reasonable breathability, which may be an effective alternative material.

The performance of these different household materials across studies is shown in Table 5 along with a visual comparison to the ASTM F3502-21 Standard Specifications in Figure 10. These values reflect the available data measured with different test setups across a wide range of particle sizes. Some of the articles did not provide specific data points and are therefore not included in the dataset. Additionally, not every study reported the differential pressure across the samples. Material selection across studies varied significantly, and specific fabric descriptions were not always given, however, some studies used N95 and surgical mask materials as a more reliable point of comparison. Rengasamy et al. used N95 controls that ranged from 95-99% filtration across face velocities at 0.02-1 μm particle sizes [58]. Zhao et al. similarly found the

N95 material had 96% filtration efficiency with a 9 Pa pressure drop, giving it a significantly higher log-based quality factor of 163 kPa^{-1} compared to the other materials [7]. A few studies found lower efficiencies for N95 materials. This may be due to differences in testing or possible limitations of the setup since respirators should be certified to filter at least 95% efficiency at $0.3 \mu\text{m}$.

Table 5. Comparison of household materials used in face coverings from recent literature

Material	Cotton	Silk	Polyester	Cotton/ Polyester	Sterilization Wrap	Coffee Filter	HEPA Filter
Filtration Efficiency (%)	4-96	5-56	1-22	5-60	20-96	34-40	94-99
Differential Pressure (Pa)	3-129	3-20	13-217	4-168	77-150	220-239	59-75
Sources	[6], [49], [54], [55], [56]	[6], [7], [57]	[49], [56]	[49], [56], [58]	[49], [54], [56]	[49], [56]	[49], [54], [56]

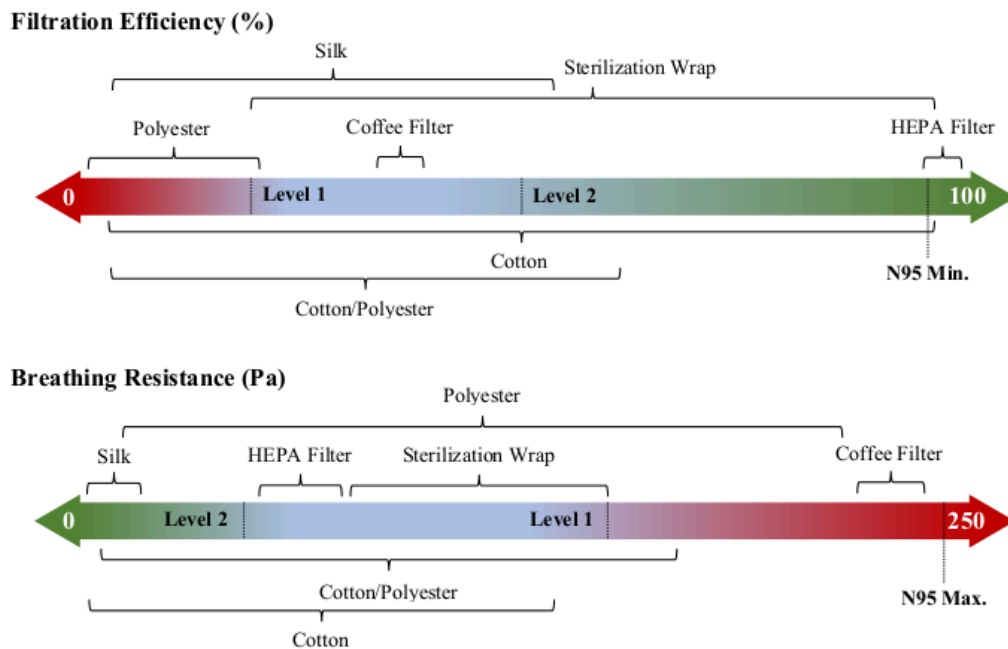


Figure 10. Material filtration efficiencies and breathing resistances reported for household materials in relation to the ASTM F3502-21 Standard Specification performance levels

Zhao et al. also found efficiencies of 19-33% for melt-blown polypropylene from two surgical masks with pressure drops ranging from 16-34 Pa. Although these materials had higher filtration than some of the household materials, their quality factors of 5-5.5 kPa⁻¹ fell below the cotton and polyester fabrics that were more breathable [7]. Zangmeister et al. found similar filtration efficiencies around 31% for two surgical masks at 0.05-0.825 µm with pressure differences of 34-47 Pa. The Q-factors determined with the natural log were 7.9-11.1 kPa⁻¹, which were significantly higher than most of the double-layer fabrics tested [49]. Hao et al. measured a surgical mask around 50% at 0.3 µm and 66% across a wider particle range 0.03-0.6 µm. Along with higher filtration, the surgical mask had a higher differential pressure of 90 Pa. However, it was still able to maintain the highest natural log-based Q-factor of 7.72 kPa⁻¹ [57]. These results ranging from 19-66% among similarly composed surgical masks suggest that the products themselves may be highly variable. More information on the specific products is needed to compare the results. Different testing parameters between sources may have contributed.

The data presented so far has been organized solely by fiber composition. Kwong et al. put together a similar review of material efficiencies across recent literature in an effort to better understand the properties that influence filtration efficacy. Some of the studies referenced have been included here. Their comparison of household materials by author and face velocity is shown in Figure 11. In an effort to compare values, the results were normalized by the surface area before analysis [59]. As shown, filtration efficiencies varied significantly among fabric types across the different studies. The woven and knit fabrics generally performed lower than the nonwoven and filter materials. However, variations across studies and even within the same article suggest that fiber content alone may not be able to differentiate performance.

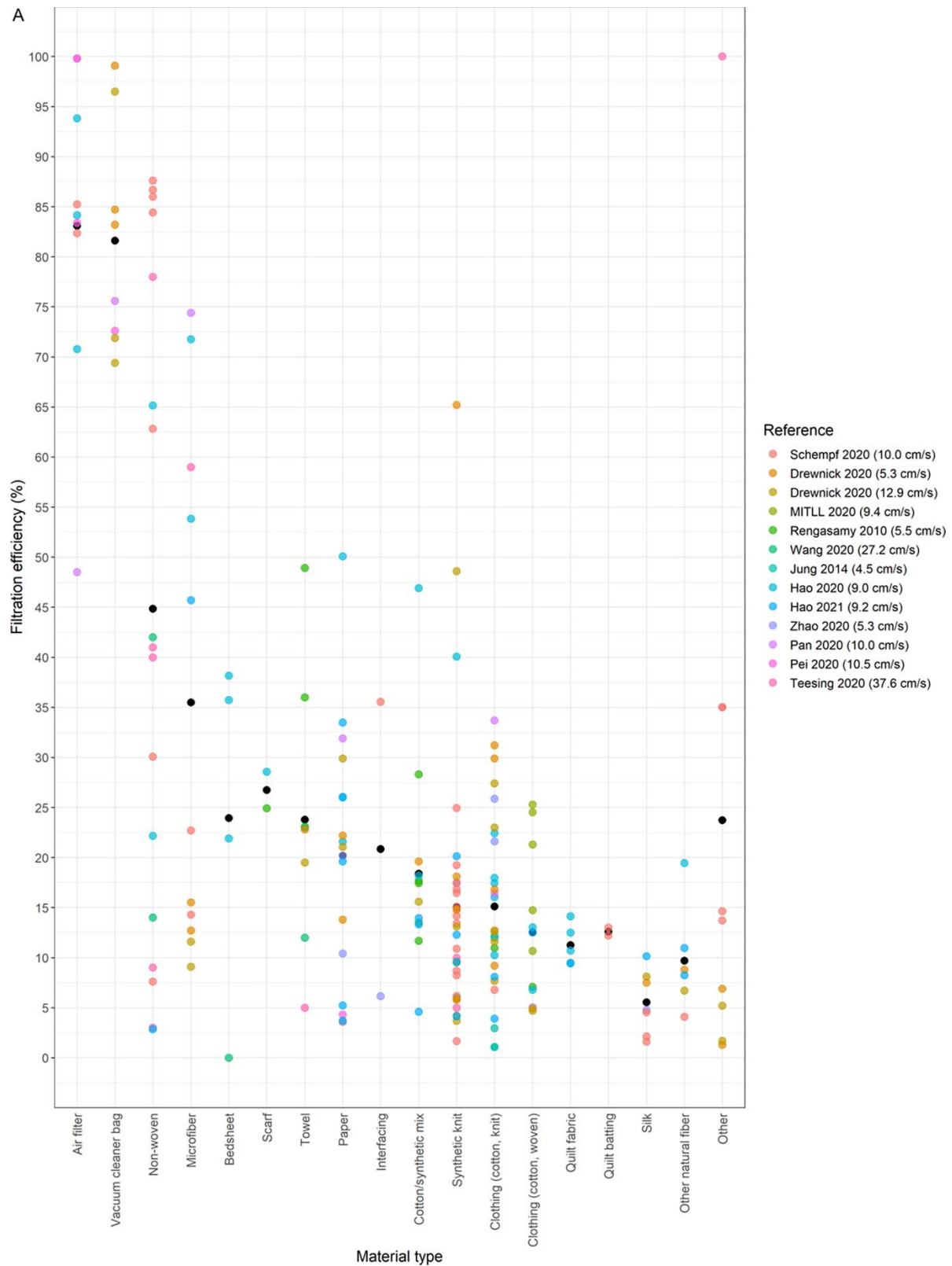


Figure 11. Filtration efficiencies of single layer materials as reported across recent literature with mean values represented by black dots [59]

2.4.2 Fabric Properties

In addition to fiber composition, the physical properties of textiles have been shown to play an important role in filtration. The fiber characteristics impact the final fabric properties. Fiber diameter and shape depend on the fiber composition. Natural fiber morphology varies based on the fiber source, whereas synthetic fibers are controlled during processing with little variation between fibers. Zangmeister et al. found that increasing the fiber diameter due to swelling reduced the filtration efficiency. They also found that the variation in fiber shape and diameter in natural fibers was able to create fiber-webs on the fabric surface that helped capture particles. The cotton flannel was able to filter 20-24% depending on fabric weight. Surprisingly, the heavy weight flannel had lower efficiency. Other cotton fabrics showed a similar surface effect to a lesser degree [49], [60]. Konda et al. found a similar improved filtration for cotton/polyester flannel; however, the 44-57% filtration across particle sizes was primarily attributed to inherent electrostatic charge that was able to help capture the smaller particles in addition to the raised surface texture [6].

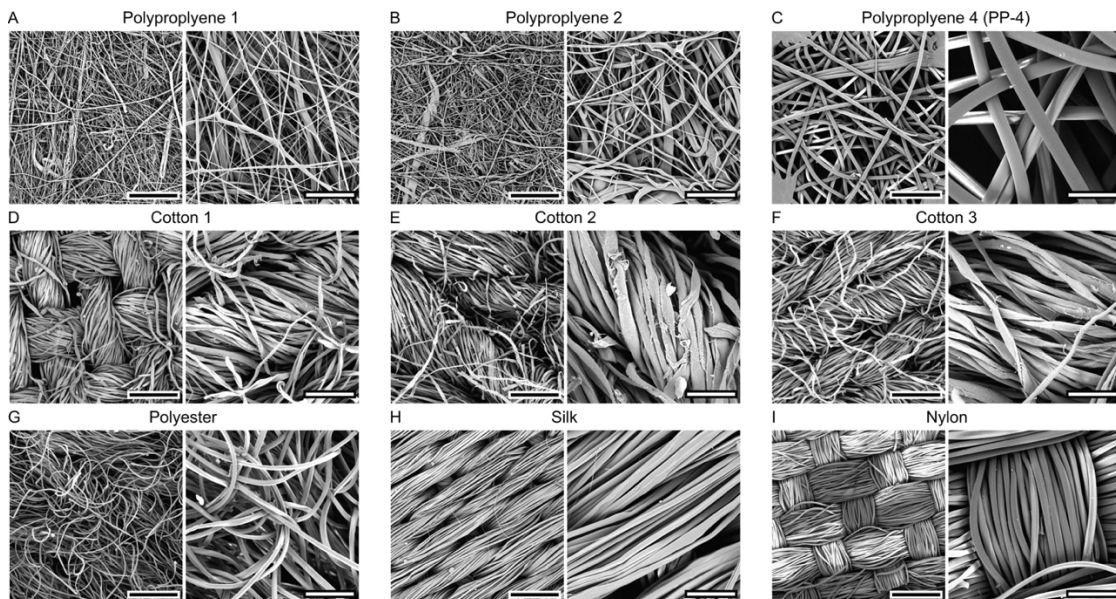


Figure 12. SEM images of household mask materials [7]

Fabric weight, thickness, and packing density are often interrelated properties. The weight of the fabric can be measured in grams per square meter (GSM). Higher GSM values result in a more densely packed fabric. These heavier weight fabrics also tend to have a greater thickness. Drewnick et al. found that thinner fabrics had lower efficiencies. As material area density increased for the textile samples, filtration efficiency generally increased. They attributed this to the increasing fabric thickness, which gives the particles more residence time as they pass through the material. Trends between area density and filtration were not clear at larger particle sizes [5]. Zhao et al. compared the fabric weights of three cotton fabrics to their visible pore size in Figure 12, labeled D, E, and F. The fabric weight and density were not shown to have a clear impact on filtration efficiency. E and F filtered around 22% and 26% even though F was twice as heavy as E. Differences in pressure drop were even smaller from 15 to 17 Pa [7]. Joo et al. were not able to determine a direct relationship with fabric thickness; however, higher filtration did appear to correspond to higher area density [56]. Hao et al. found that the filtration efficiency and airflow resistance increased with GSM [57]. The complex relationships between properties have made it difficult to determine which characteristics are the most effective at improving filtration.

Thread count is determined by the number of warp and weft threads woven in a square inch of fabric, commonly referred to as threads per inch (TPI). Higher thread counts are associated with finer, higher quality textiles. Finer threads can be more tightly woven, reducing the pore size. Konda et al. found that cotton fabric performed better at high thread counts. A single layer of 80 TPI quilter's cotton had filtration efficiencies of 9-14% across particle sizes, while the 600 TPI single layer cotton filtered from 79-98%. The breathing resistance increased slightly from 2.2 Pa to 2.5 Pa [6]. Drewnick et al. agreed that higher thread counts were generally able to

obtain higher filtration efficiencies. However, due to the relationship between thread count and fiber diameter, larger thread counts generally result in thinner materials, which can reduce filtration. This left no clear relationship between thread count and filtration [5]. Zangmeister et al. also had less conclusive results. The five highest performing fabrics had mostly moderate thread counts ranging from 102-812 TPI for 20-32% filtration efficiency. Four of the five samples had less than 250 TPI. Meanwhile, lower performing fabrics had thread counts between 25-229 TPI at 1-5% efficiency. These two ranges largely overlap [49]. Higher thread counts may contribute to fabric performance, but on their own are not enough to determine the material filtration efficiency.

Higher porosity fabrics have openings or gaps that allow air to pass through the fabric more easily. Porosity is dependent on the fabric geometry. Woven, knit, and nonwoven materials have different characteristics because of their construction. Woven materials are made by weaving warp and weft yarns perpendicular to each other in a defined pattern. Common weaves including plain, twill, and satin weaves will impact their properties. Plain weave fabrics are durable and have a high density due to the closely packed alternating yarns. Twill weaves create a diagonal pattern in the material by crossing over two yarns instead of one to make the fabric stronger. Satin weaves have long floats on the fabric surface to improve hand and luster of the more delicate material. Knits are made by interlacing loops of yarn that allow them to stretch. The type of knit varies depending on the stitching pattern. The loops in the fabric create pores that can increase when stretched. Lastly, nonwovens are made from an entangled web of fibers through fusing or bonding. This creates a thin, flexible and porous material. They will have different fabric geometries depending on the web formation. The two most common structures in filtration materials are melt-blown and spunbond.

Several studies have evaluated the impact of fabric structures on filtration. Zhao et al. found silk had a lower filtration efficiency than cotton or polyester, which was due to the long floats in the satin weave that created openings in the fabric for particles to get through. This structure is shown in Figure 12 H. From the figure, the cotton samples D, E, and F were also compared. The large visible pores in the plain weave cotton had low filtration efficiency around 5% compared to the other two knit cotton samples that ranged from 22-26%. Similar results were seen with the pressure differences from 4.5 and 15-17 Pa, respectively [7]. Drewnick et al. found similar results, very low filtration in materials with a porous structure. These materials included a couple cotton and polyester samples, silk, linen, and polyurethane foam [5]. Zangmeister et al. was not able to find a clear relationship between filtration and the type of weave. Their highest performing fabrics with 20-32% filtration included plain, poplin, block, and satin weaves. On the other hand, breathability improved with open structured fabrics that had resistances of almost zero in some cases because the air is able to move through it [49].

The effects of moisture regain should also be considered for certain fibers. Moisture absorption is the fiber fluid uptake that results in swelling the fiber diameter, which can change the fabric properties. It is heavily dependent on fiber composition and occurs more readily in hydrophilic fibers such as cotton, wool, and viscose rayon. Hydrophobic fibers will see little to no moisture regain due to the lack of polar groups in the structures. Fibers that have a higher moisture regain will swell more. They can also absorb moisture from the air. Under high humidity conditions, moisture will gradually swell hydrophilic fibers. This reduces the porosity and increases the dimensional stability of the fabric. Moisture can also impact triboelectric charge, as static occurs less often under high humidity conditions [53]. Normal breathing while wearing a face covering creates a high humidity environment inside the material. The fiber

composition of the barrier will play an important role in their performance in high moisture environments.

Zangmeister et al. studied the effects of household materials under ambient and high humidity conditions by preconditioning the samples at 30-50% and 99% relative humidity. The filtration efficiency of cotton was shown to increase by 33% under high humidity conditions, whereas there was no measurable difference among the synthetic materials as shown in the graphs in Figure 13. The pressure differential behaved similarly. Cotton airflow resistance increased by 14 Pa in high humidity and wool airflow resistance doubled, increasing by 40 Pa [49], [60]. O’Kelly et al. also evaluated the impacts of moisture by applying water directly inside the filter material. They only reported slight changes in filtration across the majority of the materials. The denim fabric and HEPA vacuum bag saw the most significant changes in performance, with denim decreasing by 15% and the vacuum bag increasing by 11% when damp. Five of the eight samples had lower filtration efficiencies when moisture was applied. There were no clear trends based on sample composition [55]. More research is needed to evaluate the impact of humidity inside and outside the mask material on filtration.

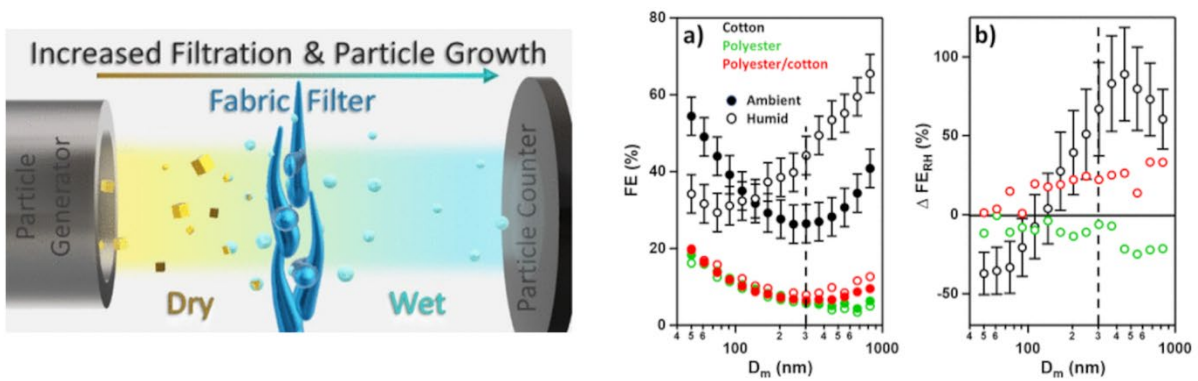


Figure 13. Filtration efficiency as a function of particle size for different fabrics under ambient and humid conditions, and the change in filtration for each fabric [60]

Another property that can impact filtration performance is electrostatic charge. The electron transfer between two materials is known as the triboelectric effect. Electrostatic properties are generally found in synthetic fibers due to their hydrophobic nature. Fabrics can exhibit inherent or applied electrostatic properties. Konda et al. found that silk, polyester chiffon, and cotton/polyester flannel had a moderate charge and were effective at improving filtration of smaller particles sizes with efficiencies of 54%, 67%, and 57% below 0.3 μm [6]. Drewnick et al. reported similar results comparing neutralized and charged particles. The highest filtration efficiencies were largely obtained by samples with strong electrostatics, although specific values for each sample were not given. However, the presence of a charge did not guarantee a higher filtration efficiency. Several samples including the silk and flannel fabrics had improved filtration using the charged particles, but their efficiency remained comparatively low [5]. Zangmeister et al. also examined the impacts of particle charge and found that aerosol reneutralization did not impact the filtration efficiency of cloth materials. The only noticeable difference was seen with the surgical masks [49]. These discrepancies may be due to differences in the fabric properties and experimental procedures.

A charge can also be applied to cloth fabrics in an effort to produce a similar triboelectric effect. Zhao et al. created a charge on the surface of a number of household materials by rubbing the fabric against latex gloves for a short period of time. They found that all the materials except cotton saw an increase in filtration efficiency with the applied charge as shown in Figure 14. This can be explained by cotton's hydrophilic nature since the presence of moisture can discharge fibers. In all of the materials, charge value decayed overtime. This decay was dependent on the fiber composition. Silk and polyester decayed relatively quickly after 30 minutes while nylon and polypropylene were able to maintain their charge significantly longer

[7]. Hao et al. similarly applied charge with polypropylene fabrics and saw a corresponding increase in filtration, however, the material lost charge rapidly over the course of 15 minutes [57]. This may have to do with the method of charge application. Zangmeister et al. also tried to apply a charge by rubbing materials together with latex gloves similar to Zhao et al. and did not see significant differences in filtration efficiency [49]. This may be a result of the difference between using charged or neutralized particles.

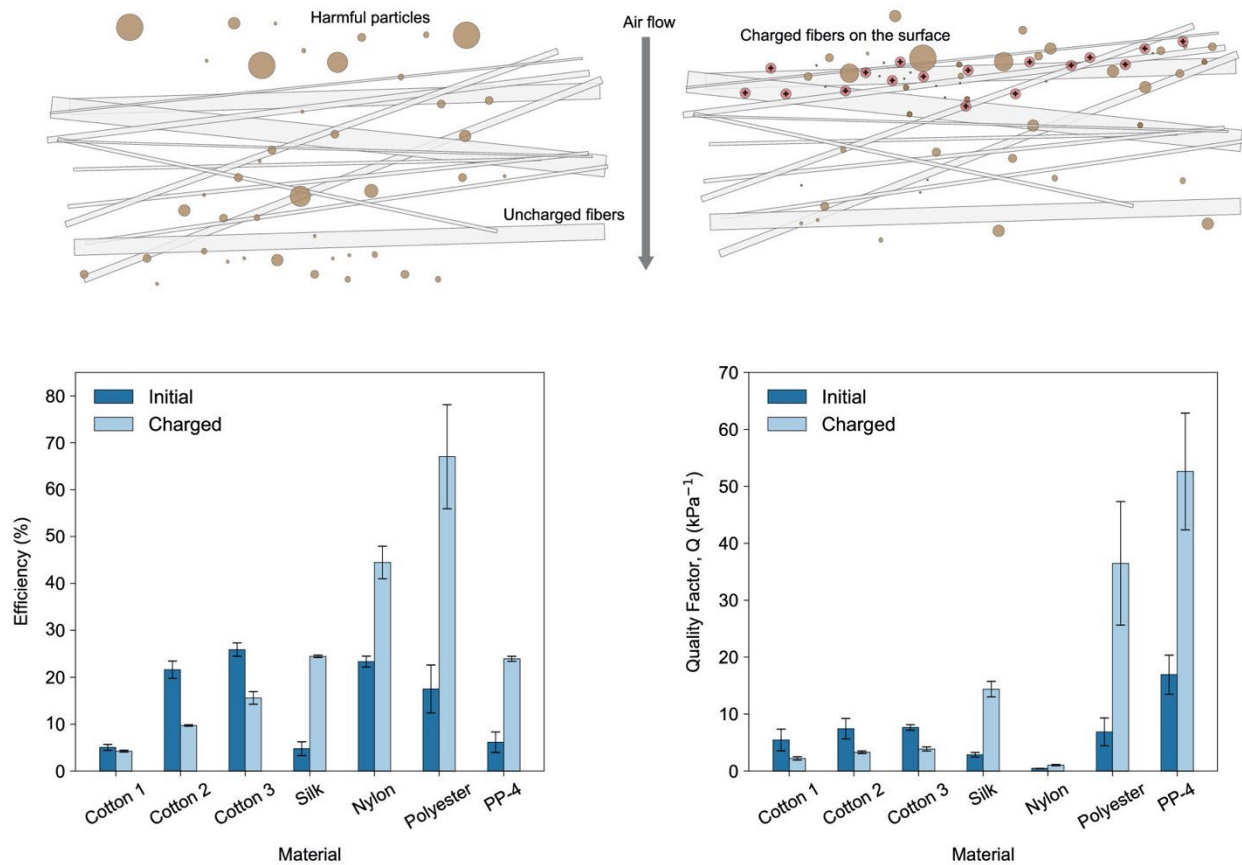


Figure 14. Visual of the triboelectric effect and measured fabric performance before and after a charge was applied with latex [7]

The relationships between properties have made it difficult to determine what impacts filtration efficiency. The general trends from the data are shown in Table 6. However, there were some contradicting views. Fabric thickness, density, and thread count were sometimes reported

to show insignificant differences in filtration. The porosity between yarns in the fabric was a significant influence on the filtration and breathing resistance, but there was not always differentiation between types of weaves. More research is needed on the influence of moisture. When a charge was present in the material, more particles were captured through electrostatic attraction. There remains some debate on the effectiveness and longevity of an applied charge. Overall, material properties should be carefully chosen in order to balance good filtration with reasonable breathability.

Table 6. Material properties influence on face covering performance

Property	Material Performance	Sources
Nap	Small, brushed fibers on the fabric surface can improve filtration efficiency	[6], [49]
Weight	Heavier weight fabrics with higher density and thickness can increase filtration and breathing resistance	[5], [56], [57]
Thread Count	Higher thread counts can contribute to higher filtration efficiency	[5], [6], [49]
Geometry	Tightly woven textiles with lower porosity can increase filtration and breathing resistance	[5], [7], [49]
Moisture	Swelling hydrophilic fibers may increase filtration and breathing resistance	[60]
Electrostatics	Materials with inherent or applied electrostatic charge can improve filtration efficiency	[5], [6], [7], [49], [57]

2.4.3 Multilayer Systems

Increasing the number of fabric layers can increase the filtration efficiency and consequently the airflow resistance by altering the thickness and porosity of the barrier. Zhao et al. demonstrated that multilayered pieces of cotton, polyester, and polypropylene could exceed the filtration efficiency of current medical masks. Five layers of spunbond polypropylene were able to provide increased filtration around 24% while maintaining an airflow resistance below 10

Pa [7]. O’Kelly et al. saw a smaller increase around 10% on average between single and double layer fabrics [55]. Joo et al. found that the filtration of two-layer systems increased by 26-51% depending on the additional layer, with cotton and drapery lining filtering up to 63%. Filtration for the three-layer systems increased less, around 13-39% from the single layer fabrics. The pressure difference also increased with additional layers from 260-400 Pa [56].

Some studies tried to find the relationship between the number of layers in the system and the increase in filtration efficiency and airflow resistance. Drewnick et al. measured one to five layers of select fabrics. They were able to approximate calculations for filtration efficiency and breathing resistance through the multiplication and summation of each respective layer. The pressure drop increased for each layer while the transmission efficiency decreased [5].

Zangmeister et al. got similar results measuring the filtration of lightweight cotton flannel after each additional layer. The filtration efficiency and differential pressure increased from one to five layers. However, the breathing resistance above four layers surpassed the NIOSH recommendations for maximum exhalation pressure at 245 Pa, indicating there is a comfort limit to these multilayered systems [49].

Konda et al. layered materials to create hybrid systems by adding a layer of fabric that had moderate electrostatic properties. These hybrids, including layered cotton and chiffon, cotton and silk, and cotton and flannel, were shown to increase efficiency and help capture smaller aerosol particles by achieving both mechanical and electrostatic filtration. They filtered 97-99%, 32-99% with and without a gap, and 95-96%, respectively. All of the combinations had breathing resistances of 3 Pa. This can be compared to the single layer of 600 TPI cotton used that had 79-94% filtration across particle sizes and 2.5 Pa resistance. The most notable difference is the increased filtration below 0.3 μm [6]. Zangmeister et al. tried to recreate these hybrid systems

and got different results. Using similar fabric combinations, they obtained significantly lower filtration efficiencies of 16% and 25% for cotton/polyester layered with cotton and a synthetic blend layered with cotton, respectively. They also had significantly higher differential pressures of 239 and 304 Pa. They did not see significant differences in filtration efficiency between the hybrids and their individual components [49]. Some of the variation between studies may be due to differences in the test aerosol and flow rate.

2.4.4 Reusability

The reusability of barrier face coverings has both environmental and economic advantages for consumers. It is important to test these fabrics after laundering in order to determine if the material performance holds up after repeated wear, washing, and drying cycles. An earlier study by Neupane et al. showed that cloth face covering fabrics can become stretched out, increasing the pore size and subsequently reducing filtration. The fabric distortion varied by material. Filtration efficiency was measured after each hand wash and air dry cycle. They found a 20% decrease in filtration after the fourth cycle. Visible differences were noticed on the fabric surface after each wash, including early changes in pore size and less microfibers on the fabric surface overtime [61]. This study only measured the impact of laundering with one type of fabric. As the distortion varied by material, changes in the filtration after laundering may depend on the textile properties.

Recent studies have shown more moderate changes in the performance of barrier face coverings after laundering. Bagheri et al. measured the filtration efficiency and breathing resistance of materials unwashed, then laundered after five and ten cycles. The fabric combinations were washed by four people. The detergent choice, washer, and dryer settings

varied. The cloth fabrics held up with no significant difference in breathability, while the multilayered cotton and sterilization wrap combination showed higher efficiency against small particles after ten washes. The HVAC filter material and wipes degraded after repeat washing and should be treated as disposable materials [54]. Hao et al. saw similar results. The samples were cleaned in a washer with detergent and then put in the dryer to mimic a typical laundry cycle. After one, five, and ten laundering cycles, they did not see a significant difference in filtration or pressure drop across the fabrics. However, disposable medical masks and N95 respirators greatly decreased filtration efficiency after laundering. The most significant drop came after the first laundering cycle. This is not surprising due to the loss of the electret charge layer and the nonwoven structure [57]. More research is needed to better understand the impacts of repeated wear on different materials.

2.4.5 Testing Parameters

Across literature, different studies have used vastly different methodologies to measure the particulate filtration efficiency and breathing resistance of fabrics. Many created modified versions of the existing NIOSH 42 CFR Part 84 and ASTM F2100-21 standards intended to evaluate N95s and medical masks. Even across standards there are differences between test agents, particle dispersity, size, and face velocity. Additional changes in particle characteristics, fabric surface area, conditioning, and laundering have been shown. These parameters can significantly impact the results, making it difficult to directly compare data between studies.

Particle properties including the type of test agent, particle size, dispersity, and charge have been shown to impact filtration efficiency. Typical aerosols including NaCl, latex spheres, and ambient air have different characteristic that may affect particle penetration. Particle size is

another significant factor in filter performance. Larger and smaller particles are easier to capture with traditional filtration mechanisms. Several studies evaluated filtration efficiency at the most penetrating particle size for filter testing, around 0.3 μm . Others have shown a steady decline in filtration as particles got smaller [4], [5]. The dispersity or particle size distribution may also impact the measurements. There were slight increases in particle penetration across different sized monodisperse aerosols compared to polydisperse aerosol [58]. Charge neutralized particles were shown to have lower efficiency than charged particles depending on the particle size [4]. However, particle charge did not significantly impact the filtration efficiency of cloth materials, which often do not rely on electrostatic attraction to filter smaller particles. More significant differences were noticed with surgical masks that use a charged electret filter layer [49].

The flow rate of the particles that pass through the fabric affect the filtration efficiency. At the material level the volume flow rate can be easily divided by the surface area of the sample to give the face velocity in cm/s . Increasing the velocity allows less time for the particles to pass through the material. Reducing the residence time reduces the number of particles captured, decreasing filtration efficiency [4], [59]. It has been suggested that this relationship may depend on particle size. Increasing face velocity reduced the filtration of smaller particles below 0.5 μm , while it increased the filtration efficiency of larger particles due to more impaction and interception [5]. In other cases, only marginal changes in filtration were measured when face velocity was increased [58]. Velocity will also impact the differential pressure across the fabric depending on the material. According to Darcy's law, the pressure drop should increase proportionally with the face velocity through a porous medium [35]. This suggests that the breathing resistance measurements at different velocities may not be comparable.

The influences of different testing parameters are summarized in Table 7. The testing equipment and procedures are also important considerations although often less quantifiable. Sample preparation may impact performance. Preconditioning materials, laundering, and material preparation in the case of multilayered or charged fabrics may change the filtration as previously discussed. Many standards require sample preconditioning to a specific temperature and relative humidity prior to testing; however, not many sources included it. Only a limited number of studies considered the effects of laundering on the filtration efficiency. The testing equipment including the test cell, particle counters, and pressure sensors varied. Instrument accuracy and sampling techniques may have contributed to the differences between studies. Lastly, the temperature and relative humidity during the test may influence the performance of certain materials. Moisture was shown to swell hydrophilic fibers, which can change fabric performance [60]. The filtration of electret filters can also be reduced due to the charge reduction at high humidity [4].

Table 7. Testing parameters influence on face covering performance

Parameter	Material Performance	Sources
Particle Size	Filtration efficiency may decrease at smaller particle sizes	[4], [5]
Charge	Charge neutralized particles can reduce filtration efficiency	[4], [49]
Dispersity	There may be marginal differences in filtration between mono and polydisperse particles depending on particle size	[58]
Face Velocity	Higher face velocity can reduce the filtration efficiency and increase differential pressure	[4], [5], [59]
Environment	Higher temperature and humidity may impact filtration efficiency	[4], [60]

2.5 System-Level Evaluations

Material testing evaluates fabric properties in a closed system. This offers an efficient and controlled measure of fabric performance. However, it may not provide the most accurate representation of the final fabric application. System-level testing offers a more realistic assessment of performance by evaluating the final product as worn. It typically involves manikin or human subject testing. Human subject testing allows the products to be worn by participants who perform complementary activities in a controlled environment. These tests tend to be more variable and expensive but provide a reasonable assessment of everyday wear. Manikin testing evaluates the product on a three dimensional form. Advanced articulated manikins can perform controlled movements in an effort to provide a more realistic simulation of wear. This offers a more repeatable method of evaluation but is limited to the proportions of the manikin used.

2.5.1 Fit Testing

System-level evaluations allow fit to be incorporated into the final measurements. Respirator fit testing is required to ensure a seal can be created and maintained so hazards cannot leak in. Following ASTM F3407-20, participants are measured wearing the product through a series of exercises including normal and deep breathing, talking, head movements, and bending over. The fit testing instrument is connected to a probe in the product that measures the concentration outside and inside the respirator. This ratio is used to determine the respirator fit capability. The RFC value is reported for each movement and then averaged together to determine the total fit factor. The higher the value, the better the fit. Respirators are required to obtain a fit factor of 100 or above [52]. However, medical masks and barrier face coverings are generally not designed to seal to the face. This can make fit testing these products more difficult.

A few studies have tried to quantify the impacts of fit on barrier face covering performance using a modified fit testing procedure. Prior to COVID-19, Davies et al. compared the fit of homemade face coverings made from cotton t-shirts with surgical masks on 21 volunteers, including males and females from 20 to 44 years old. They followed the traditional fit protocol, performing all seven exercises using a TSI PortaCount® Respirator Fit Tester to measure and report the corresponding fit factors. The homemade face coverings were able to achieve fit factors of 1-2, while the surgical masks ranged from 3-7. There were statistically significant differences between the two products across all exercises. The surgical masks showed greater variation in fit throughout the test duration, while the homemade cotton face coverings were consistently performing with a fit factor of two for almost every exercise. The lowest fit factor for each group was obtained when subjects were bending over [62].

More recently, O’Kelly et al. compared a self-performed fit check with the quantitative fit test. They used seven participants, males and females from 17 to 74 years old, to wear five N95s, a KN95, a surgical style mask, and several styles of fabric face coverings. The quantitative test setup with the TSI PortaCount® and some of the samples are shown in Figure 15. The self-checks were proven unreliable with respirators because participants were unable to consistently predict when the N95s did not fit. Two of the respirators did not fit any of the participants, while the remaining three were only able to pass above 100 with some of them. Participants were able to identify the poor fit of the KN95, surgical, and barrier face coverings in their self-checks. The KN95 had a high material filtration efficiency but showed poor fit across subjects with an average fit factor of 2.2. The surgical style mask was slightly higher with an average of 3.2, while the fabric face coverings had more consistent fit factors around 2.1. Facial features were also shown to have a significant impact on achieved fit [63].



Figure 15. Quantitative fit testing setup with N95 and KN95 samples worn by one of the participants [63]

Both studies found similar results. O’Kelly et al. had lower fit factors for the surgical mask, which may be due to the fact that it was uncertified [63]. These low fit factors of 1-2.2 for barrier face coverings and 3-7 for surgical masks suggest poor fit, low material filtration efficiency, or some combination of the two. The results were easier to compare than the material-level testing due to the use of one standard method. However, fit tests still have limitations. They do not differentiate between particle sizes and measurements permanently damage the samples, making them unwearable after testing. The new ASTM F3502-21 barrier face covering standard includes an optional fit test component where manufacturers can report the leakage ratio. This is similar to fit factor, defined as the concentration of particles outside over particles inside the barrier face covering [3]. As of September 2022, the three products that have reported leakage ratios ranged from 37-74 [50]. These results are considerably higher than literature. More research is needed to determine how much of this increase is due to improved fit.

2.5.2 Leakage

It can be difficult to quantify leakage. For respirators, the filter material is so efficient that anything that gets in during fit testing can typically be attributed to leaks in the seal. The same cannot be said for other products. Fit testing cannot differentiate between poor material filtration and leakage for medical masks and barrier face coverings. It is also important to consider possible differences between inward and outward leakage. Inward leakage refers to the percentage of particles that are able to penetrate the sample through the material or leak around the perimeter. It can be used to measure how protective a product is. Outward leakage, on the other hand, measures the percentage of particles in the environment transmitted from an infected individual to determine the level source control. Current standards focus on total inward leakage. There have been efforts to quantify outward leakage, but currently no standard exists. More research is needed to determine the relationship between inward and outward leakage.

Recent studies have found that leakage due to poor fit can decrease filtration efficiency by 60% or more [6], [9]. Konda et al. measured inward leakage by drilling small holes to create openings around the sampling tube and measuring the filtration. These holes were able to significantly reduce the efficiency in an N95, surgical mask, and several barrier face coverings [6]. Hill et al. measured the filtration efficiency of barrier face coverings fit to a soft headform and came to a similar conclusion. The filtration efficiency of all sample materials significantly dropped when measured on a headform. This was verified by sealing the masks to the headform. The sealed samples performed similarly to the material tests, confirming the drop in filtration was due to poor fit. Material permeability and pliability were also shown to influence fit [9].

Other studies used qualitative methods to visualize outward leakage. Verma et al. conducted a qualitative leakage test that illustrated the trajectory of respiratory droplets on a

hollow manikin using a laser and smoke machine as shown in Figure 16. Smaller aerosol particles followed the path of least resistance, escaping through leaks around the edge of the face covering and sometimes permeating through the materials themselves. Without a face covering, the unobstructed simulated cough traveled up to 12 feet in a short period of time [64]. A follow up study demonstrated the limitations of face shields and masks with exhalation valves. Neither were shown to be effective at blocking particles as the smoke just went around or through them [65]. Fischer et al. conducted a similar study with human subjects and a laser to illustrate the particle path during speaking. Several different face covering designs were evaluated. There was higher visible transmission for the neck gaiter and bandana [66].

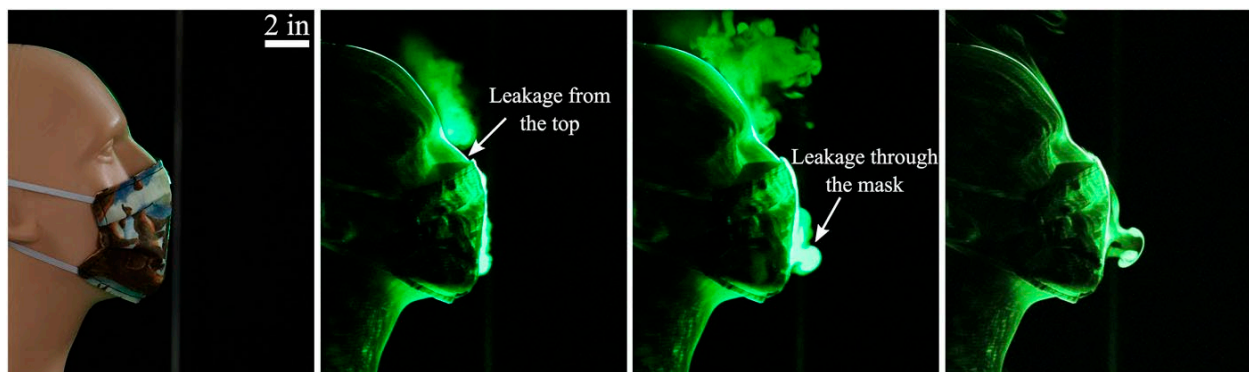


Figure 16. Visualizing leakage with a homemade barrier face covering [64]

Fit varies based on the individual, making it difficult to combat leakage with a one size fits all approach. The design of the face covering can play a significant role in improving filtration efficiency by creating a seal to the face and forcing the particles to travel through the material. Pleated face coverings have a loose fit with a higher fabric surface area compared to cone and flat shaped masks that lay closer to the face through seaming or darts. Verma et al. found cone shaped face coverings had higher upward leakage due to their tight fit creating additional gaps across the curves of the face [64]. Hill et al. suggested leakage was most prominent around the bridge of the nose, followed by the chin and jawline [9]. Aluminum

nosebands have been employed to minimize upward leakage. Strap design varies from ties and elastic bands behind the head to adjustable elastic ear loops that allow customizable sizing. The CDC recommended tying knots in the ear loops of surgical masks to improve their fit. Another suggestion was the double mask, layering a barrier face covering over a surgical mask to improve fit and filtration with additional layers of material. Brooks et al. evaluated combinations of both double masking and adjusted ear loops on an elastomeric headform. Both techniques were shown to increase the filtration efficiency of the medical or cloth mask [67].

Attachments worn over or under masks have been created to improve comfort and protection. External brackets or fitters have been studied to evaluate their impact on filtration and breathability. An exploratory study by Runde et al. made a brace from rubber bands worn overtop a surgical mask that was able to improve the seal of the mask without increasing breathing resistance [68]. Other studies used a Bellus3D face scanning application to 3D print personalized mask fitters shown in Figure 17. Liu et al. conducted fit tests wearing surgical masks with and without the mask fitter. Most of the participants passed the fit test with the fitter, with 65% passing on the first try [69]. Vichi et al. used a similar design having participants wear and evaluate the mask after one week. There was no significant change in comfort with the addition of the bracket. They noted less glasses fogging and an improved perception of fit with the attachment [70]. Other accessories are primarily marketed towards comfort, including internal brackets that keep the mask away from the face and strap adjusters. There is less quantifiable data on the impact on the filtration and airflow resistance with these products. More research is needed to evaluate how other accessories influence the fit and filtration.



Figure 17. 3D printed mask fitter using face scanning technology [70]

2.5.3 Advanced Headforms

A number of studies have modified stationary headforms to evaluate filtration efficiency on a three-dimensional model. This can provide a better assessment of fit but may not realistically evaluate daily wear. Advanced articulated headforms are robotically controlled to breathe and move similar to humans. Bergman et al. have shown that these advanced headforms are capable of simulating fit testing in a more repeatable and controlled process than typical human wear trials. They tested seven N95s on their medium sized static advanced headform (StAH) with a silicone polymer skin. The StAH was able to reduce leakage compared to previous static headforms and achieve fit factors above 100 with normal and deep breathing sequences. Higher fit factors were achieved when a leakage pre-test was performed on the headform prior to fit testing [71]. Incorporating robotically controlled movements can enable a more realistic performance assessment. The i-bodi Fully Animatronic Respirator Testing Head Form shown in

Figure 18 has these added capabilities. It allows for programmable breathing and movement sequences in order to simulate daily wear.



Figure 18. i-bodi Fully Animatronic Respirator Testing Head Form [72]

Headform testing offers a unique systemic approach to more repeatably and reliably measure fit and overall performance. However, several limitations remain. Facial features have been previously shown to significantly alter achievable fit factors [63]. Headform testing is performed on a standard size model, which may not be representative of fit for the general public. Advanced headforms can also be expensive to develop. Additional adjustments may need to be made to measure the performance of products like barrier face coverings and medical masks, which are not intended to seal to the face. There is a need to develop and validate a method to realistically evaluate the performance of these alternative products for fit and filtration efficiency using an advanced headform.

The COVID-19 pandemic brought the topic of accessible respiratory protection and source control to the general public. Wearing barrier over the nose and mouth has been shown to help reduce transmission, however alternative products have variable efficacy depending on their material, fit, and the environment they are worn in. Several studies evaluated household

materials for filtration efficiency and breathing resistance to determine what factors influence their performance. These relationship between fabric characteristics and filtration have been shown to be more complicated. A large part of this variation across studies is due to differences in methodology that can influence the results. Current standards for evaluating respirators, medical masks, and barrier face coverings complicate matters by using different testing parameters. Most research has focused on evaluating these products at the material level which does not consider leakage from poor fit that can significantly impact the filtration efficiency. Some recent studies looked at fit testing and visualizing outward leakage as a more realistic measure of performance. These advanced headforms offer an alternative method to more repeatably and reliably evaluate these products by simulating wear on a three-dimensional form.

CHAPTER 3: Development of the Headform Test Method

3.1 Introduction

The COVID-19 pandemic first surfaced in December 2019 and rapidly spread across the globe. As of September 2022, in the United States alone there have been over 94.9 million reported cases and 1.0 million deaths [1]. The coronavirus is passed through contact, aerosol, and droplet transmission. Aerosols are airborne particles with a diameter less than 5 μm that remain suspended in the air for long periods of time. Droplets have a diameter greater than 5 μm that usually settle on surfaces [2], [21]. The Centers for Disease Control and Prevention (CDC) advised the public to practice social distancing, proper hygiene, get vaccinated, and wear a mask or face covering to reduce virus transmission.

Wearing a face covering can reduce aerosol and droplet transmission by providing a physical barrier and reducing the particle velocity on impact. There are several forms of respiratory protection and source capture that have been employed throughout the course of the pandemic. Filtering Facepiece Respirators (FFRs), including N95s, are disposable air-purifying respirators made from nonwovens that must be certified by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR Part 84 to filter at least 95% of airborne particles and fit to an individual before use [37]. N95 respirators are commonly used in industrial and healthcare settings, however the sudden rise in demand due to the pandemic created severe shortages. The public was advised to instead wear medical masks or barrier face coverings to provide a simple barrier for respiratory droplets as a method of source control.

Medical masks are nonwoven, disposable masks with a liquid-repellent outer layer to protect the wearer from droplets. They are certified by the U.S. Food and Drug Administration (FDA) and fit loosely to the face. Barrier face coverings offer another comfortable and accessible

option for the public that come in a variety of materials and designs. These 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 the face covering materials and the environment in which they are worn.

There are several mechanisms of filtration that play a role in catching respiratory droplets and aerosols. Gravity sedimentation, inertial impaction, and interception are the primary mechanisms for filtering larger particles above 0.5 μm . Diffusion and electrostatic attraction are more effective at capturing smaller aerosol particles below 0.2 μm . The contribution of these mechanisms is dependent on the chemical and physical properties of the filter material in addition to external parameters including particle size, charge, and airflow [4]. The most penetrating particle size is determined from these mechanisms as the particle size most likely to get through the filter material. This particle size, often defined at 0.3 μm , is measured to ensure protection against the most difficult particles to capture and is specifically used for testing respiratory protection [36].

The rising demand for barrier face coverings has inspired a number of studies to evaluate the particulate filtration efficiency (PFE) of accessible materials. Overall, higher density materials like cotton with a tight weave and low porosity performed comparatively well to other household materials. Multiple layers of material have shown to increase PFE to a point, however, this also increased breathing resistance [5], [6], [7]. Multi-layer fabrics that include a layer with moderate electrostatic properties can help capture those smaller particle sizes [6], [7]. The variations in literature and standard testing procedures have made it difficult to directly compare data. Changes in particle size, charge, and flow rate can have a significant impact on results [8].

There are several conflicting performance standards that may confuse manufacturers and end-users trying to evaluate the efficacy of different products. The NIOSH requirements for air-purifying respirators are designed to evaluate the worst-case scenario by using a high 85 L/min flow rate and neutralized 0.3 μm NaCl particles to test the filter media. The FDA requires surgical masks to be tested for PFE using ASTM F2100-21 that tests with unneutralized 0.1 μm latex spheres within a wide allowable range of face velocities from 0.5-25 cm/sec. Bacterial and viral filtration efficiency procedures are also available; however, they use larger 3 μm particles, which lead to inherently high filtration values. None of these standard test methods are designed to test barrier face coverings, which are now widely worn by the public. As of March 2021, ASTM F3502-21 outlined a set of standard specifications for barrier face coverings 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 with an optional quantitative fit assessment.

Early literature focused largely on material evaluations which do not account for the curvatures of the face or dynamic wear. PFE has been shown to significantly drop when measured on a headform [9]. The design of the face covering can play a significant role in improving filtration if it creates a significant seal to the face. This can force the particles to travel through the material and potentially be filtered instead of leaking in or out through the gaps between the face covering and the wearer's face. Several studies have found that leakage due to poor fit can cause a decrease in PFE of 60% or more [9], [6]. These leaks are most prominent around the bridge of the nose, followed by the chin and jawline [9].

The objective of this study was to develop a baseline test method to evaluate the efficacy of various face coverings using an animatronic headform with programmable movements and

breathing parameters, following the current testing paradigm of inward leakage. This work is being conducted with the future aim of reversing the assessment approach to one of outward leakage to evaluate the products for source capture in a standardized repeatable manner. For this initial study, a select number of face coverings were tested alongside a N95 respirator control that is certified to filter 95% or above at 0.3 μm and seal to the face. These samples were used to determine the validity and reliability of the proposed method across a wide range of efficiencies.

3.2 Methodology

3.2.1 Samples



Figure 19. Samples from left to right: N95 respirator, KN95 style mask, surgical style mask, cotton face covering, athletic face covering, and hybrid face covering

Six commercially-available face coverings were evaluated as shown in Figure 19. These samples were chosen to represent a range of possible filtration performance and design characteristics listed in Table 8. The first sample used in this method was a certified N95 respirator that served as a control to which the other products were compared. Prior to testing, all samples were preconditioned at $20 \pm 2^\circ\text{C}$ and $65 \pm 5\%$ relative humidity for a minimum of 25 hours. Samples were transported from the conditioned space in a sealed container and then tested within five hours. Each face covering was carefully fitted to the headform and adjusted based on the design after visual inspection. The ear loops on the surgical/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 replicates of each face covering were completed. Testing was conducted over multiple days by three different operators.

Table 8. Selected product characteristics

Sample	Material	Structure	Design	Layers	Retention	Nose Clip
N95 Respirator	Polypropylene	Nonwoven	Cup Shape	4	Head Straps	Metal
KN95 Style Mask	Polypropylene	Nonwoven	Flat Fold	3	Ear Loops	Plastic
Surgical Style Mask	Polypropylene	Nonwoven	Pleated	3	Ear Loops	Metal
Cotton Face Covering	Cotton	Knit	Pleated	3	Ear Loops	Plastic
Athletic Face Covering	Polyester, Polyurethane foam, Nylon/Elastane	Knit with Foam Spacer	Fitted	3	Ear Loops	Metal
Hybrid Face Covering	Polyester and Nylon	Woven, Mesh, Nano Fabric	Fitted	4	Adjustable Ear Loops	Metal

3.2.2 Headform Specifications

An animatronic headform was used to develop a system-level evaluation of face covering performance as shown in Figure 20. The Fully Animatronic Respirator Testing Head Form from i-bodi Technology uses a digital breathing machine connected to the mouth cavity to simulate breathing. The headform is capable of sinusoidal, triangular, and trapezoidal respiration patterns, and can simulate breathing between 5 and 60 breaths per minute (BPM) with a tidal volume up to 6 L. It performs basic movements and can simulate talking by opening and closing the jaw. The headform software allows for customizable breathing and movement sequences. It has a

compressible silicone skin surface to allow for the formation of a realistic seal to the face. The headform is enclosed in an acrylic and aluminum chamber with a volume of $3.43 \times 10^5 \text{ cm}^3$. The front of the chamber has a removable door that provides access to the headform and allows tubing to connect outside the system.

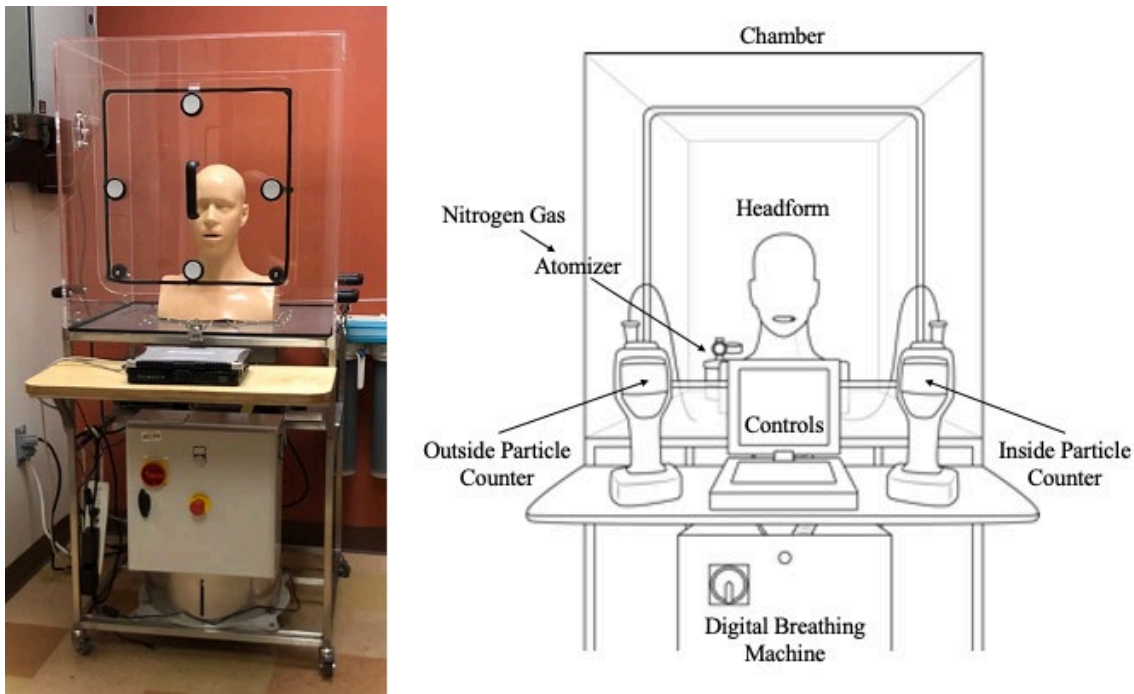


Figure 20. Picture and diagram of the animatronic headform test apparatus

3.2.3 Measurements

Two six-channel Fluke® 985 particle counters capable of measuring 0.3, 0.5, 1, 2, 5, and 10 μm particles were used for the testing. 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 within range at $4.52 \pm 3.11\%$ for 0.3 μm . 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 with a flow rate of 2.83 L/min. Data-logged timestamps were used to obtain corresponding inside and outside measurement values, which were then used to calculate the filtration efficiency.

The term total filtration efficiency (TFE) is used to distinguish this system-level test from the material-based PFE methods. TFE can be defined as the percentage of particulates that are filtered by the face covering during simulated breathing and wear. It takes into account particles that penetrate the material as well as those that may leak around the barrier. This value encompasses the combined effects of the materials, design, and fit of the sample being tested. The TFE was calculated for the cumulative and differential particle counts at each minute using Equation 4. In this equation, the percent penetration (%P) or total inward leakage, was determined by the ratio of particles inside to outside recorded at corresponding timestamps.

Equation 4. Total filtration efficiency

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

3.2.4 Procedure

The headform procedure was developed by referencing previous standards. Testing was conducted when ambient particle counts measured below 100,000 particles/min at 0.3 μm on the Fluke® counters sampled at 2.83 L/min. This was around 35 particles/cm³ to ensure enough particles could be generated inside the chamber without oversaturating the particle counters. Temperature and relative humidity were recorded daily, but the testing environment was not controlled. An unneutralized, polydisperse aerosol was generated with the TSI Single-Jet Atomizer 9302, using a 2% NaCl solution. The atomizer was connected to a cylinder of compressed nitrogen gas outside the system. During testing, the atomizer was turned on to 2.0 $\pm$ 0.5 psi and placed in the back left corner of the chamber, approximately 49 cm from the outside

and inside counters, respectively. The chamber was filled with the generated aerosol for approximately 15 seconds while the door was fitted in place and before the test began. Each sample was donned before the aerosol was generated.

Each test cycle consisted of one five-minute segment of static breathing with no headform movement and then a second five-minute segment of dynamic movement with breathing. There was a 10-minute break in between segments where the face covering was completely removed from the system while the chamber aired out. 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 programmed movements at a rate of 24 reps/min, followed by one minute of stationary breathing. The dynamic protocol included head shaking (side-to-side), head nodding (up and down), jaw biting (opened and closed), and head wobbling (ear-to-shoulder) to mimic a respirator fit test on a headform as shown in Figure 21.



Figure 21. Headform movements from left to right: head nod up and down, head shake side to side, jaw bite opened and closed, and head wobble shoulder to shoulder

Testing was repeated at two different sinusoidal respiration patterns. The first breathing sequence was programmed at 16.26 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 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 similar penetration to the 85 L/min constant flow used in respirator testing. After completing 10 replicates at each flow rate, the products were sealed to the headform with 3M Transpore™ tape around the perimeter of each sample to compare the material PFE to the systemic TFE on the headform. This is shown with the surgical style mask in Figure 22. 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.



Figure 22. Sealing the surgical style mask to the animatronic headform

3.2.5 Statistical Analysis

The statistical analysis was performed using JMP® Pro 16.0 statistical software. An assumption of normality was made due to the high number of observations in each data set. The Analysis of Variance (ANOVA) test was used for the comparative analysis between each test variable and the filtration efficiency at 0.3 μm . The null hypothesis assumed all sample means were equivalent. A p-value (P) of less than 0.05 was used to indicate significance and reject the null hypothesis. This identifies that at least one sample mean is different from the others. 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. Clinically significant changes in TFE were considered to be statistically significant differences of 5% or more.

3.3 Results

3.3.1 Total Filtration Efficiency

The mean cumulative and differential TFE values were determined for each sample along with their standard deviation at both flow rates, approximately 16 and 28 L/min, as shown in Table 9. The 5 and 10 μm values have been excluded due to the limited number of particles generated at these sizes but remain included in the calculation of the cumulative results. For this study, the MPPS was the focus of the statistical analysis. The N95 respirator maintained a consistent TFE across all particle sizes with an average filtration efficiency of 88-94% at 0.3 μm . The KN95 and surgical style masks averaged between 58-76% TFE. These two samples had the highest standard deviation across all six products around 13-18% at the lower flow rate. The hybrid face covering made with a layer of nano material was also able to perform near this range, filtering 54-59% at 0.3 μm . The cotton and athletic face coverings had the lowest TFE between 24-53%, which was expected due to their relatively loose-fit and open knit structures. The barrier face coverings all had standard deviations around 7% or more at either flow rate. All samples increased filtration efficiency as particle size increased up to 2 μm at both flow rates as shown in Figure 23.

Table 9. Total filtration efficiency of each product at both flow rates

Sample	Flow Rate	Mean Total Filtration Efficiency ($\pm$ Standard Deviation) %				
		0.3 μm	0.5 μm	1.0 μm	2.0 μm	Cumulative ^A
N95 Respirator	16 L/min	94.19 (5.83)	95.45 (5.26)	95.81 (5.10)	96.62 (4.43)	94.55 (5.65)
	28 L/min	87.72 (10.51)	92.27 (6.72)	94.52 (4.53)	96.33 (3.14)	89.11 (9.16)
KN95 Style Mask	16 L/min	66.97 (18.03)	75.87 (16.05)	77.31 (15.58)	83.06 (10.70)	69.52 (17.33)
	28 L/min	76.26 (6.83)	84.03 (6.80)	86.77 (5.98)	89.35 (4.95)	78.50 (6.87)
Surgical Style Mask	16 L/min	57.93 (13.20)	68.19 (12.44)	69.06 (13.18)	73.58 (14.46)	60.95 (12.50)
	28 L/min	71.10 (5.78)	79.74 (5.90)	82.24 (5.67)	87.29 (4.46)	73.50 (5.62)
Cotton Face Covering	16 L/min	24.33 (6.90)	48.81 (11.31)	57.78 (11.28)	72.42 (8.50)	30.72 (8.34)
	28 L/min	53.45 (7.93)	69.97 (12.69)	75.34 (12.06)	82.13 (8.51)	58.19 (9.17)
Athletic Face Covering	16 L/min	32.81 (7.32)	50.40 (10.93)	57.27 (10.91)	72.73 (9.06)	37.40 (8.18)
	28 L/min	26.32 (11.56)	43.05 (16.17)	52.16 (16.77)	69.85 (10.59)	31.57 (11.38)
Hybrid Face Covering	16 L/min	58.58 (12.73)	75.12 (12.70)	79.96 (10.83)	87.64 (6.63)	62.62 (12.42)
	28 L/min	54.31 (9.92)	71.52 (10.13)	77.27 (9.07)	85.35 (6.14)	58.91 (9.12)

^A Cumulative results were calculated as the sum of all particle sizes from 0.3-10 μm

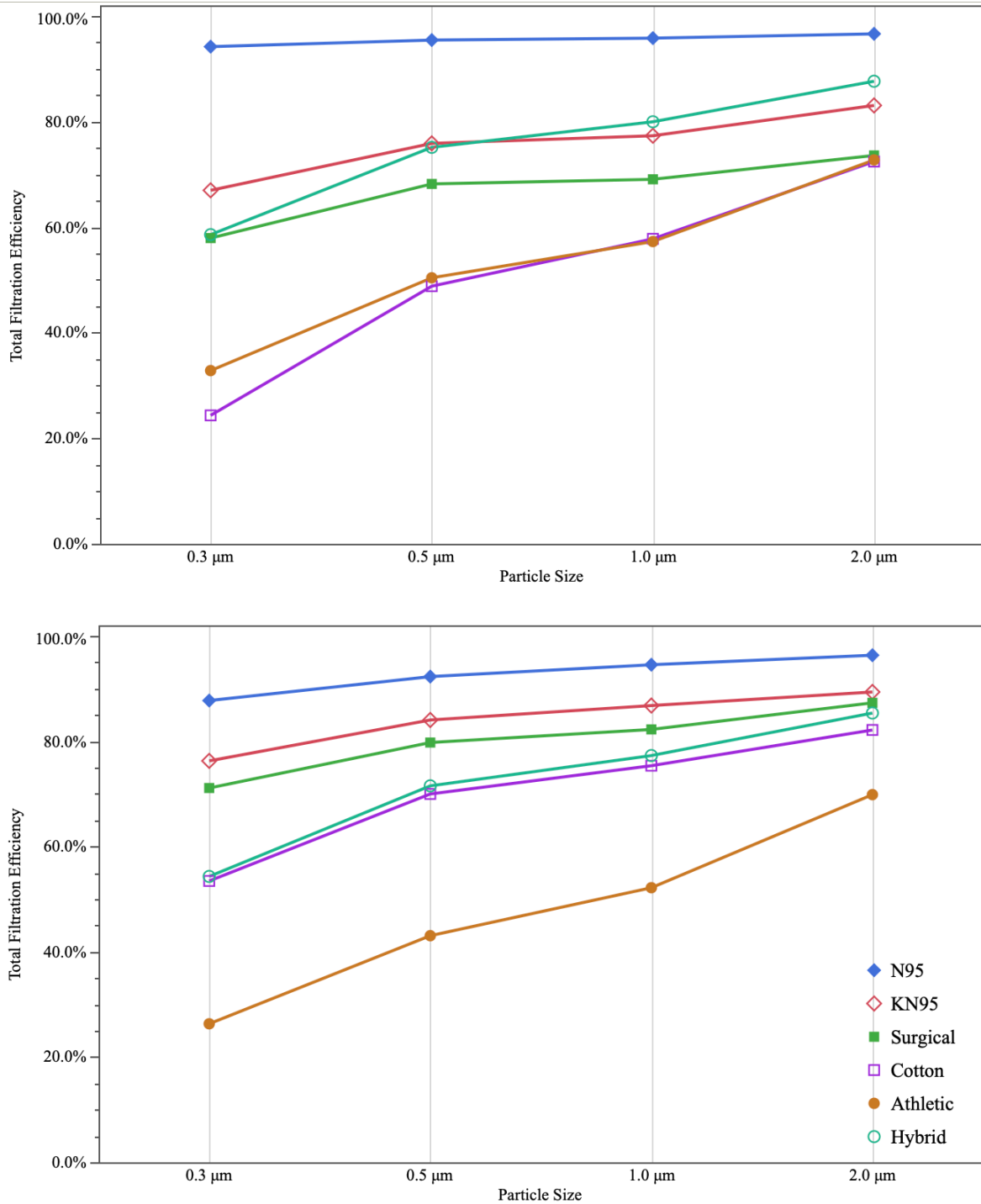


Figure 23. TFE for all six samples across each particle size measured at 16 L/min (top) and 28 L/min (bottom)

3.3.2 Flow Rate

A one-way ANOVA test was used to identify any statistical differences in TFE at 0.3 μm across the six products for each flow rate. At 16 L/min, the resulting $P < 0.0001$ indicated that at least one sample was statistically different from another. Tukey's HSD test was then used to identify pairwise statistical differences. The only sample means that were not found to be statistically different from each other were the hybrid face covering and surgical style mask. All other pairs were statistically different with $P < 0.0001$. The smallest significant difference detected was around 8% between the KN95 style mask and hybrid face covering. The higher 28 L/min flow rate performed similarly with $P < 0.0001$. Tukey's HSD test identified that 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 performance of most products.

The distribution of TFE for each sample at both flow rates is shown in Figure 24. The interaction between sample type and breathing flow rate was compared using a two-way ANOVA test. The main effects and their interaction were all found to be significant with $P < 0.0001$. Across the entire data set, the 28 L/min flow rate had a higher average TFE. This was shown in three of the six face coverings. The KN95, surgical, and cotton face coverings had higher TFE at 28 L/min, while the N95, athletic, and hybrid face coverings had lower TFE. From the pairwise analysis, the only sample that did not show a significant change in performance at different flow rates was the hybrid face covering. The cotton, surgical, and KN95 style masks all had $P < 0.0001$ with differences in TFE of 9-29%. The N95 and athletic face coverings also had significant values where $P = 0.0006$ for changes around 6%. Breathing flow rate was shown to

significantly influence performance, but whether it increased or decreased efficiency depended on the sample.

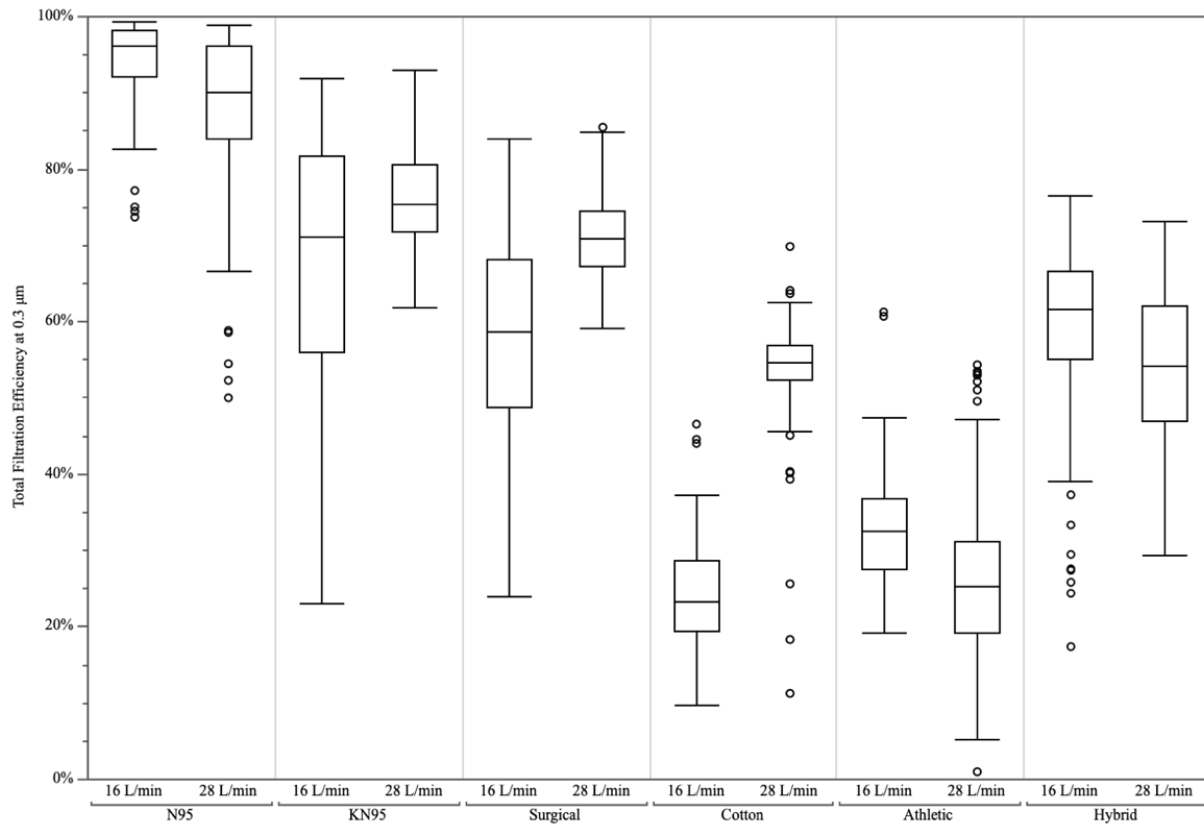


Figure 24. Box plot for TFE at 0.3 μm comparing breathing flow rates by sample

3.3.3 Movement

TFE during the static and dynamic segments was evaluated to identify if headform movement had a significant impact on face covering performance. Two-way ANOVA tests were used to evaluate the impact of sample type, test segment, and their interaction on TFE at 0.3 μm . At 16 L/min, both the main effects and their interaction were identified as statistically significant with $P < 0.0001$. Looking across all of the data, the average TFE was considerably lower during the dynamic segment. Analyzing the data by sample provided additional information on how movement may impact TFE differently depending on the style or design of the face covering.

TFE was higher when the headform was static for four of the six samples shown in Figure 25. Performance 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 using Tukey's HSD test. They had $P < 0.0001$ across the two segments with average differences in TFE between 11-12%. The cotton and hybrid face covering performed inversely, with slightly higher TFE during their dynamic testing. The design, fit, and material filtration are likely the reason for this.

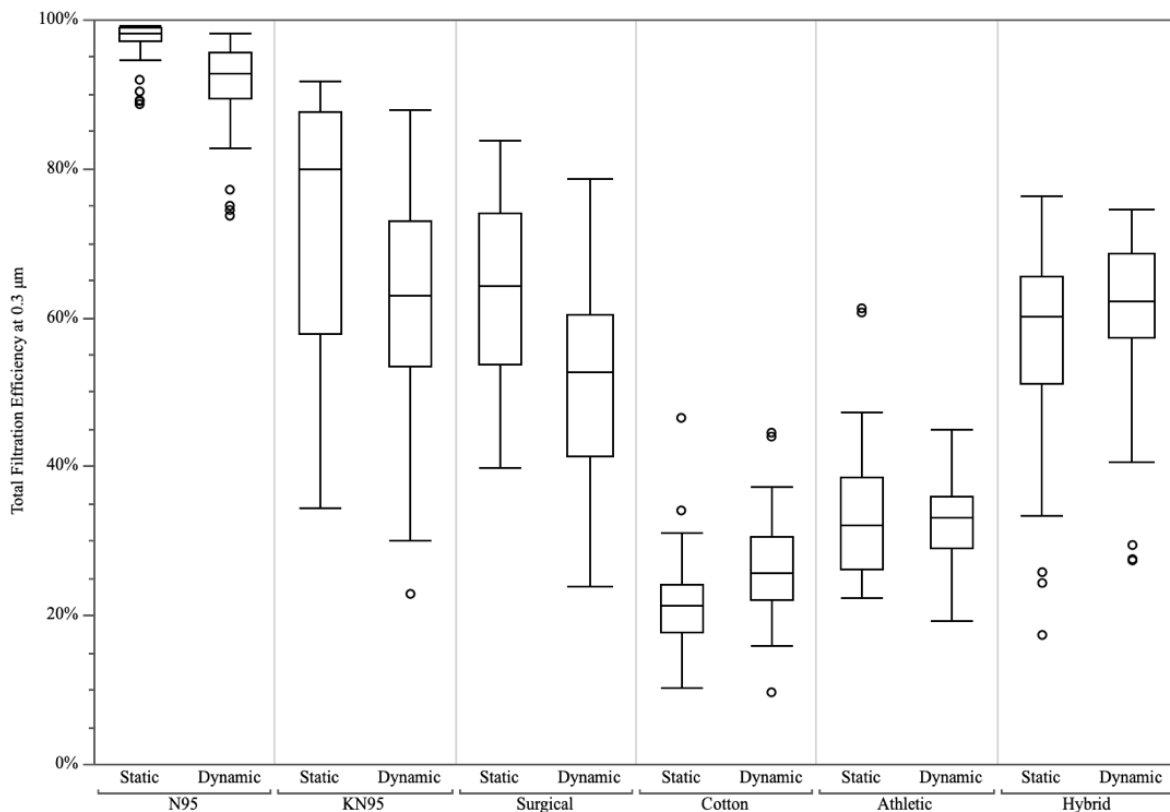


Figure 25. Box plot for TFE at $0.3 \mu\text{m}$ comparing the static and dynamic segments by sample at 16 L/min

At 28 L/min, the sample type, test segment, and their interaction were all identified as significant as well, with $P < 0.0001$ for the main effects and $P = 0.0134$ for their interaction. The

average TFE across the data set remained lower during the dynamic segment at the higher flow rate. TFE at 0.3 μm decreased from the static to dynamic segments in all six samples shown in Figure 26. Pairwise analysis showed that this drop in filtration was only considered statistically significant in two of the six products with a decrease of 6-8% TFE. The N95 had the largest change in performance during movement with $P = 0.0008$, while the athletic face covering had a larger $P = 0.0356$. These two samples also had the largest data spread during the movement protocol which may be attributed to higher variability in the product performance or fit.

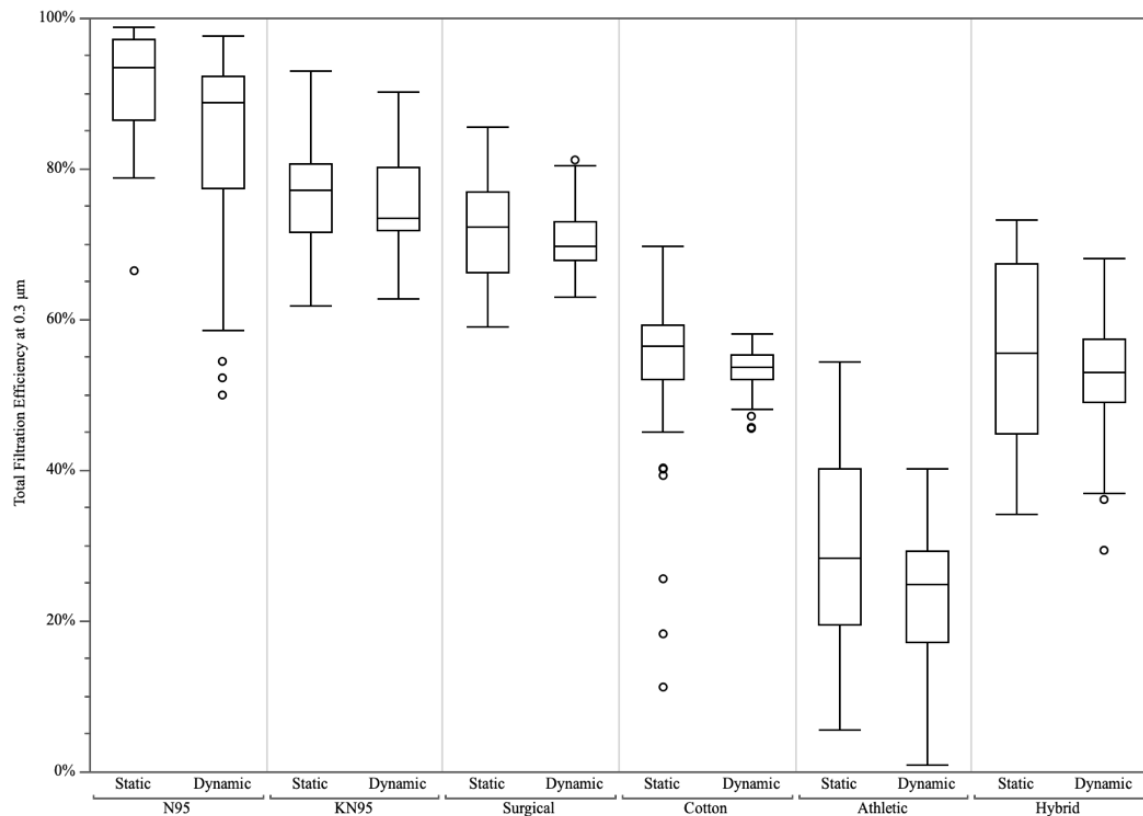


Figure 26. Box plot for TFE at 0.3 μm comparing the static and dynamic segments by sample at 28 L/min

Both test segments were further evaluated each minute. The static segment consisted of five minutes of stationary breathing. A two-way ANOVA test was used to determine if the

filtration changed significantly over the course of the test. At 16 L/min, the main effects of sample type and time during testing were both found to be significant with $P < 0.0001$ and $P = 0.0007$, respectively. Average TFE decreased over the duration of the test. A pairwise analysis showed significant differences of 6-8% between the first minute of testing with the third, fourth, and last minute where $P = 0.0014$, $P = 0.0109$, and $P = 0.0362$. The interaction between the sample type and time was not found to be significant, but five of the six samples saw a visible drop in TFE by the end of the static segment shown in Figure 27. Only the N95 maintained efficiency over the five-minute test.

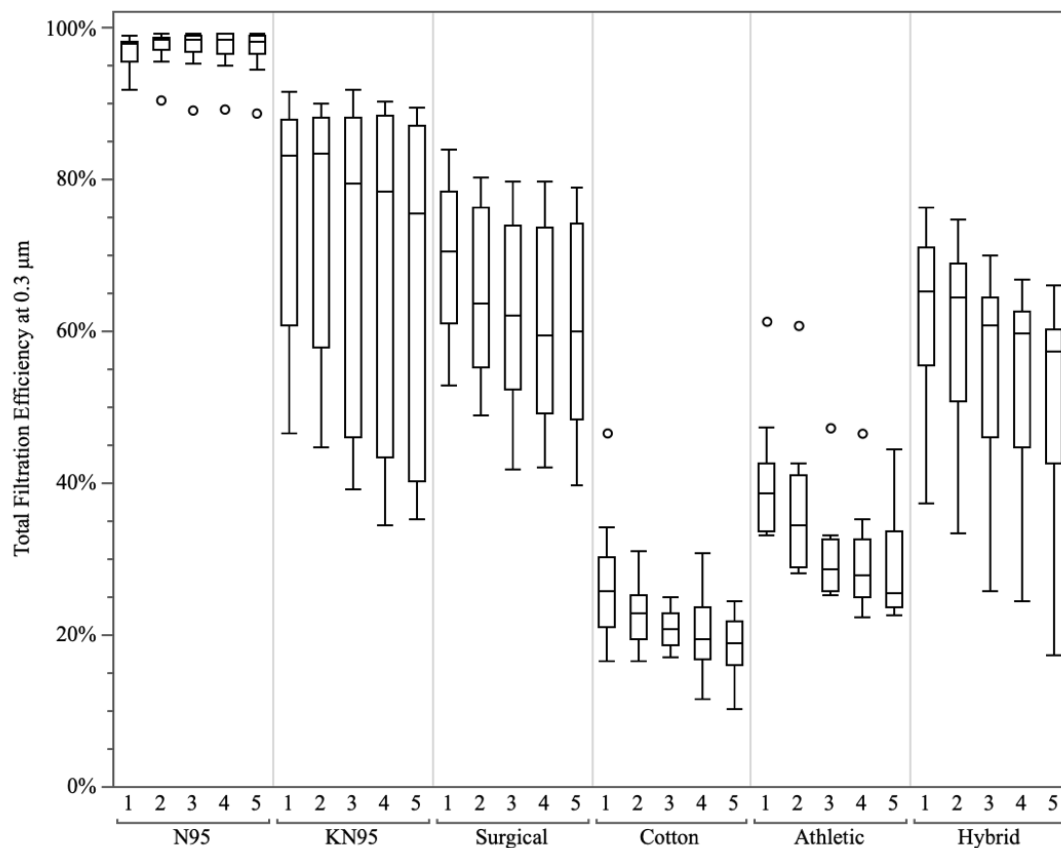


Figure 27. Box plot for TFE at 0.3 µm comparing the five minutes of stationary breathing from the static segment by sample at 16 L/min

The analysis at 28 L/min showed a similar change over time. The two-way ANOVA test identified significant differences between sample type at $P < 0.0001$ and the interaction of each sample and time at $P = 0.0175$. The effect of time itself was not significant at the higher flow rate. The KN95 and cotton face covering had lower TFE in the first minute that substantially increased by the second minute. The other four samples showed the same gradual decrease in efficiency identified at the lower flow rate as shown in Figure 28. Tukey's HSD test only identified notable differences between times in one sample. The cotton face covering had significant differences in TFE between the first minute and the second, third, and fourth minute with $P = 0.0063$, $P = 0.0133$, and $P = 0.0174$, respectively and a difference of 17-19%. This initial drop in filtration may suggest residual particles in the breathing cavity or a sampling error.

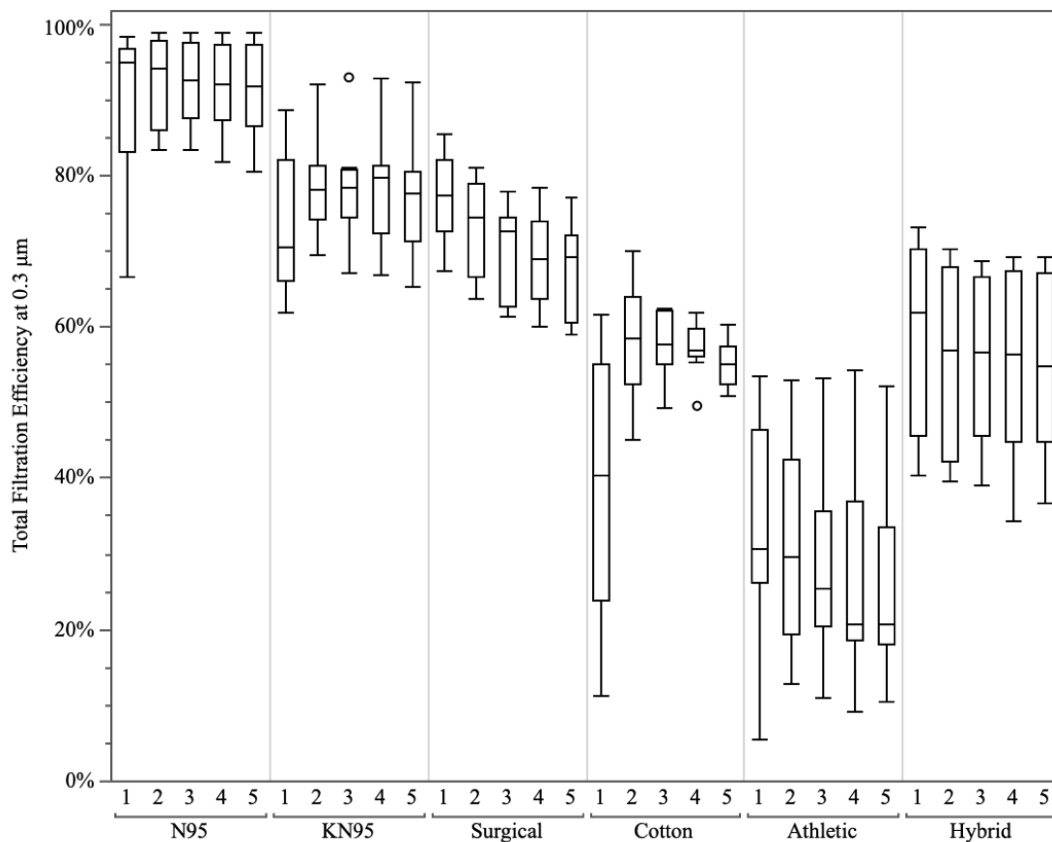


Figure 28. Box plot for TFE at $0.3 \mu\text{m}$ comparing the five minutes of stationary breathing from the static segment by sample at 28 L/min

The headform movements in the dynamic segment were analyzed by their activity each minute at the 0.3 μm particle size. Another two-way ANOVA test was used to identify any interaction between sample type and headform activity. Looking across the entire data set at 16 L/min, TFE decreased over the course of the five-minute test. The main effect of headform movements was shown to be significant with $P = 0.0215$, however, the interaction between the sample and activity was not. There was no clear pattern across the different products shown in Figure 29. A closer pairwise analysis of the five activities showed that the only notable difference was between the head shake and stationary breathing with $P = 0.0112$ and 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 filtration over time.

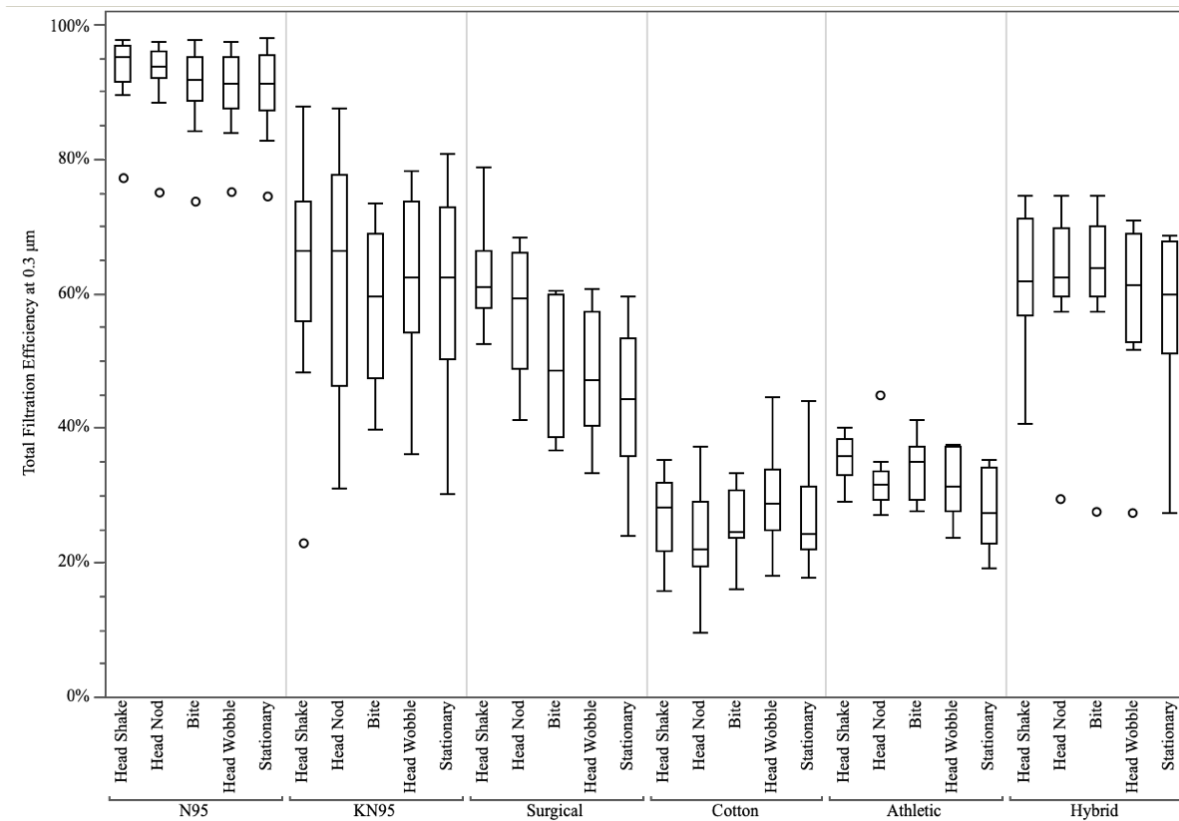


Figure 29. Box plot for TFE at 0.3 μm comparing the five headform movements from the dynamic segment by sample at 16 L/min

Both the main effects and their interaction between headform activity and sample type were significant at 28 L/min. The type of movement had a high $P = 0.0491$ which suggests at least one mean is statistically different from another. However, a closer analysis with Tukey's HSD test showed none of the activities were significantly different from each other. There were still visual trends in the data. The bite showed the lowest filtration efficiency across the data set. There was a small 2% decrease in TFE from the beginning to the end of the test although this value is too low to be considered clinically significant. The interaction between specific headform movements and the sample were also significant with $P = 0.0073$. From the graph in Figure 30, it is hard to determine if one activity influenced TFE more than another. The pairwise analysis showed only one pair of movements that differed in one of the samples. The N95 head nod and bite movements were significantly different with $P = 0.0001$. This led to an average decrease in TFE of 17% which increased again when the bite stopped. None of the other activities across the other samples had statistical differences. It remains unclear how much of an impact movement makes over time and if one movement type is largely responsible.

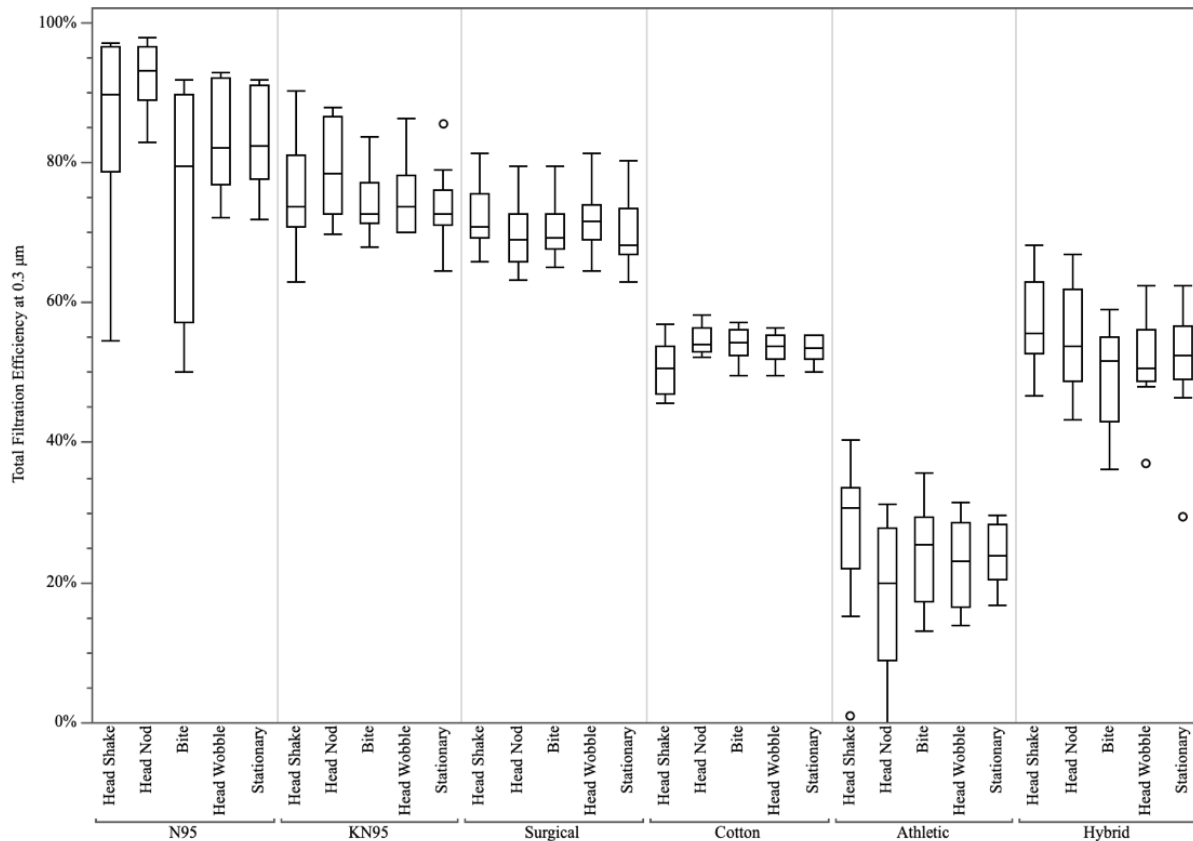


Figure 30. Box plot for TFE at 0.3 μm comparing the five headform movements from the dynamic segment by sample at 28 L/min

3.3.4 Operator

Three trained operators conducted the tests. All followed the same procedure and tested every type of face covering multiple times. 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 visible differences in mean TFE, and the data spread between operators for some of the products is shown in Figure 31. A two-way ANOVA test was used to determine significance between the main effects of product and operator along with their interaction. All three were considered statistically significant with $P < 0.0001$. The second operator had lower TFE across the data set. Tukey's HSD test determined three of the six

products tested had notable differences between operators where $P < 0.0001$. These included the KN95, surgical, and hybrid face coverings with differences in average TFE between operators around 11-17%.

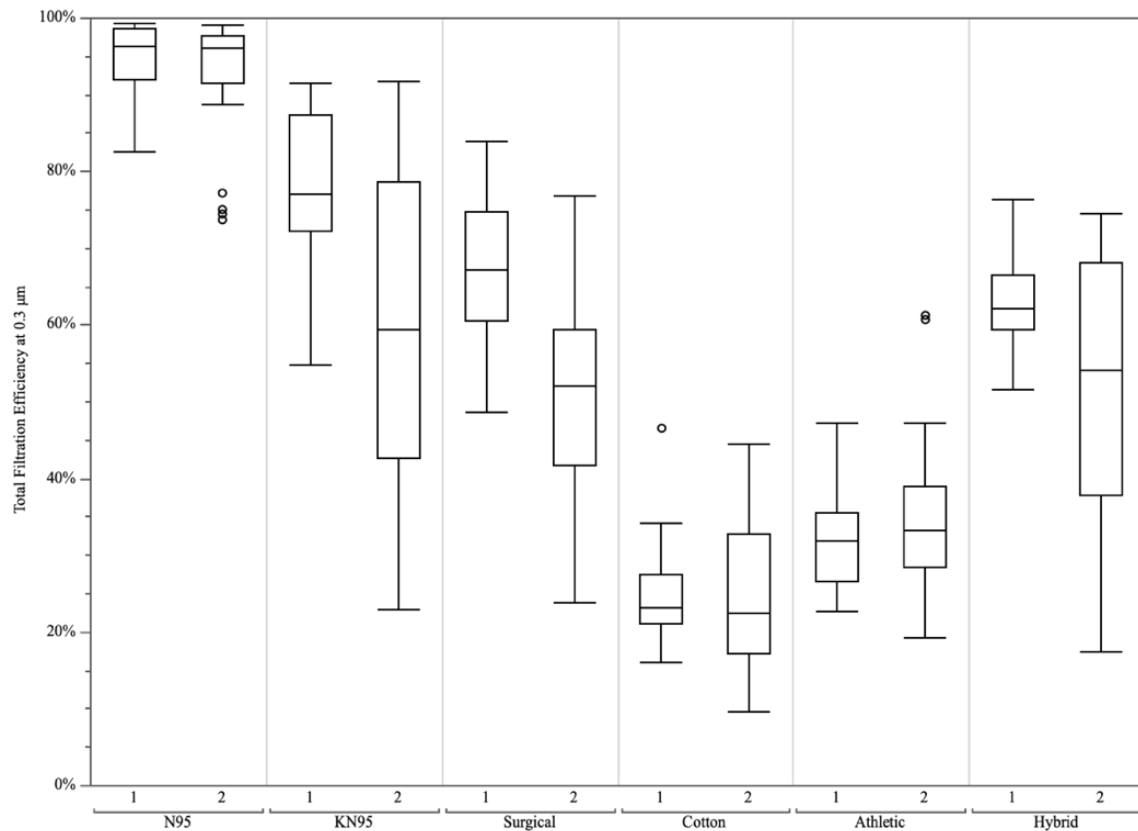


Figure 31. Box plot for TFE at $0.3 \mu\text{m}$ comparing the operator for each test cycle at 16 L/min

Operators #1 and #3 were responsible for testing the samples 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 shown in Figure 32. A two-way ANOVA identified the main effects and their interaction as significant, with $P < 0.0001$ for the sample type and interaction of sample and operator, while the effect of operator alone had $P = 0.0002$. Looking at the entire data set, operator three measured higher TFE. This corresponds to the sample data, with higher average TFE measured for five of the six products tested by operator

three. The pairwise analysis identified the difference between operators was only significant for the KN95 and surgical style masks with a change of 6-7% TFE where $P = 0.0051$ and $P = 0.0346$, respectively. These two products showed significant differences between operators at both flow rates, suggesting there may be a higher variability in fit for these styles.

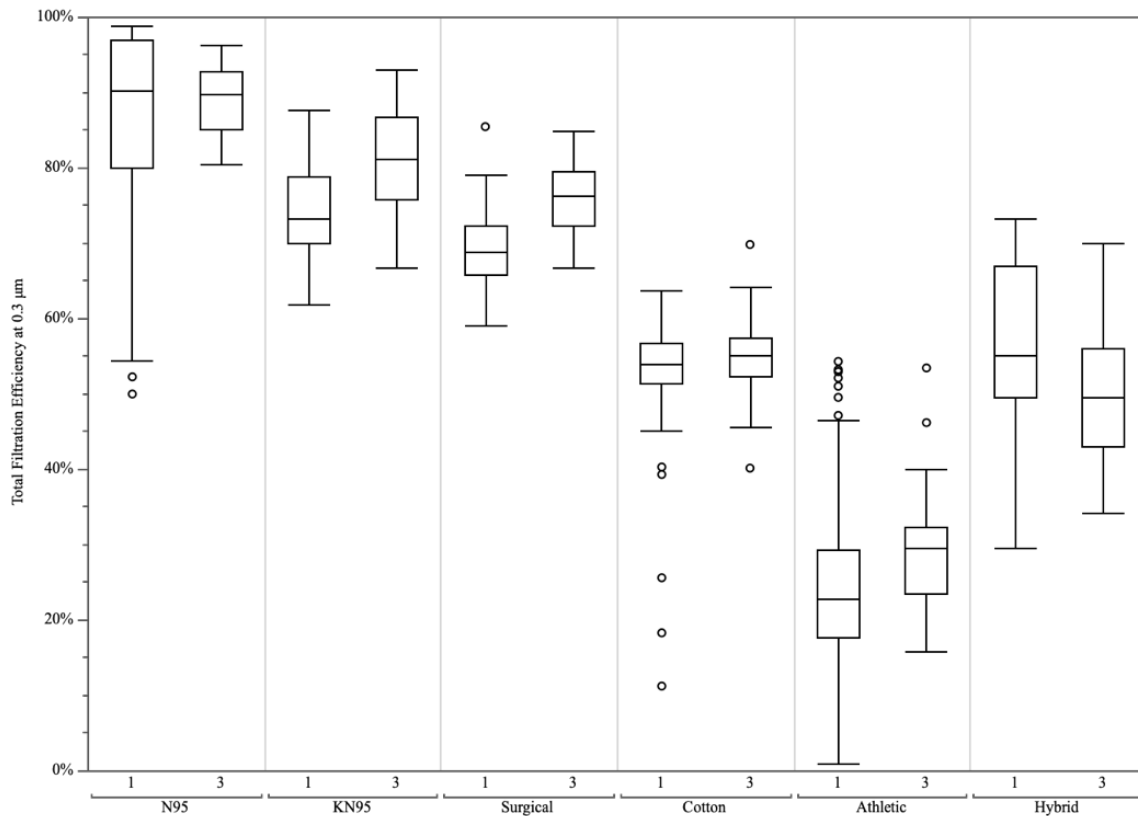


Figure 32. Box plot for TFE at 0.3 μm comparing the operator for each test cycle at 28 L/min

3.3.5 Variability Analysis

The coefficient of variation (CV) for each sample at 16 and 28 L/min is shown in Table 10. This was computed using the standard deviation over the mean multiplied by 100. These values give a better idea of the measurement stability in the method. The N95 respirator control 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 that increased slightly to 11.98% at 28 L/min. Most of the samples

fell within the 10-30% range at 0.3 μm offering good or acceptable variation from the mean. The KN95, surgical, cotton, and hybrid face coverings all had lower CVs at the higher flow rate. The only exception was the athletic face covering at 28 L/min with a larger CV of 43.93% at 0.3 μm because of the high variation relative to a considerably lower mean TFE value. Generally, CV decreased as the particle size increased across samples at both flow rates. All of the CVs fell below 20% at 2 μm .

Table 10. Coefficients of variation for each product at both flow rates

Sample	Flow Rate	Coefficient of Variation %				
		0.3 μm	0.5 μm	1.0 μm	2.0 μm	Cumulative
N95 Respirator	16 L/min	6.19	5.51	5.32	4.58	5.98
	28 L/min	11.98	7.29	4.79	3.26	10.27
KN95 Style Mask	16 L/min	26.93	21.15	20.15	12.88	24.92
	28 L/min	8.95	8.09	6.89	5.54	8.75
Surgical Style Mask	16 L/min	22.78	18.25	19.08	19.66	20.51
	28 L/min	8.13	7.40	6.90	5.11	7.65
Cotton Face Covering	16 L/min	28.37	23.17	19.53	11.74	27.15
	28 L/min	14.84	18.14	16.01	10.36	15.76
Athletic Face Covering	16 L/min	22.30	21.70	19.05	12.46	21.87
	28 L/min	43.93	37.56	32.14	15.17	36.06
Hybrid Face Covering	16 L/min	21.74	16.91	13.55	7.57	19.84
	28 L/min	18.27	14.17	11.74	7.19	15.48

An analysis was also conducted on the different test variables with the variance component estimates shown in Table 11. The analysis looked at the sample, flow rate, movement, movement type, time, and operator to see which parameters caused the most variation in the baseline test method. The asterisk indicates the crossed effects or interaction between variables. This analysis revealed that the sample type contributed the most to the overall

variability at 66.10%. The within value or inherent variability from unexplained error can be used to determine the repeatability. From this analysis, it was 11.40% demonstrating that the test method variation was relatively low compared to the variation between sample types. The interaction between sample and flow rate was similar at 11.20%. The reproducibility can be determined by looking at the effect of operator and the interaction between operator and sample, which came to relatively small percentages of 3.10% and 4.20%, respectively. The remaining 4% can be attributed to the summation of other effects that were comparatively low.

Table 11. Variance components

Component	Variance Component	Percent of Total
Sample	0.0440	66.10%
Within	0.0075	11.40%
Sample*Flow Rate	0.0074	11.20%
Sample*Operator	0.0028	4.20%
Operator	0.0021	3.10%
Other	0.0027	4.00%
Total	0.0665	100.00%

3.3.6 Sealed

Each of the six samples was taped to the headform in order to measure the material PFE by eliminating leakage around the edges of the face coverings. The sealed sample data at both flow rates is shown in Table 12. The N95 continued to filter around 94% at 0.3 μm . The other nonwoven samples, the KN95 and surgical style masks, performed around 84-90% PFE. The hybrid face covering had the next highest efficiency at both flow rates from 62-66%, while the cotton and athletic face coverings varied more significantly across rates from 40-78%. The sealed filtration efficiency increased as a function of particle size for all six samples. Most

products had lower standard deviation sealed to the headform with the exceptions of 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.

Table 12. Sealed particulate filtration efficiency of each product at both flow rates

Sample	Flow Rate	Mean Particulate Filtration Efficiency ($\pm$ Standard Deviation) %				
		0.3 μm	0.5 μm	1.0 μm	2.0 μm	Cumulative ^A
N95 Respirator	16 L/min	93.61 (4.12)	95.69 (2.70)	96.24 (2.55)	97.28 (1.74)	94.34 (3.41)
	28 L/min	94.44 (2.90)	96.55 (2.08)	97.24 (1.87)	98.40 (1.13)	95.31 (2.46)
KN95 Style Mask	16 L/min	90.41 (5.04)	94.39 (4.82)	95.59 (3.23)	97.04 (1.93)	92.24 (4.58)
	28 L/min	84.24 (9.07)	92.54 (4.28)	95.06 (2.36)	96.56 (1.81)	87.72 (7.04)
Surgical Style Mask	16 L/min	85.74 (2.97)	91.07 (3.10)	92.26 (3.41)	93.88 (2.94)	87.42 (3.11)
	28 L/min	87.10 (5.40)	92.26 (4.09)	94.01 (3.34)	96.35 (2.26)	89.37 (4.81)
Cotton Face Covering	16 L/min	55.22 (14.32)	76.56 (9.58)	85.59 (6.43)	93.23 (3.19)	62.88 (14.03)
	28 L/min	77.64 (5.07)	92.36 (3.03)	95.73 (1.94)	98.27 (1.11)	82.70 (4.81)
Athletic Face Covering	16 L/min	49.88 (8.03)	61.81 (9.22)	69.21 (7.87)	82.13 (5.30)	55.95 (8.11)
	28 L/min	39.83 (16.41)	59.49 (18.34)	73.05 (11.42)	88.39 (4.73)	49.59 (16.39)
Hybrid Face Covering	16 L/min	61.92 (10.63)	76.33 (9.35)	83.07 (7.01)	90.39 (4.06)	68.95 (9.94)
	28 L/min	66.35 (9.18)	83.63 (6.82)	88.43 (5.59)	93.00 (3.76)	71.50 (8.70)

^A Cumulative results were calculated as the sum of all particle sizes from 0.3-10 μm

The five replicates of each product sealed to the headform were compared with the first five replicates from the original unsealed method to assess the impact of fit. As a result, the unsealed sample means varied slightly from those reported in previous sections. A two-way ANOVA test was used to compare the effects of fit, sample, and their interaction. At 16 L/min, both main effects and their interaction were shown to be significant with $P < 0.0001$. Across the data set, the sealed filtration efficiency was significantly higher. Five of the six samples had higher filtration when sealed to the headform as shown in Figure 33. The N95 was the only

exception, with a 1% decrease when taped. Tukey's HSD test determined that four samples showed a significant difference in means between test methods. The KN95, surgical, cotton, and athletic face coverings all had $P < 0.0001$ significance between the sealed and unsealed tests, suggesting their performance was considerably impacted by fit. This equated to a drop in TFE of 13-32% when donned as worn depending on the sample type.

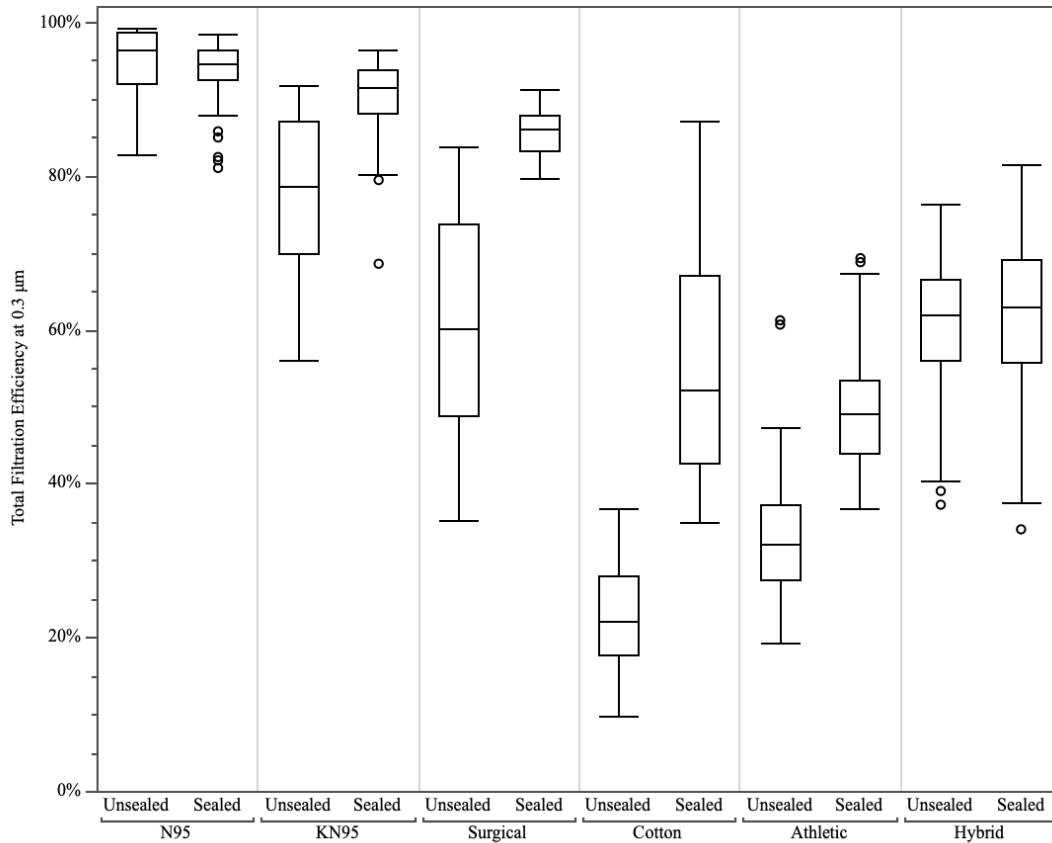


Figure 33. Box plot for TFE/PFE at 0.3 μm comparing the unsealed and sealed products on the headform at 16 L/min

Testing at 28 L/min showed similar results, with $P < 0.0001$ for the interaction between sample and fit along with their main effects. Sealed PFE remained significantly higher across the entire data set. Similarly, all six samples had higher efficiency when sealed to the headform as shown in Figure 34. A pairwise analysis indicated five of the six samples had significant

differences in filtration efficiency across methods. The surgical, hybrid, cotton, and athletic face coverings all had $P < 0.0001$ indicating a strong difference in performance when they were worn as intended, not sealed to the headform. They decreased in TFE 14-25% depending on the product. The KN95 style mask also had a notable difference of around 8% with $P = 0.0010$. This illustrates a clear difference in product performance when evaluated as a sealed material rather than a system that incorporates fit and leakage into the filtration measurement.

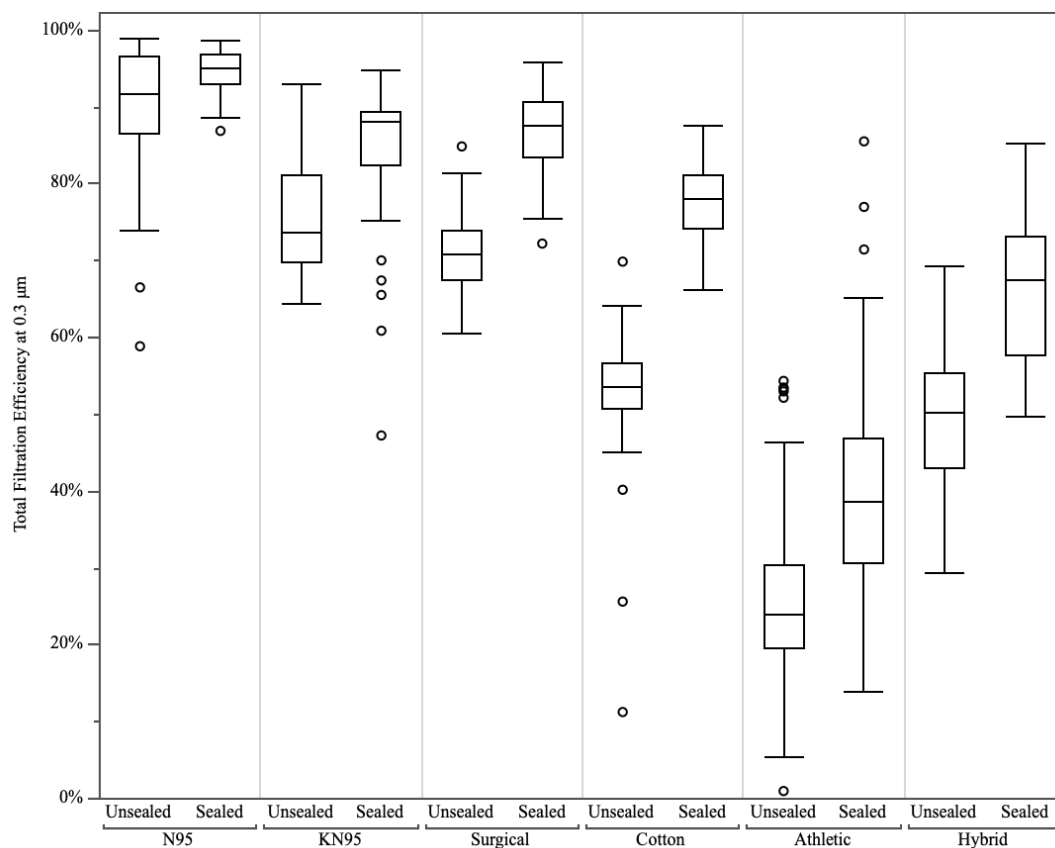


Figure 34. Box plot for TFE/PFE at $0.3 \mu\text{m}$ comparing the unsealed and sealed products on the headform at 28 L/min

3.4 Discussion

The baseline headform test method is a system-level test capable of evaluating the efficacy of respirators, medical masks, and barrier face coverings. As such, it was important for

this test method to distinguish between filtration levels across a wide range of products. It is a reasonable inference that the test method's ten replicates consisting of 100 observations were capable of visually and statistically distinguishing between products with a difference of means greater than approximately 5% TFE at 0.3 μm . The N95 respirator control was used to determine if this test system could effectively measure the respirator within its certified level of protection. The average TFE for the N95 was just below 95% filtration at 16 L/min and around 88% at 28 L/min. It maintained consistently higher TFE than the other samples as expected due to the high filtration standard and required seal to the face. However, the lower values less than 95% may be attributed to leakage due to fit challenges on the headform which appeared exaggerated at the higher flow rate.

Changing breathing flow rates was shown to significantly influence TFE depending on the sample. Overall, the higher 28 L/min sinusoidal flow appeared to increase filtration efficiency contrary to earlier literature. It was previously shown that increasing the flow rate reduces the efficiency of smaller particles by shortening the residence time through the material [4], [59]. This increase in TFE at the higher breathing rate was seen in three of the six samples, the KN95, surgical, and cotton face covering. The performance 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 mask were composed of high filtering materials that showed considerable variability in fit. At high volume flow rates, the samples were visibly sucked into the mouth cavity during inhalation. This may have created a vacuum around the opening, pulling particles through the material without incorporating leakage into the TFE percentage. The three samples that decreased TFE at the higher flow rate including

the 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 performance across the combined data sets. This behavior was expected since movement can shift the positioning of the face covering on the headform which can break the seal to the face, allowing additional inward leakage and reducing filtration efficiency. Pairwise analysis showed that a significant decrease across the static and dynamic segments only occurred for select samples, 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 actually become seated better on the headform, reducing gaps at the skin interface. In general, variations in performance during movement became more noticeable in loose-fitting face coverings where the sample 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 performance over time. Most of the samples 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 samples saw a visible change during or after the bite. 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 appeared to impact the seal of the N95, decreasing TFE by an average of 17% which was partially recovered when the movement changed. Extending the jaw was also shown to shift the position of the face covering. This displacement was most noticeable in 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 particular movement was more responsible for the changes in performance or if these differences are more closely related to testing duration.

The TFE measurement allowed for the incorporation of fit into the filtration value. Poor fit has been shown to cause significant reductions in performance due to leakage through gaps around the interface of the face covering and the skin [6], [9], [64]. The importance of fit was clearly identified in the statistical differences between the three operators. The KN95 and surgical style masks were difficult to consistently don the same way. At 16 L/min, these two masks had the largest data spreads of all samples, so some of the 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 from the high filtering material pulling more particles around the barrier when a seal is not maintained. The variability analysis indicated that the operator may have contributed, but the majority of the variability in the test system was due to the sample 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 should be able to determine the inward leakage around the product. Almost all of the samples had higher PFE as expected, with the exception of the N95 at 16 L/min that decreased 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 25-32% in the cotton face covering. The large decrease in filtration due to leakage was consistent with previous literature [6], [9]. It

suggests the loose fitting pleated design had difficulty creating a seal around the face. Similarly, the surgical style mask had a 16-25% decrease in filtration efficiency as worn while the athletic face covering showed a change of 14-17%. 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.

The current headform test method was able to differentiate between samples and measure TFE within their respective filtration range. However, there are still some limitations. A standard size headform was used to conduct all testing. This does not take into account the possibility of variable fit across different facial shapes and sizes which would be more representative of the general public. The generation of NaCl aerosol particles should be investigated. The current method placed 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. The current method does not neutralize the particles, which may contribute to overestimating filtration efficiency [8]. Neutralizing and stabilizing the NaCl particles may be considered in the future to evaluate the worst-case scenario.

The experiment was conducted in an acrylic chamber, but the conditions inside the enclosure remained highly dependent on the external environment. The ambient particle counts fluctuated daily. There was no clear relationship between TFE and the temperature, relative humidity, or ambient particle count across the data set as shown in Appendix A. However, many of the trials were recorded at high relative humidity (above 40%) which had the potential to agglomerate the aerosol particles and may impact particle charge. 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 [60]. All these testing conditions and parameters should be taken into account when comparing TFE results.

3.5 Conclusions

This study evaluated six different face coverings at two breathing flow rates that were able to produce a wide range of TFE values ranging from 24-94% at 0.3 μm . The statistical analysis proved the headform test method could statistically and clinically differentiate between sample types. The N95 control had the highest and most consistent level of filtration 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 performance, but whether filtration increased or decreased depended on the sample type. There were statistical differences 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. Using the variance component estimates, the biggest contribution to the overall variability was shown to be the sample type. This demonstrates the repeatability and robustness of the current test method. Despite significant differences between operators, their variance components showed good reproducibility. Additional research will be needed to see if the within variation in the method can be reduced.

The headform assessment was able to effectively evaluate a range of face coverings, however, the method still has room for further development. Some of these changes may examine the effects of sizing, neutralizing and stabilizing particles, particle size distribution, and controlling the environmental conditions in an environmental chamber. Future research will look

into evaluating differential pressure on the headform and comparing the animatronic headform test method to related standards including ASTM F3502-21 in an effort create a final optimized test method.

CHAPTER 4: Comparative Analysis of the Headform Test Method and ASTM F3502-21

4.1 Introduction

Barrier face coverings are products that are worn over the nose and mouth as a method of source control. They are not classified as respirators or medical masks regulated by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR Part 84 and by the U.S. Food and Drug Administration (FDA) under ASTM F2100-21, respectively. The Standard Specification for Barrier Face Coverings ASTM F3502-21 came out in direct response to the COVID-19 pandemic to help manufacturers and consumers navigate the rapidly developing market for these alternative products. It uses a modified version of the NIOSH N95 test to establish minimum performance requirements. However, the differences in testing parameters between respirators, KN95s, medical masks, and barrier face coverings can report different results.

This chapter expanded the sample size from the previous study to incorporate a broader range of products available to the general public. The additional samples were used to validate the earlier analysis of the baseline headform method before comparing the measurements on the headform to the new ASTM F3502-21 Standard Specification. These two methods are both designed to assess the performance of barrier face coverings that are not designed to seal to the face. However, the standard evaluates the samples as a sealed product which eliminates leakage from the equation, while the headform tests the products as worn allowing fit to factor into the filtration efficiency.

4.2 Methodology

4.2.1 Samples



Figure 35. Selected respiratory devices (R), medical masks (M), and barrier face coverings (B)

Twenty-four different products covering a broad range of materials and designs were selected counting the six from the previous study shown in Figure 35. This included two N95 respirators, three KN95 style masks, four surgical style masks, three procedural masks, four woven face coverings, four knit face coverings including one with an insertable filter, and four hybrid face coverings with incorporated membranes or nano materials. Detailed descriptions of each product can be found in Appendix B. Due to the large number, each product was given a sample ID. The first letter R, M, or B indicated the product grouping for respiratory devices (R), medical masks (M), and barrier face coverings (B). The second letter indicated the specific sample within each category.

All samples were preconditioned for at least 25 hours at $20 \pm 2^\circ\text{C}$ and $65 \pm 5\%$ relative humidity prior to testing. Each product was tested as received without laundering. The samples were carefully fit to the headform each test. Any necessary adjustments were made after a visual inspection. Products with adjustable ear loops were tightened on the headform. The elastic ear loops on the medical masks were all tied to improve their fit. One face covering was used per test cycle, conducted by two operators over the course of several months. Ten replicates were completed for each product. In addition to headform testing, the samples were sent out to two third party labs for ASTM F3502-21 testing.

4.2.2 Baseline Headform Test Method

The Fully Animatronic Respirator Testing Headform enclosed in an acrylic chamber ($3.43 \times 10^5 \text{ cm}^3$) from i-bodi Technology shown in Figure 20 was used to evaluate a broader range of products with the previous baseline test method. The robotic headform was covered in a realistic silicone skin and connected to a digital breathing machine through the mouth cavity to simulate respiration. Software allowed programmable breathing and movement sequence to realistically assess daily wear. The headform was connected to two Fluke® 985 particle counters outside the system via 80 cm of tubing. This configuration facilitated measuring the particles on either side of the sample, “outside” in the environment and “inside” in the mouth cavity of the headform. The background difference between the two particle counters fell within a reasonable range of $4.52 \pm 3.11\%$ at $0.3 \mu\text{m}$. The six-channel counters sampled at a flow rate of 2.83 L/min and recorded the differential particle counts at 0.3, 0.5, 1, 2, 5, and $10 \mu\text{m}$ each minute. The term total filtration efficiency (TFE) was used to describe the systemic filtration efficiency measurement that incorporated both fit and material filtration into the final value. TFE was

calculated each minute by subtracting the percent penetration (%P), the ratio of particles measured inside the sample over the particles measured outside in the chamber, from 100 as shown in Equation 5.

Equation 5. Total filtration efficiency

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

The temperature and relative humidity were recorded each day. Across days, temperature ranged from 21.1-23.8°C with relative humidity from 26.2-69%. The ambient particle counts were also monitored to ensure they did not exceed concentration limits of the instruments. Testing was conducted when ambient counts fell at or below 100,000 particles/min at 0.3 µm, around 35 particles/cm³. An additional unneutralized, polydisperse 2% NaCl aerosol was generated in the chamber for each test with a TSI Single-Jet Atomizer 9302 set to 2.0 ± 0.5 psi to maintain particle generation through the duration of each five-minute test. The atomizer was connected to compressed nitrogen gas outside of the system. Between tests, the chamber door was removed to air out the particles and reset the environment.

Each test cycle consisted of two independent five-minute test segments where the headform was breathing. A sinusoidal respiratory rate was programmed to 16.26 BPM with a tidal volume of 0.98 L to achieve a minute volume flow rate around 16 L/min during each segment. This obtained a peak inspiratory flow of approximately 50 L/min. The static segment measured the samples during five minutes of stationary breathing. There was a ten-minute break in between, where an air purifier was run to clear out the aerosol. The dynamic segment maintained breathing during a five-minute movement protocol where the headform completed a series of programmed movements at 24 reps/min before returning for one last minute of stationary breathing. The four movements included a minute of the head shaking side-to-side,

nodding up and down, biting opened and closed, and wobbling shoulder-to-shoulder to simulate routine wear.

4.2.3 ASTM F3502-21 Test Method

The Standard Specification for Barrier Face Coverings ASTM F3502-21 established minimum design and performance requirements for source control devices that are not classified as medical masks or respirators. The standard detailed the testing requirements for particulate filtration efficiency (PFE) and inhalation airflow/breathing resistance (BR). There are four possible performance classifications, Level 1 and 2 PFE and BR shown in Table 13. Lower Level 1 performance requires a PFE of 20% or more and BR at or below 15 mm H₂O. Higher Level 2 performance has PFE at or above 50% and a BR of 5 mm H₂O or less. The two criteria can be mixed and matched [3].

Table 13. Classification of barrier face covering performance with ASTM F3502-21 [3]

Performance Criteria	Level 1	Level 2
Particulate Filtration Efficiency	$\geq 20\%$	$\geq 50\%$
Airflow/Breathing Resistance	$\leq 15 \text{ mm H}_2\text{O}$ (~147 Pa)	$\leq 5 \text{ mm H}_2\text{O}$ (~49 Pa)

All 24 samples were sent out to Intertek Testing Services (Intertek) in Cortland, NY for ASTM F3502-21 testing. Five replicates instead of the standard ten were completed for each product due to cost constraints. Seven of the 24 samples were previously sent to the Nonwovens Institute (NWI) in Raleigh, NC with ten replicates completed per sample in compliance with the standard. All samples were preconditioned at $38 \pm 2.5^\circ\text{C}$ and $85 \pm 5\%$ relative humidity for 24-26 hours prior to testing. The entire product was mounted on a printed adult medium face form

ISO #16900-5-2016 and sealed around the edges to prevent leakage as shown in Figure 36. At Intertek, each sample was tested at a face velocity of 10 ± 0.5 cm/s with flow rates between 36-71 L/min depending on the surface area. NWI used a constant flow rate of 85 ± 4 L/min for each product. This was the only observed change between the two labs that is technically permissible under the standard.

Testing was conducted at $25 \pm 5^\circ\text{C}$ and $30 \pm 10\%$ relative humidity. PFE and BR measurements were obtained on the same test setup using the TSI 8130a Filter Tester. PFE was evaluated using a neutralized NaCl aerosol with a count mean diameter of 75 ± 20 nm at concentrations up to 200 mg/m^3 . It was calculated with the same Equation 5 used on the headform to determine TFE. The airflow resistance was measured at the same flow rate without the aerosol to determine the change in pressure across the sample. The optional quantitative leakage assessment and laundering considerations were not evaluated at this time.



Figure 36. ASTM F3502-21 Standard Specification testing with the printed adult medium face form (left), mounted sample (middle), and test setup (left) from Intertek

4.2.4 Statistical Analysis

All statistical analysis was completed using JMP® Pro 16.0 software. An assumption of normality was made based on the high number of observations and confirmed by the predicted residuals. The Analysis of Variance (ANOVA) test was used to compare TFE and BR on the headform and across test methods. The null hypothesis assumed all means were equivalent. The null hypothesis was rejected when the p-value (P) was below 0.05, indicating at least one mean was statistically different from another. When $P < 0.05$, Tukey's Honest Significant Difference (HSD) test was used to conduct a pairwise analysis to determine which specific pairs were statistically different. Clinical significance was defined as a change in TFE of 5% or more and a change in BR greater than or equal to 10 Pa.

4.3 Results

4.3.1 Total Filtration Efficiency

The average TFE and standard deviation across 0.3, 0.5, 1, and 2 μm particle sizes is reported for all 24 products in Table 14. The individual TFE values for the larger 5 and 10 μm ranges were left out because of the limited number of particles generated at those sizes. Due to the large sample size, the products were broken down into three categories based on their typical classification as respiratory devices, medical masks, or barrier face coverings. The two N95 respirator controls (R-a and R-b) performed consistently high around 92-94% at 0.3 μm . The other respiratory devices, three KN95 style masks (R-c, R-d, and R-e), reported efficiencies between 59-67% at the same size. The medical masks (M-a, M-b, M-c, M-d, M-e, M-f, and M-g) fell into a wider performance range from 49-69% at 0.3 μm with the ear loops adjusted for fit. The barrier face coverings had the largest range of performance across the three categories from 13-69% filtration at 0.3 μm . They can be further analyzed by fabric structure. The woven

products (B-a, B-b, B-c, and B-d) ranged from 13-25%, the knit products (B-e, B-f, and B-g) from 24-33%, and the hybrid systems (B-h, B-i, B-j, B-k, and B-l) that incorporated an additional filter layer, membrane, or nano fabric into their composition ranged from 43-69% TFE at 0.3 μm .

Table 14. Total filtration efficiency of each product with the baseline method

Sample	Mean Total Filtration Efficiency ($\pm$ Standard Deviation) %				
	0.3 μm	0.5 μm	1.0 μm	2.0 μm	Cumulative ^A
R-a	94.19 (5.83)	95.45 (5.26)	95.81 (5.10)	96.62 (4.43)	94.55 (5.65)
R-b	92.32 (6.18)	94.45 (4.72)	94.38 (5.62)	95.18 (5.91)	92.71 (6.05)
R-c	63.72 (8.44)	73.88 (9.03)	76.08 (9.67)	80.33 (8.46)	67.06 (8.75)
R-d	59.37 (13.44)	70.96 (12.07)	72.28 (13.41)	78.84 (11.18)	61.59 (13.50)
R-e	66.97 (18.03)	75.87 (16.05)	77.31 (15.58)	83.06 (10.70)	69.52 (17.33)
M-a	57.92 (13.20)	68.19 (12.44)	69.06 (13.18)	73.58 (14.46)	60.95 (12.50)
M-b	57.51 (8.26)	71.46 (10.16)	71.20 (11.62)	76.76 (9.98)	60.18 (8.35)
M-c	51.27 (8.98)	65.07 (11.28)	65.43 (12.04)	72.20 (11.58)	54.43 (9.08)
M-d	69.02 (9.86)	78.00 (9.40)	79.33 (10.09)	82.81 (10.36)	71.07 (9.87)
M-e	60.30 (7.09)	70.63 (9.02)	70.96 (9.94)	76.50 (9.48)	62.67 (7.58)
M-f	52.08 (8.51)	64.22 (10.97)	64.99 (11.64)	72.14 (10.26)	54.76 (8.86)
M-g	49.02 (6.63)	62.08 (9.27)	63.15 (10.56)	69.58 (10.91)	52.21 (7.40)
B-a	15.05 (5.89)	40.07 (12.65)	47.90 (13.60)	65.68 (9.42)	19.59 (7.18)
B-b	17.43 (6.37)	34.94 (19.74)	42.88 (17.70)	55.28 (16.04)	20.22 (8.38)
B-c	12.69 (5.29)	25.01 (17.05)	28.44 (15.94)	41.10 (19.32)	14.95 (6.51)
B-d	25.01 (6.99)	50.07 (11.33)	50.69 (16.01)	45.84 (53.14)	28.66 (8.18)
B-e	24.33 (6.90)	48.81 (11.31)	57.78 (11.28)	72.42 (8.50)	30.72 (8.34)
B-f	32.81 (7.32)	50.40 (10.93)	57.27 (10.91)	72.73 (9.06)	37.40 (8.18)
B-g	32.78 (10.19)	62.41 (14.30)	74.64 (11.33)	86.16 (7.80)	39.70 (10.32)
B-h	58.57 (12.73)	75.12 (12.70)	79.96 (10.83)	87.64 (6.63)	62.61 (12.42)
B-i	60.41 (10.38)	76.64 (8.16)	78.55 (7.86)	84.59 (6.07)	63.81 (10.34)
B-j	42.99 (12.68)	64.13 (15.49)	73.24 (14.66)	82.90 (10.58)	49.09 (13.48)
B-k	68.89 (7.20)	80.20 (8.26)	83.82 (7.97)	86.63 (9.27)	71.95 (7.46)
B-l	66.18 (12.92)	77.88 (10.58)	82.25 (9.87)	88.22 (7.97)	68.18 (12.74)

^A Cumulative results were calculated as the sum of all particle sizes from 0.3-10 μm

The TFE distributions for each product at 0.3 and 2 μm in descending order of performance are shown in Figure 37 and Figure 38, respectively. Looking across 0.3 μm , the top performing half of the products included all the respiratory devices, three medical masks (M-d, M-e, and M-a), and four barrier face coverings (B-k, B-l, B-i, and B-h) with TFEs ranging from 58-94%. The four barrier face coverings in this range were all considered hybrid products that incorporated nano fabrics (B-h and B-i), a membrane (B-k), or an additional filter layer (B-l) into their design. The remaining 12 samples included the rest of the medical masks and barrier face coverings in that order. This demonstrated the product performance at the most penetrating particle size, the metric used to determine the filtration efficiency in the worst-case scenario. Most of the samples increased TFE as particle size increased. Comparing the TFE at a larger 2 μm particle size can offer a better indication of fit, since larger particles are more easily captured by traditional filter mechanisms. At 2 μm , the top 12 performing products shifted. The KN95s and medical masks moved lower down the performance rank, while several barrier face coverings improved. All five respiratory devices remained in the top half, in addition to one medical mask (M-d), and six barrier face coverings (B-l, B-h, B-k, B-g, B-i, and B-j) ranging from 79-97% TFE. The new group of barrier face coverings included the other hybrid product (B-j) and a knit barrier (B-g). The remaining medical masks and barrier face coverings made up the lower half.

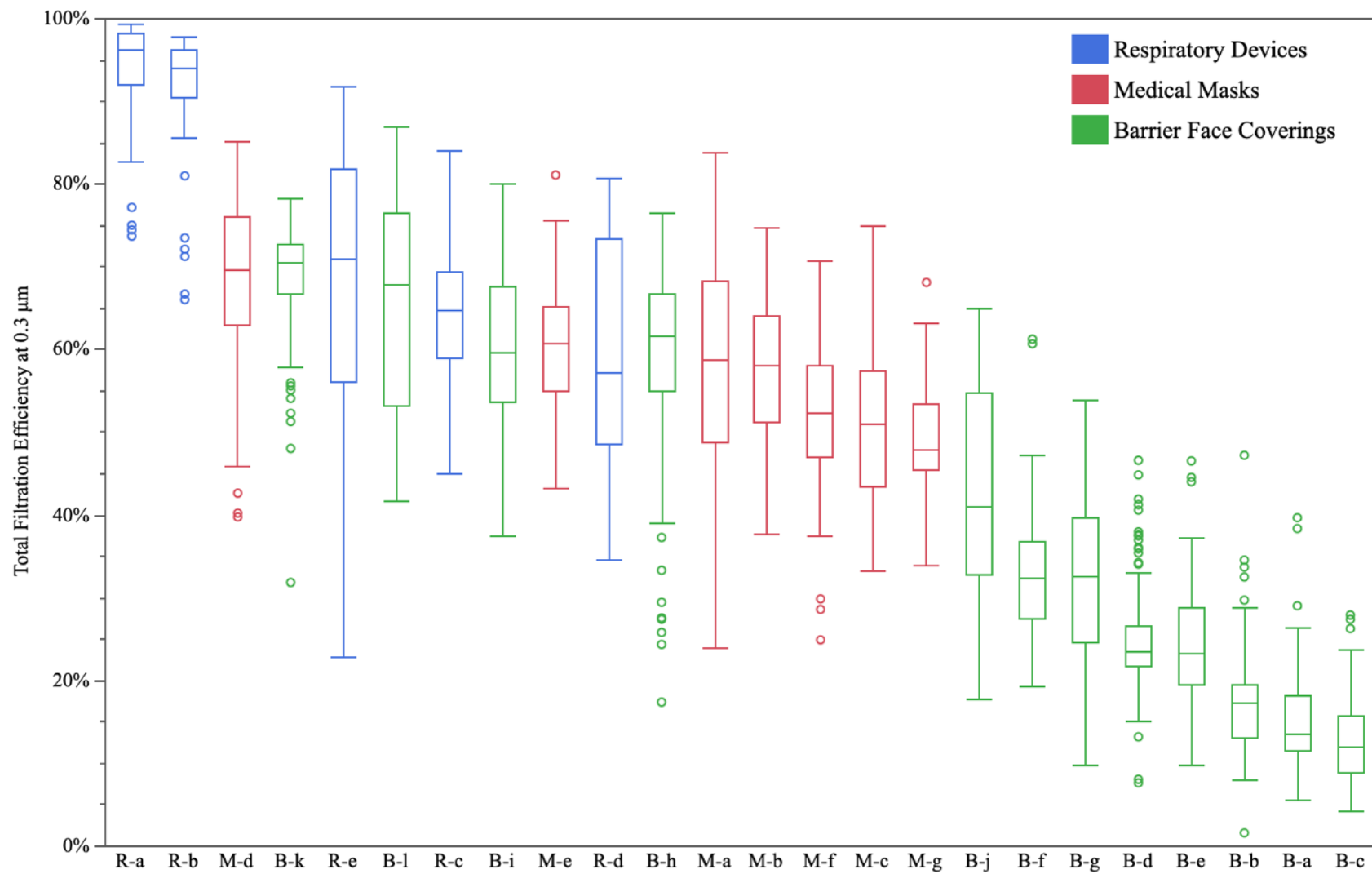


Figure 37. Box plot for TFE at 0.3 μm by sample in descending order of performance

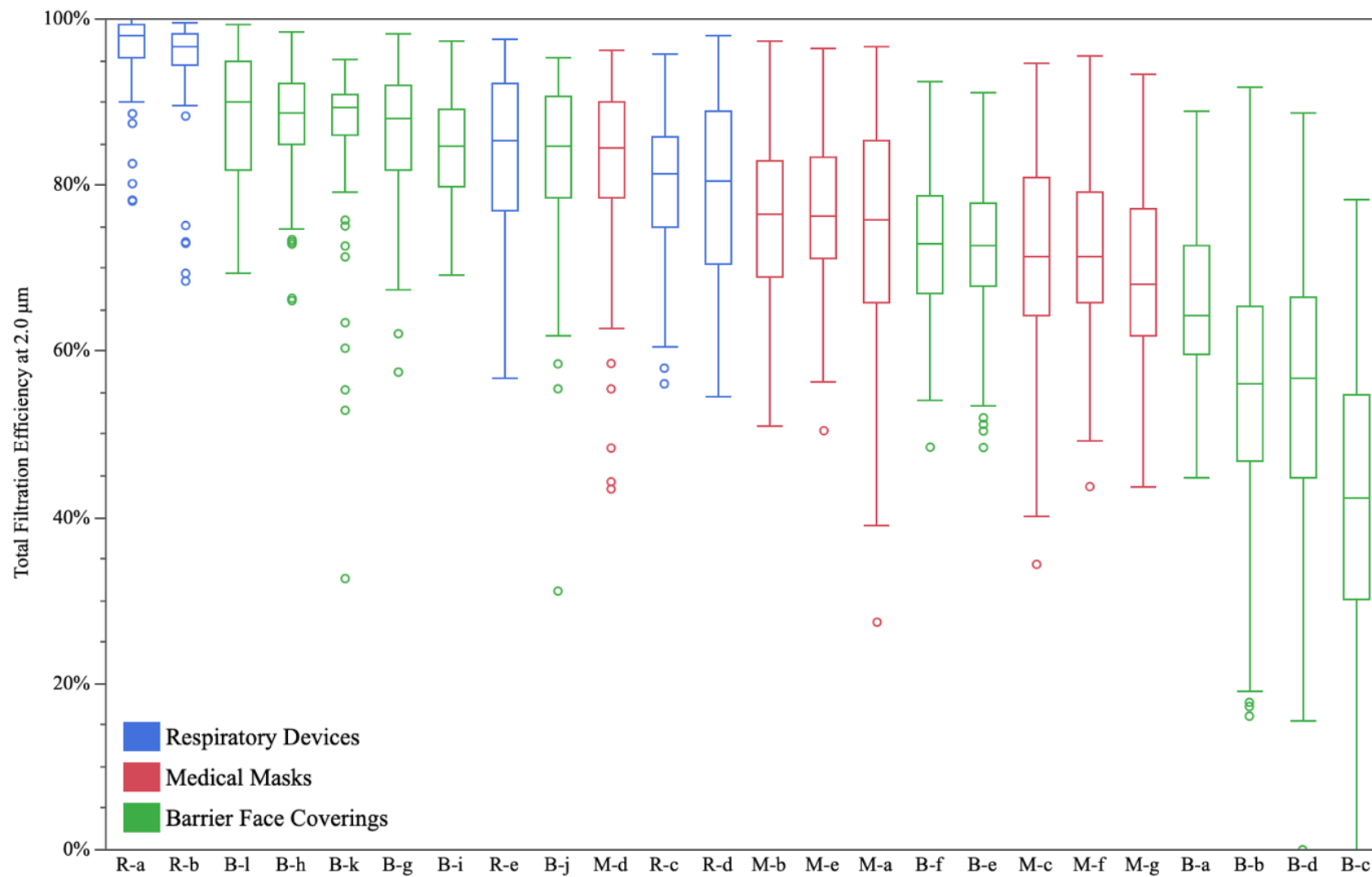


Figure 38. Box plot for TFE at 2.0 μm by sample in descending order of performance

The TFE data across product categories and material structures is shown in Figure 39. A one-way ANOVA test was used to determine if the baseline headform method could differentiate between the three product categories after incorporating a larger sample selection. The type of product was shown to be significant with $P < 0.0001$. A closer pairwise analysis using Tukey's HSD test found that all three groups, respiratory devices, medical masks, and barrier face coverings, were significantly different from each other at $P < 0.0001$ with differences across categories of 18-37% TFE at $0.3\ \mu\text{m}$. A similar analysis was used to compare the sample groups by their fabric structures. The woven, knit, and hybrid materials used in barrier face coverings were compared to the nonwovens typically found in N95s, KN95s, and medical masks. The one-way ANOVA test found at least one mean was statistically different from another across the four structures with $P < 0.0001$. Pairwise analysis identified that the means of each structure were considered statistically different from each other with $P < 0.0001$ for all pairs and differences in TFE between 7-47%. The largest change in TFE was between the nonwoven and woven samples.

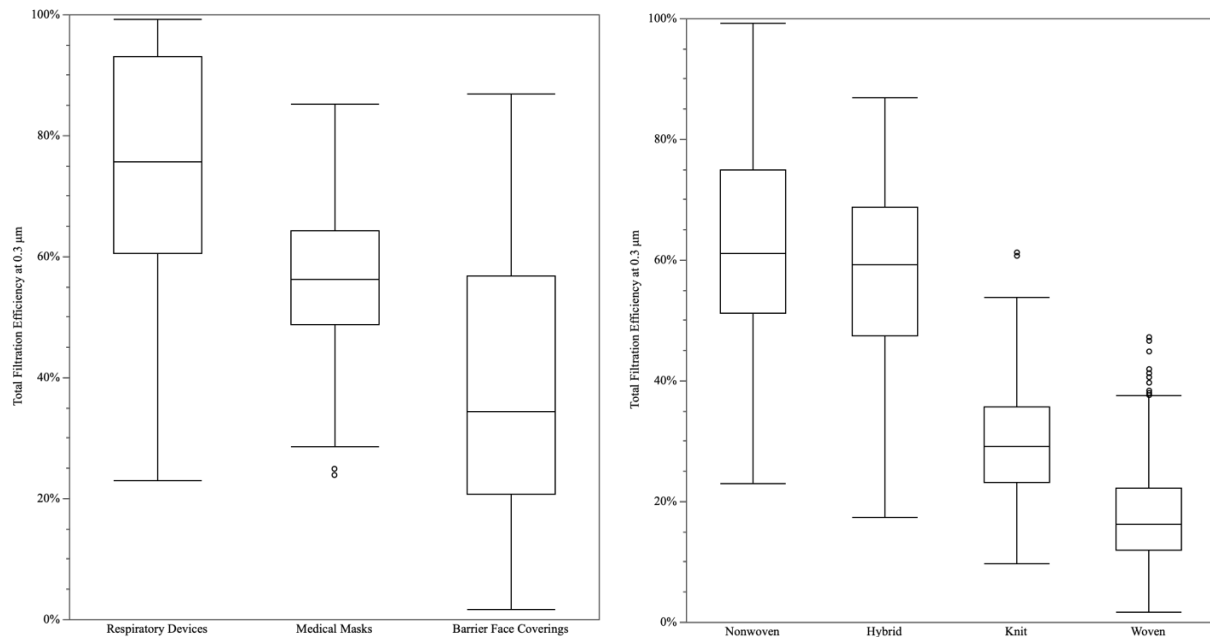


Figure 39. Box plots for TFE at $0.3\ \mu\text{m}$ comparing the three product categories (left) and the four material structures (right)

Earlier effects of movement, movement type, and the change over time on TFE at 0.3 μm were analyzed with two-way ANOVA tests by product category. The main effect of movement and the interaction between movement and product type were not statistically significant. Across the data, TFE during the static segment was less than 1% higher than the dynamic segment. A closer look at the dynamic segment found that the effect of the type of movement on the headform was significant at $P = 0.0346$ while its interaction with each product group was not. Visually, the bite movement still saw a decrease in TFE across the data set of around 4% from the head shake to the bite. However, the only statistically significant difference identified between activities with Tukey's HSD test was the 5% drop in TFE between the head shake and the last minute of stationary breathing at $P = 0.0219$. The main effect of time over the course of the static segment also showed statistical significance in the two-way ANOVA test with $P = 0.0001$. There was an 8% decrease in filtration from the beginning to the end of the five-minute test. A pairwise analysis across TFE data each minute found that the first minute of testing was statistically different from the fifth, fourth, and third minutes with $P = 0.0002$, $P = 0.0053$, and $P = 0.0250$, respectively. The second minute was also statistically different from the fifth minute at $P = 0.0270$. These all had clinically significant differences of 5% or more. However, the interaction between time and category was not found to be significant.

4.3.2 ASTM F3502-21

All 24 products were sent out to a third-party lab (Intertek) for ASTM F3502-21 testing. A subset of those samples had been previously tested at another facility (NWI). The mean and standard deviation (SD) of the particulate filtration efficiency and breathing resistance for each sample are reported from both labs in Table 15. Looking across the Intertek data, the respiratory

devices had PFEs between 92-100% and breathing resistances of 72-139 Pa. This would theoretically place them all at ASTM F3502-21 Level 2 filtration and Level 1 breathability. The medical masks performed similarly with 72-99% PFE and lower breathing resistances of 19-92 Pa, offering Level 2 filtration and both Level 1 and 2 breathability depending on the sample. The barrier face covering performance covered a much wider range of efficiencies from 1-91% and breathing resistances of 14-260 Pa. Three of these samples were in the Level 1 filtration range (B-d, B-h, and B-j) and another four made it to Level 2 filtration efficiency (B-c, B-i, B-k, and B-l). Of these seven products, three fell within Level 1 breathability (B-d, B-j, B-l) and two obtained Level 2 breathability (B-h and B-i) based on each mean. Their performance relative to the ASTM F3502-21 performance levels can be seen in Figure 40. It should be noted that the standard specifies that products should be classified by their minimum filtration or maximum breathing resistance, whereas this study uses the mean. This testing was completed to compare the results to the baseline headform method, not assess compliance to any performance levels.

A scatter plot of the filtration and breathing resistance for each sample tested at Intertek is shown in Figure 40. Pearson's correlation coefficients were used to determine the relationship, if any, between the two variables. Across the data set, the correlation coefficient was 0.3207 which indicated a weak positive relationship between filtration and breathing resistance. This relationship was further explored within each product category. The respiratory devices had a correlation coefficient of 0.0418 that showed no relationship between the two axes. The medical masks had the highest correlation at 0.7455 showing a moderate positive relationship between filtration and breathing resistance. Barrier face coverings also showed a moderate positive correlation between them at 0.5990. This indicated that higher filtering materials generally had higher breathing resistances.

Table 15. Filtration efficiency and breathing resistance of each product with ASTM F3502-21

Sample	Flow Rate L/min	Intertek		Flow Rate L/min	NWI	
		PFE ($\pm$ SD) %	BR ($\pm$ SD) Pa		PFE ($\pm$ SD) %	BR ($\pm$ SD) Pa
R-a	42.5	99.30 (0.45)	73.16 (4.47)	85.1	99.07 (0.20)	76.17 (4.24)
R-b	70.8	99.64 (0.09)	61.78 (5.19)	-	-	-
R-c	56.9	93.18 (0.96)	117.48 (3.43)	-	-	-
R-d	58.3	99.92 (0.08)	139.06 (7.70)	-	-	-
R-e	45.5	91.60 (0.72)	72.18 (7.29)	85.0	95.51 (0.59)	52.61 (2.26)
M-a	46.6	93.56 (0.35)	92.18 (1.96)	85.4	91.09 (0.60)	124.94 (2.11)
M-b	50.5	72.38 (1.04)	19.22 (0.54)	-	-	-
M-c	52.9	87.26 (0.80)	56.49 (2.83)	-	-	-
M-d	59.7	89.42 (0.33)	68.25 (2.91)	-	-	-
M-e	45.4	97.12 (0.37)	63.35 (2.46)	-	-	-
M-f	49.6	93.18 (0.40)	76.30 (4.97)	-	-	-
M-g	48.1	98.98 (0.40)	58.84 (1.55)	-	-	-
B-a	55.2	14.22 (1.83)	30.01 (3.64)	-	-	-
B-b	52.8	7.52 (1.08)	13.53 (1.28)	-	-	-
B-c	56.4	61.84 (3.26)	260.07 (21.95)	-	-	-
B-d	46.7	30.66 (4.87)	98.85 (7.83)	-	-	-
B-e	37.8	8.76 (1.07)	45.90 (3.13)	85.6	32.13 (4.45)	67.95 (4.93)
B-f	45.6	6.82 (1.23)	39.42 (3.35)	85.5	34.52 (4.66)	58.04 (7.32)
B-g	35.6	1.14 (0.73)	19.61 (2.69)	85.1	31.34 (7.00)	39.00 (5.56)
B-h	42.7	45.62 (8.74)	34.13 (6.26)	85.2	66.19 (7.02)	35.20 (9.45)
B-i	58.1	72.22 (7.94)	40.60 (11.45)	-	-	-
B-j	54.3	26.66 (2.74)	111.21 (10.02)	-	-	-
B-k	46.7	91.46 (1.07)	173.77 (12.16)	-	-	-
B-l	64.4	62.80 (4.09)	82.96 (9.19)	-	-	-

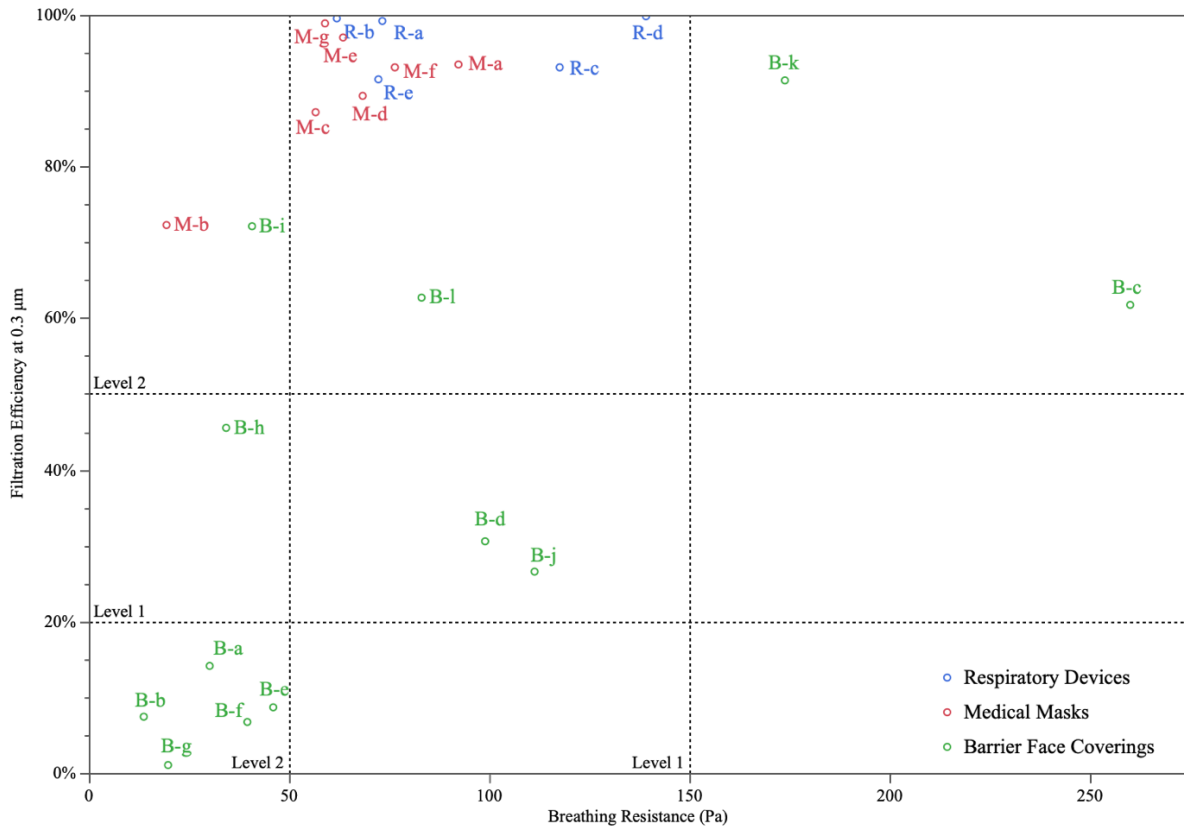


Figure 40. Scatter plot of the relationship between filtration and breathability across ASTM F3502-21 testing at Intertek by sample

One-way ANOVA tests were used to determine if there were significant differences between product categories and material structures as previously shown on the headform. The box plots showing these distributions are in Figure 41. At least one product category was found to be statistically different from another with $P < 0.0001$. Tukey's HSD test found that barrier face coverings were significantly different from respiratory devices and medical masks with a difference in means of around 54-61% PFE and $P < 0.0001$. The 6% difference between medical masks and respiratory devices was not statistically significant. Similarly, a separate ANOVA test found there was statistical significance between the material structure and the filtration efficiency. Pairwise analysis showed that nonwovens, hybrid systems, knit, and woven fabrics

were all statistically different from each other with $P < 0.0001$ and a difference in means of 23-87% PFE. The largest difference was between the nonwoven materials and the knit fabrics, which dropped noticeably lower than previously measured on the headform.

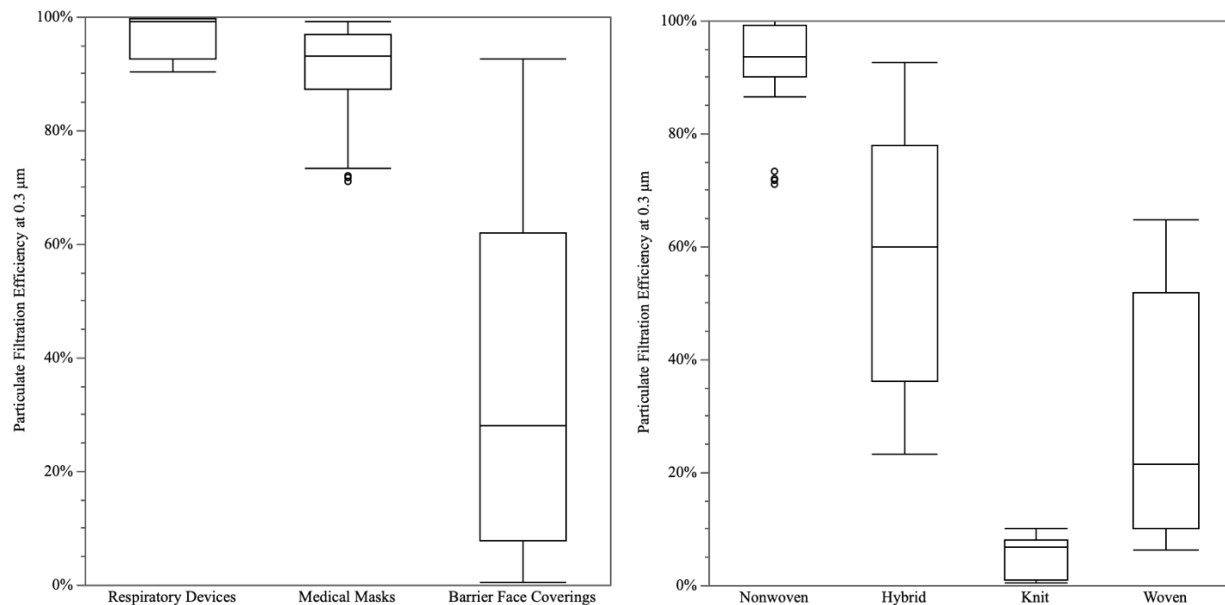


Figure 41. Box plots for PFE at 0.3 µm comparing the three product categories (left) and the four material structures (right) from ASTM F3502-21 testing

Seven of the products were tested at both third-party labs, Intertek and NWI. Different interpretations of the standard led to the samples being tested at considerably different flow rates. As a result, the filtration efficiency and breathing resistance measurements varied as shown in Figure 42. A two-way ANOVA test was used to determine if there was a significant difference in measurements across labs. First, the filtration efficiency at 0.3 µm was compared. Both the main effects of sample, lab, and their interaction identified at least one significant difference between means with $P < 0.0001$ across all three variables. The average PFE at Intertek was found to be significantly lower than NWI, around a 15% difference across the data set. Five of the seven samples had lower efficiencies at the lower flow rates ranging from 36-47 L/min. According to

Tukey's HSD test, all four barrier face coverings had significant differences between means where $P < 0.0001$ at a change in PFE of 21-30%. Meanwhile, the N95, KN95, and medical mask did not have significant differences between labs. A similar analysis was conducted to compare the influence of the main effects on breathing resistance. Both the main effects of sample, lab, and their interaction were significant with $P < 0.0001$. The average breathing resistance across the data set was significantly different between labs, around 11 Pa lower at Intertek. Pairwise analysis identified five statistically different pairs including a medical mask (M-a), KN95 (R-e), and three of the barrier face coverings (B-e, B-f, and B-g) all with $P < 0.0001$ and a difference in resistance of 19-33 Pa.

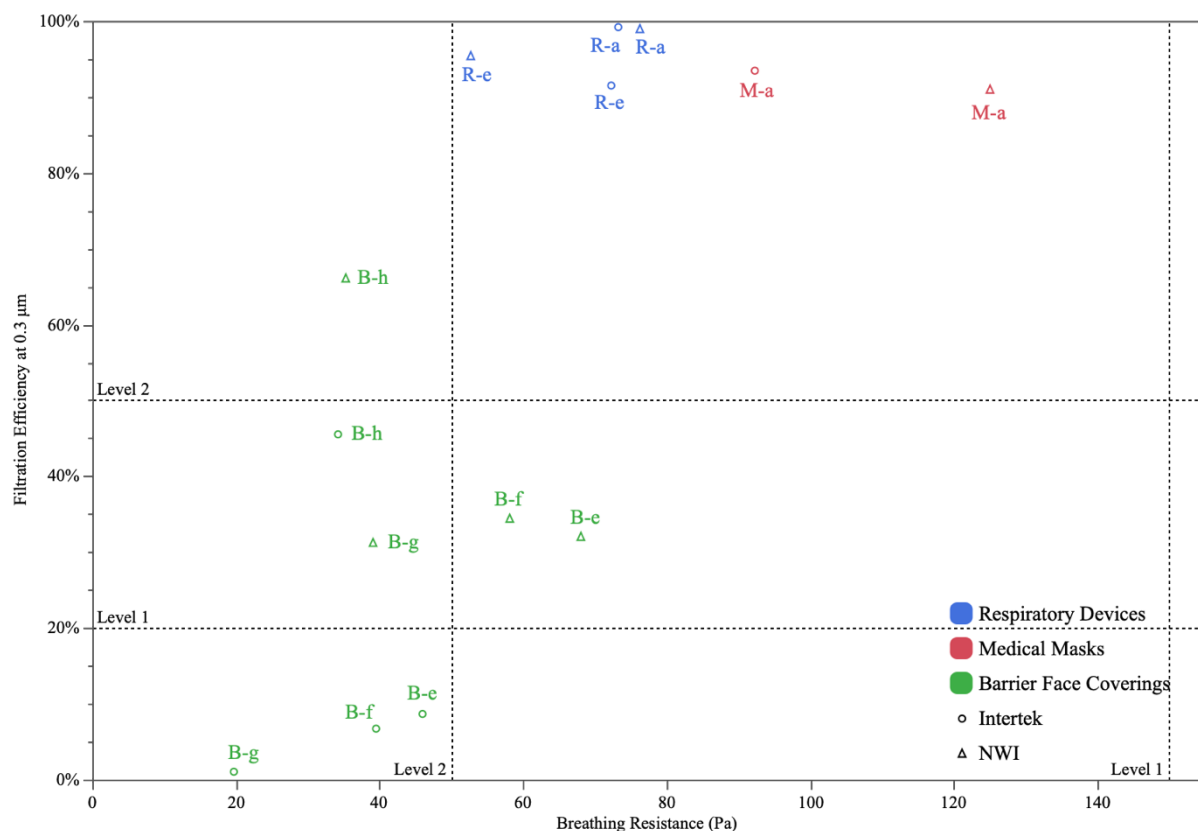


Figure 42. Scatter plot of the relationship between filtration and breathability across ASTM F3502-21 testing completed at two different labs by sample

4.3.3 Comparison of the Headform and ASTM F3502-21

The Intertek data using the ASTM F3502-21 Standard Specification was compared to the headform TFE at 0.3 μm in Figure 43 and Figure 44. PFE is measured by testing the product as a sealed system that behaves closer to the material filtration. As expected, the PFE with ASTM F3502-21 was higher than the headform TFE for all respiratory devices and medical masks; however, there were deviations in the barrier face coverings. Only four of the twelve samples (B-c, B-d, B-i, and B-k) had higher PFE compared to the headform. A two-way ANOVA test compared the filtration efficiency of both methods by product category. The main effects of category and method along with their interaction were all found to be statistically significant with $P < 0.0001$. Across the data set, there was a 13% decrease in filtration efficiency on the headform. Further pairwise analysis found that the respiratory devices and medical masks were both statistically different across methods, with $P < 0.0001$ for both and decreases in filtration efficiency of 21% and 34%, respectively. The 2% increase in filtration on the headform for barrier face coverings was not considered significant.

Another two-way ANOVA test was conducted to identify differences across methods for individual samples. Similarly, the main effects and their interaction were all found to be significant at $P < 0.0001$. Tukey's HSD test identified statistically significant differences between means for 13 of the 24 samples. This included the three KN95s (R-c, R-d, and R-e), six of the medical masks (M-a, M-c, M-d, M-e, M-f, and M-g), and four of the barrier face coverings (B-c, B-f, B-g, and B-k). Almost all pairs had $P < 0.0001$, except for B-k with $P = 0.0002$ and M-d with $P = 0.0027$. The smallest detected difference between means was seen in M-d with a 20% change in efficiency between methods. The remaining samples did not see a statistically significant change, although larger differences may still be considered clinically important.

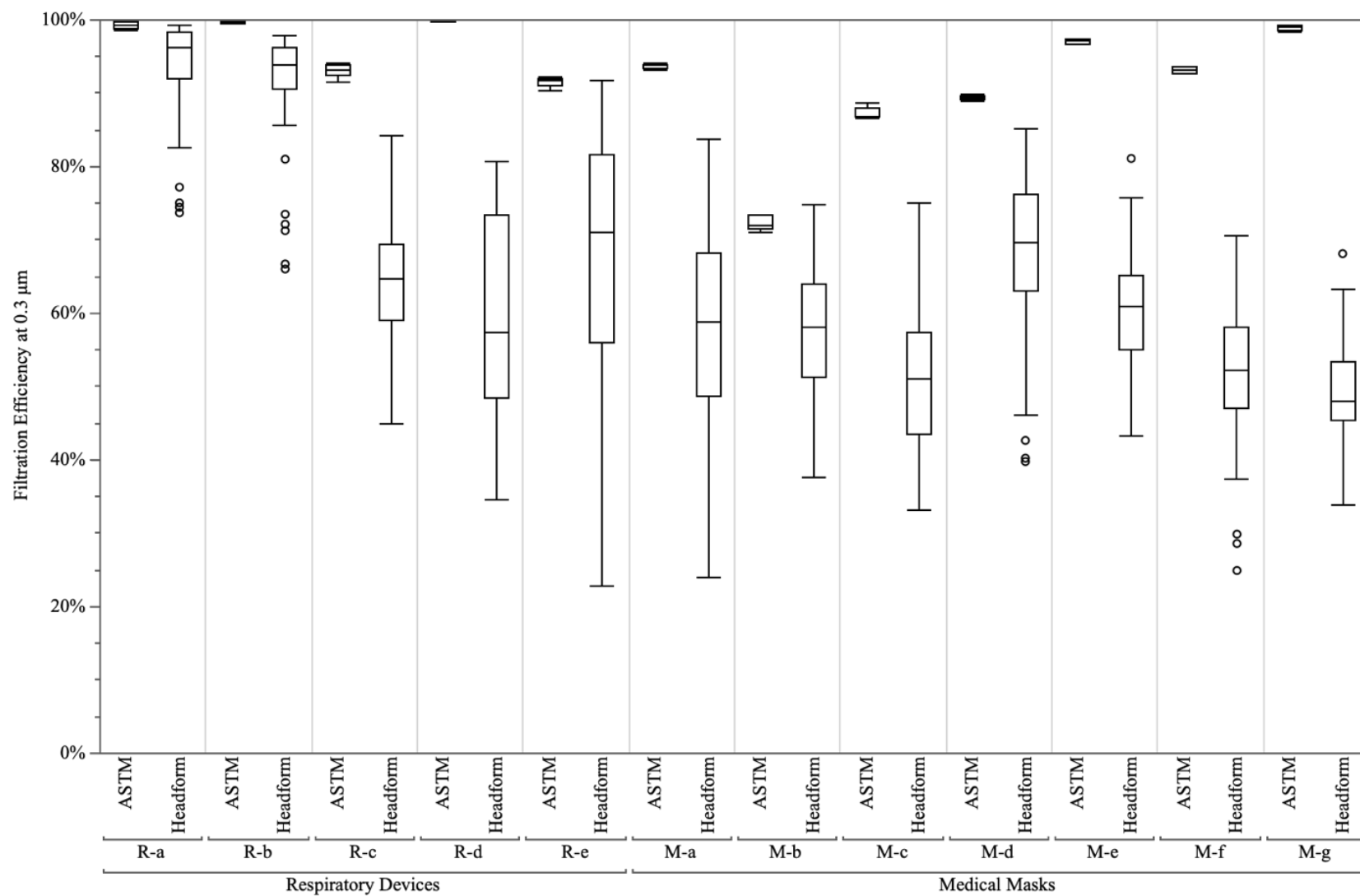


Figure 43. Box plot for TFE/PFE at 0.3 μm comparing the ASTM F3502-21 and headform method with respiratory devices and medical masks

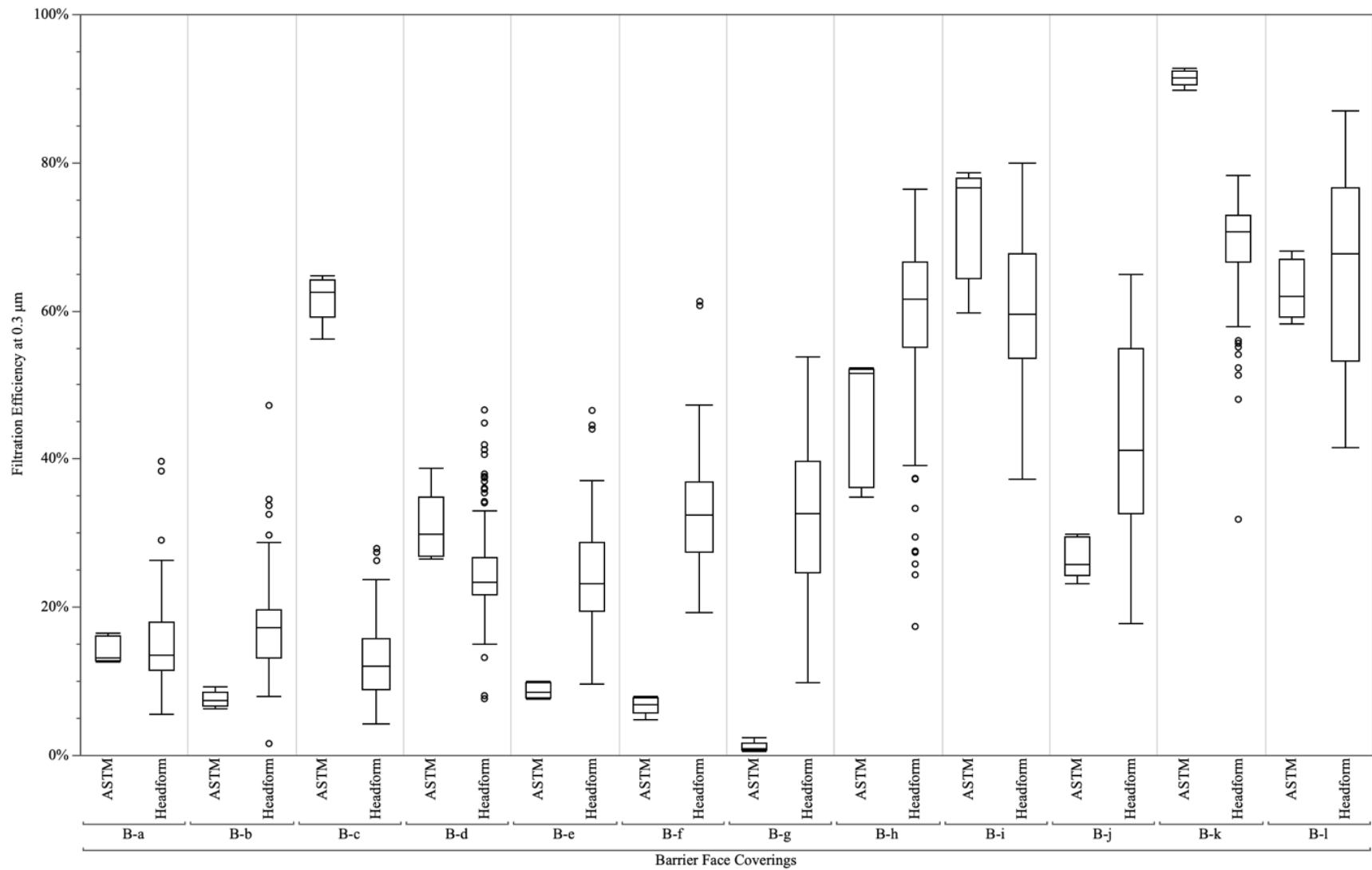


Figure 44. Box plot for TFE/PFE at 0.3 μm comparing the ASTM F3502-21 and headform method with barrier face coverings

The standard ASTM F3502-21 performance levels determined from the PFE and TFE values can also be compared. The two methods agreed on the classification levels for 75% of the samples. All respiratory devices achieved Level 2 filtration with both methods. Similarly, all medical masks had Level 2 filtration with the exception of M-g on the headform that fell to Level 1. Both tests placed three barrier face coverings (B-i, B-k, and B-l) at Level 2 and two (B-d and B-j) at Level 1 filtration. The remaining barrier face coverings saw some deviation between methods. The headform TFE for B-h reached Level 2, while the PFE was in the Level 1 range. Three samples (B-e, B-f, and B-g) could be classified at Level 1 filtration on the headform but did not make it above 20% PFE. B-c was also reported as Level 2 filtration from Intertek but had 13% TFE measured on the headform. This shows a reasonable agreement between methods despite their differences.

4.4 Discussion

The rising demand for barrier face coverings during the COVID-19 pandemic rapidly expanded the selection of products on the market. This study incorporated a wider variety of materials and designs to better assess the performance of products available to the general public. All 24 samples were evaluated on the animatronic headform using the baseline test method. The respiratory devices included two certified N95 respirator controls and three KN95s. The two N95s maintained performance across particle sizes and test methods as expected. The KN95s showed variable performance on the headform, filtering around 59-67% at 0.3 μm as opposed to their 95% or higher material filtration efficiency requirement. The decrease in filtration is likely due to difficulties fitting the samples. It also demonstrates the differences between the retention systems of the N95 head straps with the KN95 ear loops. Despite being categorized as a

respiratory device, the lower filtration efficiency of the KN95s largely overlapped with the performance of the medical masks.

Among the seven medical masks selected, five were certified under ASTM F2100-21 including one Level 1, two Level 2, and two Level 3. Another surgical style mask was classified as Level 2 for filtration and breathing resistance under ASTM F3502-21. Interestingly, the lowest performing medical masks on the headform were the two Level 3 samples (M-c and M-g) that theoretically should have had the highest performance. The only difference between Level 2 and 3 certification is the level of fluid resistance. This higher liquid resistance in the Level 3 mask may have made it more difficult for air to pass through, forcing particles to find a path around the mask instead of filtering through it. However, it is important to remember that medical masks were not designed for respiratory protection, rather as a method of source control and a physical barrier to bodily fluids that can be encountered in healthcare settings.

The barrier face coverings were able to obtain a range of filtration efficiencies on the headform depending on their material and design. The knit fabrics were shown to have higher TFE than the woven fabrics, which was surprising. Previous literature suggested multiple layers of tightly woven fabric were the best option for homemade face coverings due to their high density and low porosity [5], [7]. However, the knit samples were able to stretch and conform to the curves of the face, offering a closer fit than some of the woven materials. The knit fabrics were also thicker, and heavier weight fabrics have been shown to increase filtration [5]. This demonstrates the complex interplay of material properties and filtration efficiency. The hybrid systems had the highest TFE of the group due to their additional layers of nano fabric or nonwoven filters that helped capture smaller particles. This additional material filtration

efficiency increased the overall performance, making them more comparable to some of the other medical masks and KN95s.

Fit is another important consideration that can be assessed on the animatronic headform. A comparison of TFE across particle sizes offered a better indicator of each sample's ability to fit to the face. Across the 0.3 and 2 μm particle sizes, the barrier face coverings saw an improvement in TFE at the larger particle size. This suggested that many of these products were able to obtain a reasonable fit compared to the other samples. Of the barrier face coverings, the hybrid materials had the highest filtration at 2 μm , followed by the knit and woven samples but there were no clear trends across product designs. The medical masks noticeably fell further down the order of performance at 2 μm due to their loose-fitting pleated design. The KN95s also saw a shift in position from 0.3 to 2 μm likely from difficulties with consistently fitting the headform.

The three product categories (respiratory devices, medical masks, and barrier face coverings) were all shown to be clinically and statistically different from each other. This demonstrated that the baseline method could reliably distinguish between groups. The effects of movement, movement type, and time on TFE across the data set showed some changes from the earlier analysis. There was not a significant difference between the static and dynamic segments across product categories. The type of movement during the dynamic segment appeared to have a similar decrease in TFE during the bite movement, but the only statistical difference was between the head shake and stationary breathing in the first and last minute of the test. This may be more closely related to the change in performance over time as opposed to these specific activities. There was a significant decrease in filtration from the first minute to the last three

minutes of the static segment as previously suggested. These are important considerations for products that are intended to be worn for extended periods of time during regular activity.

All samples were sent to a third-party lab, Intertek, for ASTM F3502-21 testing. The respiratory devices and medical masks all fell within the two classification levels. However, it is important to note that this standard is not intended to evaluate the performance of either group, which have additional requirements depending on their application. Five of the twelve barrier face coverings also fell within standard performance levels including one woven sample (B-d) and four of the hybrid systems (B-h, B-i, B-j, and B-l). There was a weak positive correlation between filtration efficiency and breathing resistance across the entire data set. A more moderate correlation was apparent within the medical mask and barrier face covering categories. Statistical analysis confirmed that the standard test was able to clinically and statistically differentiate this selection of barrier face coverings from the other two product categories.

Seven of the samples were also sent to another third-party lab, NWI. There were significant differences between the results from both labs because testing was completed at different flow rates. The ASTM F3502-21 Standard Specification leaves too much room for interpretation when deciding the appropriate flow rate or face velocity at which to test the products. In one section, it states that a face velocity of 10 cm/s should be used for testing. A later section says that the samples should be tested at a flow rate of 85 L/min unless the product is tested flat, then flow rate should be calculated using a 10 cm/s face velocity and the surface area of the sample. Both groups of products were mounted on a molded face form which arguably leaves both interpretations of the standard correct. However, testing at the higher 85 L/min flow rate was shown to have significantly higher filtration efficiency. All four barrier face coverings were found to have statistically different PFE and three of them had significant

differences in breathing resistance as well. While this did not impact the ASTM F3502-21 classification of the respiratory devices and medical masks, all four of the barrier face coverings were placed in a different level of filtration, breathability, or both depending on the lab. This is especially important considering the standard is intended to evaluate these types of products.

A comparison between ASTM F3502-21 and the baseline headform method was conducted with the Intertek data. The ASTM products were mounted and sealed around the edges during testing, which does not consider leakage due to poor fit that has been shown to reduce filtration efficiency [9]. The headform measures the sample on a three-dimensional form as worn, which allows fit to be incorporated into the TFE value. The performance of respiratory devices and medical masks notably decreased when they were measured on the headform. However, several barrier face coverings saw higher TFE with the baseline method. This may be related to differences in flow rates between the lower sinusoidal breathing on the headform and the high constant flow on the filter tester. The inherent variability of system-level testing may have also contributed. Despite these differences, overall, there was a 13% decrease in filtration efficiency measured on the headform. This demonstrates the importance of incorporating fit into the measurement of these alternative products that do not seal to the face.

This comparison had several limitations. There were only five replicates of the ASTM F3502-21 testing from Intertek, when the standard and the current headform method both require ten. The headform data was only compared to the Intertek data that tested the samples at lower flow rates based on their surface area and a 10 cm/s face velocity. However, the analysis could be very different if all the testing had been at 85 L/min instead. Only seven samples were tested at both labs, which made for a limited comparison. The Intertek testing was done in two groups while the NWI testing was completed in one. The data was later analyzed based on the mean as

opposed to the minimum or maximum reported values, which may lead to higher suggested classification levels.

4.5 Conclusions

The baseline headform method was able to consistently differentiate between respiratory devices, medical masks, and barrier face coverings across the larger sample size. As previously discussed, TFE significantly decreased over the course of the test. However, movement played less of a role in TFE across the larger data set. The differential particle counts also allowed for a comparison in filtration efficiency across particle sizes. The changes in TFE from 0.3 to 2 μm were a good indicator of fit. This method was compared to the Standard Specification for Barrier Face Coverings, ASTM F3502-21. ASTM testing was done at two third-party labs, producing statistically different results because they measured at different flow rates based on separate interpretations of the same standard. The Intertek data was ultimately compared to the headform. There was an overall decrease in filtration efficiency between the ASTM F3502-21 sealed product test and the headform method. The decrease in TFE on the headform can largely be attributed to leakage around the perimeter of the face due to poor fit. However, the two methods agreed on the product performance levels under ASTM F3502-21 around 75% of the time, indicating similarities between the material and system-level tests.

Additional research may further analyze the differences between the ASTM F3502-21 results to confirm if flow rate is the only variable significantly impacting the data. It would also be helpful to measure the differential pressure on the headform to compare the breathing resistance during the baseline method to the ASTM F3502-21 results and determine if a similar correlation between filtration and breathability exists on the headform. Ultimately, the baseline

headform method will be optimized to create a more streamlined test in a controlled environment to reduce the variability within samples.

CHAPTER 5: Validation Study of the Optimized Headform Test Method

5.1 Introduction

Literature has largely focused on determining the factors that influence the filtration efficiency of barrier face coverings on the material level. Recently, there has been greater recognition of the importance incorporating leakage into the performance value. The ASTM F3502-21 Standard Specification for Barrier Face Coverings offers an optional leakage assessment using a modified version of the respirator fit test to determine the leakage ratio on a bivariate panel of participants. Fit factors for barrier face coverings can be very low and difficult to compare across products. They also do not differentiate between low filtration efficiency and poor fit. Several studies have been able to qualitatively assess outward leakage with a laser to illustrate transmission. Particles were shown to follow the path of least resistance, escaping around gaps around the bridge of the nose, under the chin, and at the sides of the face [64], [66]. As source control devices, outward leakage is of considerable interest. Currently, there is no standard method to quantify outward leakage.

This study developed an optimized headform method to evaluate inward leakage by making small modifications to the baseline method to condense the protocol and reduce the variability within each sample. The goal is to be able to reverse the direction of particle generation in the future to quantifiably compare inward and outward leakage on the headform. A smaller selection of samples was used to incorporate a range of respiratory, medical mask, and barrier face covering designs. A closer analysis on the fit of surgical masks was conducted to assess their variable filtration efficiency. The optimized method was compared back to the original test to determine the effectiveness of these changes.

5.2 Methodology

5.2.1 Samples



Figure 45. Simplified sample selection including several respiratory devices (R), medical masks (M), and barrier face coverings (B)

Twelve commercially available products were down selected from the previous study to include three respiratory devices, three medical masks, and six barrier face coverings shown in Figure 45. These samples were chosen to represent the different styles available to the general public during the COVID-19 pandemic. The three respiratory devices included a certified N95 respirator control and two styles of KN95s. The three medical masks across different certification levels were selected to cover a range of performance. The six barrier face coverings were composed of two woven fabrics, two knit fabrics, and two hybrid systems that incorporated nano fabrics in their construction through various designs. Additional sample characteristics can be found in Appendix B.

The face coverings were preconditioned for at least 25 hours and tested in an environmental chamber under standard conditions of $20 \pm 2^\circ\text{C}$ and $65 \pm 5\%$ relative humidity [73]. Each sample was carefully donned and fit to the headform. In an effort to reduce the variability of fit within each style, adjustable straps were fit on the headform before the first trial then measured to adjust the remaining samples accordingly. The three medical masks were tested

twice, once with the 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 ten replicates tested as received. These twelve face coverings were compared to their earlier performance measured using the baseline test method. However, there were some differences in the newer batch. A similar N95 (R-a) from the same brand was selected based on availability. The surgical style mask (M-b) appeared to have changed ear loops, while the knit cotton face covering (B-e) was slightly smaller than the original.

5.2.2 Baseline Headform Test Method

The i-bodi Fully Animatronic Respirator Testing Headform was previously used to develop a baseline method to evaluate the efficacy of alternative products like medical masks and barrier face coverings that are not intended to seal to the face. It allows the incorporation of fit into the final performance value. The robotic headform is covered in a silicone skin to achieve a realistic fit. It is connected to a digital breathing machine below, with tubing that comes through the mouth cavity of the headform to simulate breathing. The i-bodi software allows for programmable breathing and movement protocols. The headform is enclosed in a $3.43 \times 10^5 \text{ cm}^3$ acrylic chamber with a removable front loading door to connect outside the system.

Two six-channel Fluke® 985 particle counters were connected inside the chamber and mouth cavity of the headform through two pieces of 80 cm tubing to measure the cumulative and differential particle counts upstream and downstream. The ratio between the particle counters varied within acceptable limits, approximately $4.52 \pm 3.11\%$ at $0.3 \text{ }\mu\text{m}$. The particle counts at $0.3, 0.5, 1, 2, 5,$ and $10 \text{ }\mu\text{m}$ inside and outside the sample were recorded each minute with a flow rate of 2.83 L/min . These values were used to calculate the total filtration efficiency (TFE) every

minute using Equation 6. The percentage of particles that penetrate the sample (%P) or total inward leakage is determined by the ratio of particles measured inside the sample over the particles in the outside environment. The term TFE is used to describe the systemic measurement of filtration efficiency that incorporates both fit and material performance into the final filtration value.

Equation 6. Total filtration efficiency

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

In the baseline method, temperature and relative humidity were recorded but not controlled. Temperatures ranged from 21.1-23.3°C and 26.2-63.5% relative humidity across days. Testing was conducted when ambient particle counts fell below 100,000 particles/min or approximately 35 particles/cm³ at 0.3 µm to ensure the generated 2% NaCl aerosol did not exceed concentration limits of the particle counters. The unneutralized, polydisperse aerosol was generated inside the chamber using a TSI Single-Jet Atomizer 9302 connected to a tank of compressed nitrogen gas outside the system. The atomizer was turned on at a low pressure around 2.0 ± 0.5 psi before the start of each test and run through each five-minute segment. An air purifier was run in-between, and the sample was removed from the chamber in order to reset the environment.

Each test cycle consisted of a pair of test segments, a static and dynamic protocol. The static segment consisted of five minutes of stationary breathing. After a ten-minute break to clear out the chamber, the dynamic segment ran through five minutes of a programmed movement protocol. It included a minute of head shaking side to side, nodding up and down, biting opening and closing the jaw, wobbling shoulder to shoulder, and one last minute of stationary breathing. Each movement operated at a speed of 24 reps/min. A sinusoidal breathing sequence programmed to 16.26 BPM with a tidal volume of 0.98 L ran during each segment. This equates

to a minute volume flow rate of approximately 16 L/min and a peak inspiratory flow rate of around 50 L/min. Ten replicates of this test cycle were completed for each sample by two different operators.

5.2.3 Optimized Headform Test Method

The optimized method used the same advanced headform and particle counters with some adjustments to the testing parameters. The headform was moved into an environmental chamber for testing to control temperature and relative humidity. These two setups can be compared in Figure 46. Testing was carried out in the same standard conditions that the samples were previously preconditioned to at $20 \pm 2^{\circ}\text{C}$ and $65 \pm 5\%$ relative humidity. Additional dehumidifiers were used as needed to maintain these conditions. The chamber is approximately 300 ft² and equipped with several temperature and humidity probes across the space to continuously monitor the environment. The wind speed, temperature, and relative humidity were also measured directly next to the headform using two Kestrel 5000 anemometers. A wind speed of 0.7-0.8 m/s was recorded throughout the trial. The chamber measurements for temperature and relative humidity were later pulled and matched to the TFE data based on their time stamps.

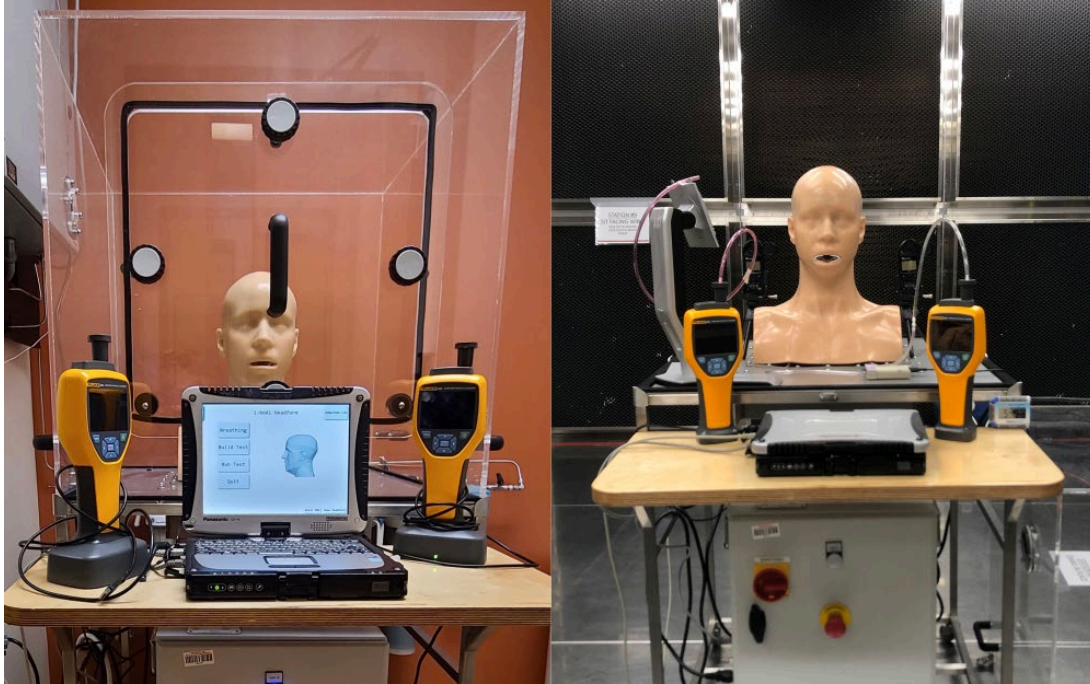


Figure 46. Baseline (left) and optimized (right) test method setups with the advanced animatronic headform

The headform was positioned in the middle of the chamber facing away from the wind. A TSI Particle Generator 8026 was placed six feet directly behind it and ran continuously to generate a polydisperse NaCl aerosol to fill the chamber. An air purifier was used simultaneously in the opposite corner to help control particle concentrations. Testing was conducted between 50,000-150,000 particles/min or 18-53 particles/cm³ at 0.3 μ m from the combined ambient and aerosol particles. The particle generator was able to maintain a more consistent concentration throughout testing without needing to reset the environment.

A combined protocol was designed to replace the two static and dynamic segments in the baseline method. The new ten-minute test consisted of two minutes of stationary breathing followed by a minute of each of the movements bite, head nod, and head shake at 24 reps/min. These three movements were repeated for another three minutes before ending the test with two more minutes of stationary breathing. An additional two minutes of stationary breathing were

added to the beginning of the protocol before measurements began to clear out any residual particles in the mouth cavity. The breathing protocol was also adjusted based on the reported respiratory rates from ISO 16976-1:2015. A sinusoidal breathing rate of 15.12 BPM with the same 0.98 L tidal volume was used for a volume flow rate of approximately 15 L/min based on the calculated minute volume to perform a light workload for a healthy medium sized adult [74], [75]. This corresponds to a peak inspiratory flow of around 46 L/min. An open 3D printed mold was added inside the mouth cavity of the headform to keep the silicone lips from being sucked into the mouth while breathing. A single operator conducted all ten replicates for each sample type.

5.2.4 Statistical Analysis

The data was analyzed using JMP® Pro 16.0 statistical software to determine the repeatability of the optimized test method and compare it back to the baseline. The data was analyzed by its residuals to confirm normality. The statistical analysis followed the same process as previous chapters. An Analysis of Variance (ANOVA) test was used to compare the total filtration efficiency at 0.3 μm across the different samples and experimental conditions. A p-value (P) below 0.05 was considered significant enough to reject the null hypothesis that assumed all sample means were equivalent. This identified that at least one mean TFE value was different from another. Despite the identification of statistically significant differences, clinical significance was further defined as a change in TFE of 5% or more. If $P < 0.05$, Tukey's Honest Significant Difference (HSD) test was used for post hoc testing to comparatively analyze the differences between pairs.

5.3 Results

5.3.1 Total Filtration Efficiency

The mean TFE and standard deviation for each sample evaluated with the optimized headform test method are reported in Table 16. TFE was measured differentially at 0.3, 0.5, 1, 2, 5 and 10 μm particle sizes. The 5 and 10 μm particles were included in the calculation of cumulative TFE but excluded from the table due to the small number of particles generated at those sizes. The N95 respirator control (R-a) maintained 93-97% TFE across particle sizes. The two KN95s (R-c and R-d) filtered around 46-53% at 0.3 μm . The three medical masks were tested as received and then adjusted to improve their fit. Unadjusted, the three products (M-b, M-c, and M-d) performed around 37-45% at 0.3 μm . When the ear loops were tightened, all three masks increased efficiencies from 44-53% in the same range as the KN95s. These moderately performing products showed the highest standard deviation but remained below 10% at 0.3 μm . The hybrid face coverings (B-h and B-j) were next, ranging from 28-57% TFE. B-h was notably higher than the other nonwovens. Lastly, barrier face coverings made from knit and woven fabrics (B-b, B-d, B-e, and B-f) filtered from 14-18% at 0.3 μm . Almost all samples increased TFE across particle sizes shown in Figure 47, with the exception of two barrier face coverings (B-d and B-j) that saw uncharacteristic drops at 2 μm . This may be due to poor fit or possible material shedding.

Table 16. Total filtration efficiency of each product with the optimized test method

Sample	Mean Total Filtration Efficiency ($\pm$ Standard Deviation) %				
	0.3 μm	0.5 μm	1.0 μm	2.0 μm	Cumulative ^A
R-a	92.69 (2.82)	95.21 (1.88)	96.11 (1.74)	96.69 (2.77)	92.93 (2.74)
R-c	53.34 (6.77)	68.34 (5.70)	74.65 (4.83)	79.31 (6.95)	55.07 (6.47)
R-d	45.72 (3.91)	62.01 (3.28)	70.70 (3.27)	77.03 (5.04)	47.60 (3.88)
M-b	44.79 (4.56)	59.20 (4.13)	68.91 (4.22)	77.34 (4.61)	47.29 (4.43)
M-b Adjusted	48.00 (4.61)	62.07 (3.84)	71.29 (3.29)	76.01 (5.29)	50.98 (4.37)
M-c	36.54 (4.13)	53.36 (3.86)	65.57 (3.92)	75.81 (4.81)	39.58 (4.12)
M-c Adjusted	44.30 (5.67)	60.94 (4.50)	71.42 (3.85)	76.80 (5.93)	47.68 (5.43)
M-d	45.48 (6.04)	60.95 (5.13)	68.76 (4.50)	74.85 (6.41)	47.43 (5.89)
M-d Adjusted	53.19 (8.20)	64.95 (6.61)	74.45 (5.16)	80.51 (5.55)	55.61 (7.84)
B-b	13.87 (1.24)	43.57 (2.51)	56.13 (3.68)	62.25 (13.79)	16.81 (1.33)
B-d	16.05 (2.62)	44.49 (4.82)	56.23 (5.03)	49.11 (37.42)	18.90 (2.69)
B-e	17.83 (2.26)	48.27 (5.08)	64.31 (5.44)	68.91 (18.01)	21.03 (2.38)
B-f	16.89 (2.28)	36.22 (3.56)	51.57 (4.49)	65.18 (6.36)	20.35 (2.39)
B-h	57.01 (4.65)	77.68 (3.52)	84.89 (3.37)	89.72 (4.05)	59.04 (4.57)
B-j	28.36 (4.51)	52.84 (6.13)	66.69 (9.92)	8.21 (196.81)	32.36 (4.49)

^A Cumulative results were calculated as the sum of all particle sizes from 0.3-10 μm

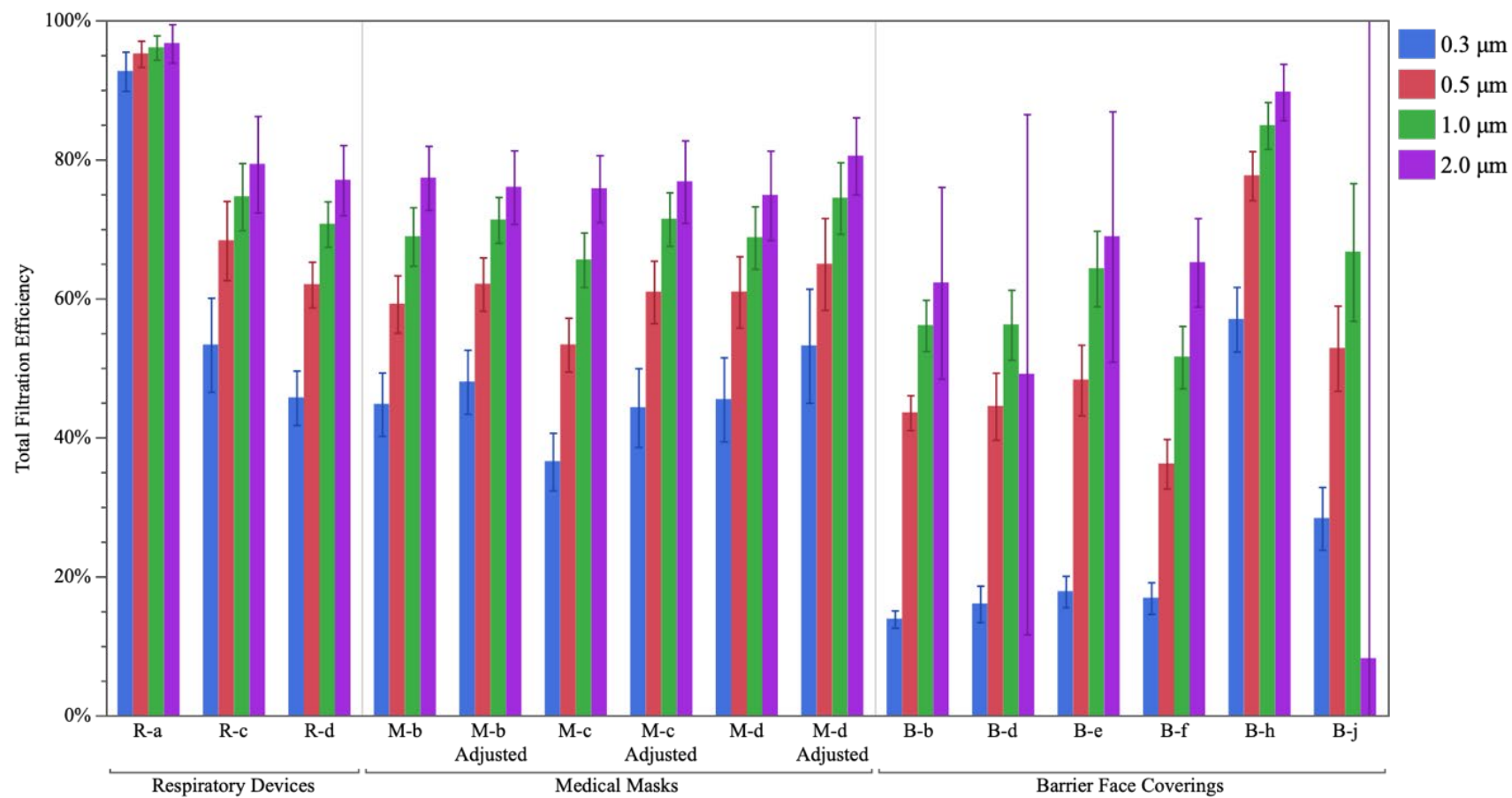


Figure 47. TFE for all samples across each particle size with the optimized test method

The TFE distributions across groups and individual samples at 0.3 μm are shown in Figure 48. A one-way ANOVA test was used to determine if the optimized method could differentiate between the average TFE for each of the three product categories. The resulting $P < 0.0001$ indicated there was a statistically significant difference between at least one of the means. Tukey's HSD test showed that the overall TFE for respiratory devices, medical masks, and barrier face coverings were all significantly different from each other, varying 19-39% TFE with $P < 0.0001$. This demonstrated that the optimized method was able to differentiate between the three product groups.

Another one-way ANOVA test was used to compare all of the samples across categories and found similar results with $P < 0.0001$. The pairwise analysis identified that the majority of samples were statistically different from each other, while only around 10% of the pairs were not. Most of these indistinguishable differences in means were between samples in the same product group. The test also had difficulty differentiating between the KN95s and medical masks. The lowest measurable significant difference in TFE reported at 0.3 μm was around 2% between R-d and the adjusted M-b with $P = 0.0391$. 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 $P \leq 0.0001$. This 3-8% increase in TFE showed that tightening the ear loops improved performance, reiterating the importance of fit in total filtration efficiency.

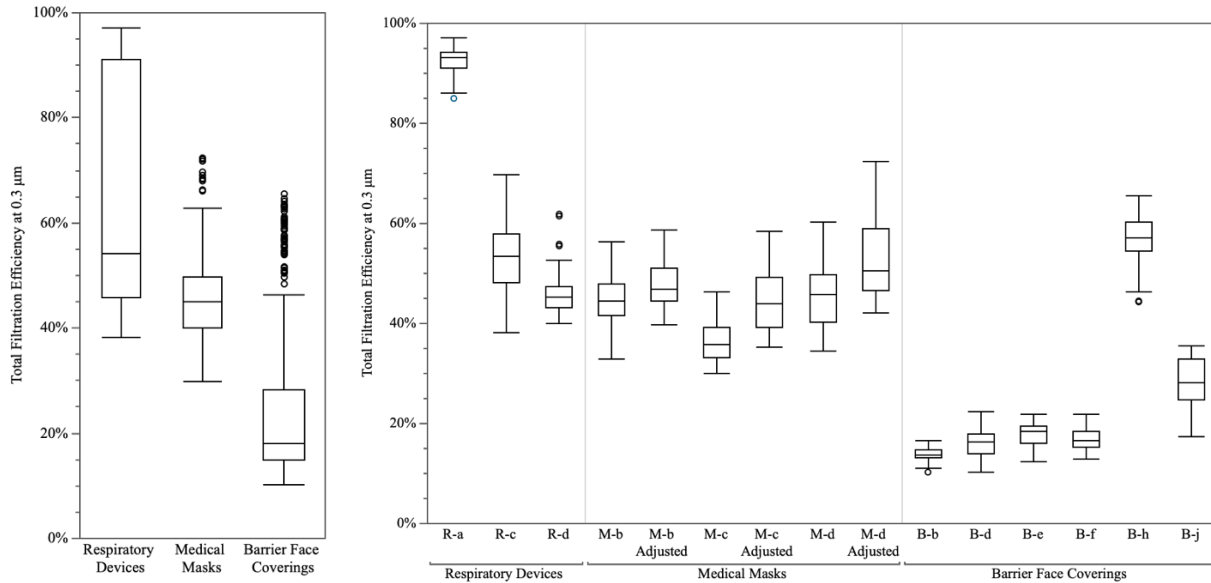


Figure 48. Box plots for TFE at 0.3 µm comparing the three product categories (left) and the individual products (right)

5.3.2 Movement

The combined headform protocol consisted of both static and dynamic activities. There were four minutes of stationary breathing, two at the beginning and two at the end that made up the static data set, while the dynamic data set comprised of the six minutes of movement in between. The difference in TFE at 0.3 µm across static and dynamic sections of the test for each sample are shown in Figure 49. A two-way ANOVA test was used to statistically analyze the main effects of sample, movement, and their interaction. Sample and the interaction of sample and movement were both found to be significant with $P < 0.0001$. However, the static and dynamic sections themselves were not statistically different across the data. A pairwise analysis was conducted to determine which samples were influenced by headform movement. Only two samples had statistical differences in TFE, both were adjusted medical masks (M-d and M-c) with $P < 0.0001$ and $P = 0.0130$, respectively. This represented a decrease in TFE of 4-5% at 0.3 µm during the dynamic section, which was only clinically significant for the adjusted M-d. This

correlated with the results from the baseline method. However, the majority of samples actually appeared to have marginally higher TFE when the headform was moving.

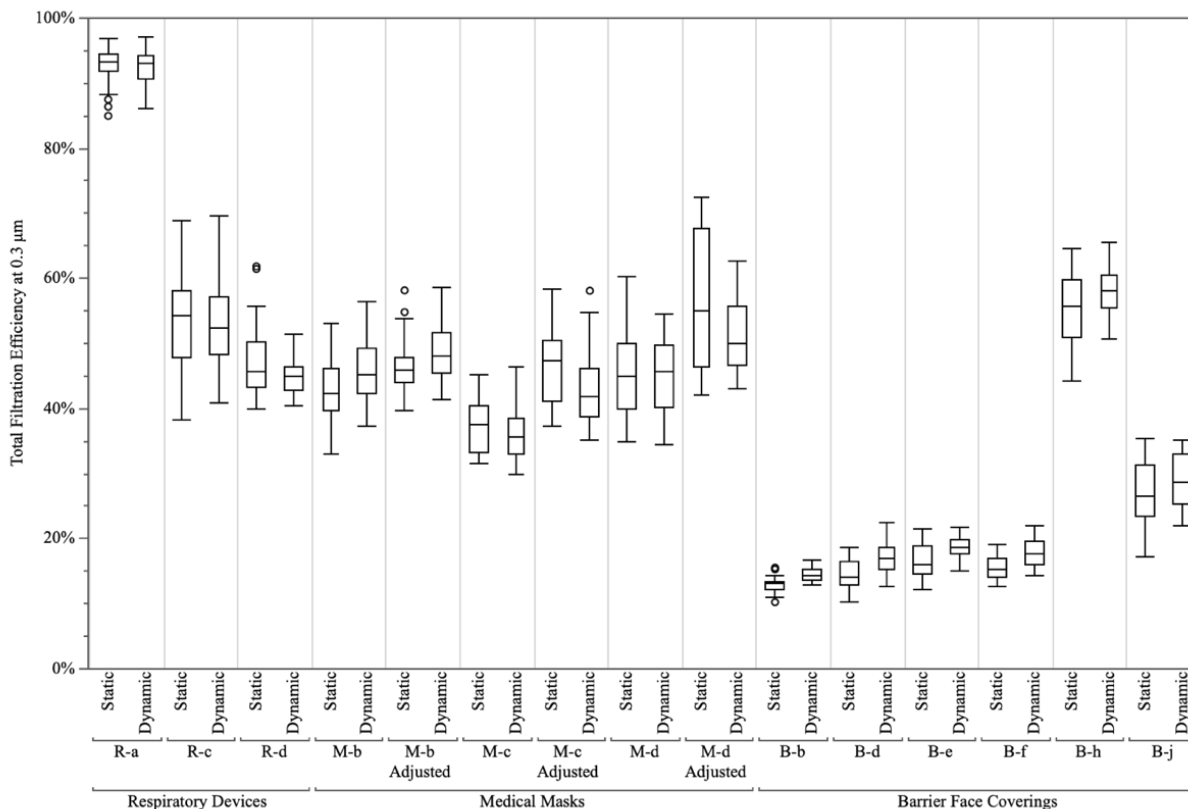


Figure 49. Box plot for TFE at 0.3 μm comparing the static and dynamic sections of the optimized test method by sample

The static and dynamic sections can be broken down by individual activities as shown in Figure 50. The protocol included two minutes of each movement for the bite, nod, and head shake along with four minutes of stationary breathing. A two-way ANOVA test was used to analyze these activities and their interaction with the samples. Both the main effects and their interaction were statistically significant with $P < 0.0001$. Across the data set, the bite was identified as statistically different from the other three movements at $P < 0.0001$ showing a 2-3% increase in TFE that was not considered clinically significant. The pairwise analysis of the

interaction between sample and activity identified significant differences in six of the samples, the flat fold KN95 (R-c), all three of the adjusted medical masks (M-b, M-c, and M-d), and two of the unadjusted medical masks (M-b and M-d). TFE during the bite was 6-7% higher than other activities for five of these samples including the KN95 (R-c) and both the regular and adjusted medical masks (M-b and M-d) with $P = 0.0001$ - 0.0220 or below. Two of the adjusted medical masks (M-c and M-d) had comparatively higher TFE at $0.3\ \mu\text{m}$ from 5-9% when the headform was stationary with $P = 0.0196$ and $P < 0.0001$, respectively. These clinical and statistical differences suggested certain movements had more influence over the filtration of these mid-range, looser fitting products.

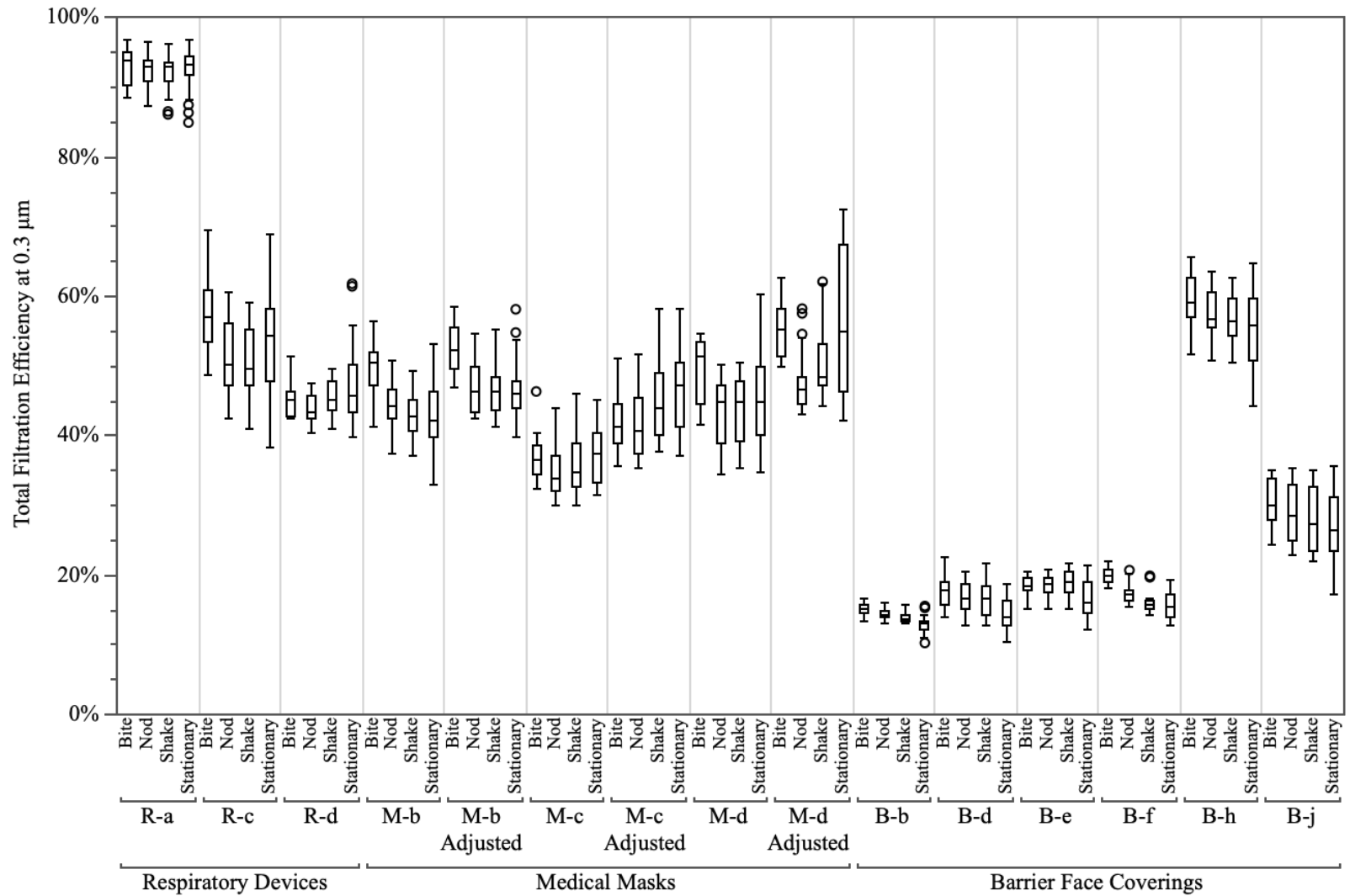


Figure 50. Box plot for TFE at 0.3 μm comparing the four headform movements by sample

To evaluate TFE over the duration of the ten-minute test, the first and last two minutes of stationary breathing for each sample were compared in Figure 51. The main effects of sample, time, and their interaction were all found to be statistically significant with $P < 0.0001$ from the two-way ANOVA test. Pairwise analysis identified significant differences between the first two minutes and the last minute where $P < 0.0001$, and between the first two minutes and the second to last minute where $P = 0.0021$ from the first minute and $P = 0.0073$ from the second. This corresponded to a decrease in TFE at $0.3\ \mu\text{m}$ of around 3% over time which was not clinically significant. Visually, TFE appeared to decrease for all the nonwoven products and two of the barrier face coverings. A closer look at the interaction between time and sample using Tukey's HSD test found that this trend was significant for two samples, one of the adjusted medical masks (M-d) and the flat fold KN95 (R-c). The adjusted M-d had statistical differences between the first two and last two minutes, all with $P < 0.0001$, showing a 13-15% decrease in TFE by the end of the test. R-c had a significant decrease from the first two minutes to the last minute around 13% with $P < 0.0001$. The first two minutes were also statistically different from the ninth minute around a 10% decreased in TFE with $P = 0.0026$ and $P = 0.0060$ for the first and second minute, respectively.

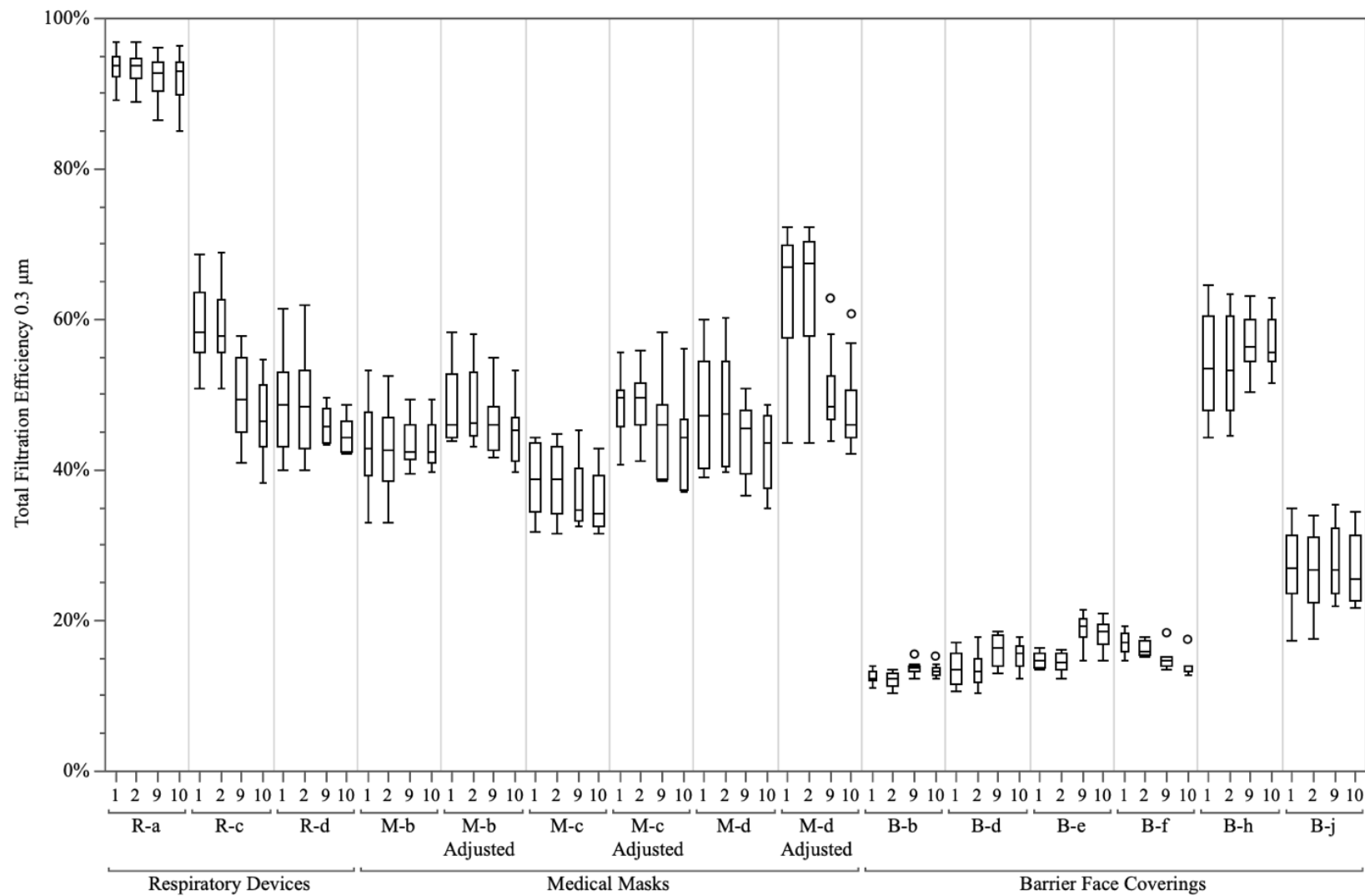


Figure 51. Box plot for TFE at 0.3 μm comparing the first (1-2) and last (9-10) two minutes of stationary breathing by sample

5.3.3 Variability Analysis

The TFE measurements were used to determine the coefficient of variation (CV) for each sample across particle sizes in Table 17. All of the sample CVs had good variation from the mean below 20% at 0.3 μm . Five of them fell below 10% including the N95 control that had a low CV of 3.04% at 0.3 μm . This showed that the optimized test method was able to obtain stable measurements across products. The CV typically decreased as particle size increased. The majority of samples had very good CVs below 10% at 0.5, 1, and 2 μm . There were a few notable exceptions at the 2 μm particle size as previously mentioned. More research is needed to determine the reason for this large variation in select products.

Table 17. Coefficients of variation for each product using the optimized method

Sample	Coefficient of Variation %				
	0.3 μm	0.5 μm	1.0 μm	2.0 μm	Cumulative
R-a	3.04	1.98	1.81	2.87	2.95
R-c	12.70	8.34	6.47	8.76	11.74
R-d	8.56	5.29	4.63	6.55	8.14
M-b	10.17	6.98	6.12	5.96	9.37
M-b Adjusted	9.61	6.19	4.62	6.96	8.57
M-c	11.32	7.24	5.98	6.35	10.41
M-c Adjusted	12.79	7.38	5.39	7.72	11.40
M-d	13.29	8.41	6.54	8.56	12.41
M-d Adjusted	15.42	10.18	6.92	6.89	14.09
B-b	8.97	5.76	6.56	22.15	7.94
B-d	16.29	10.83	8.94	76.20	14.25
B-e	12.67	10.53	8.46	26.14	11.32
B-f	13.49	9.84	8.71	9.76	11.75
B-h	8.15	4.53	3.97	4.51	7.74
B-j	15.91	11.60	14.87	2398.35	13.88

The variance component estimates in Table 18 were used to determine which effects and interactions contributed to variability in the optimized method. The analysis examined the effect of sample, movement, movement type, and change over time on the TFE at 0.3 μm . Sample type continued to make up the majority of the overall variability at 95.10%. The within component or unexplained error was minimal at only 3.70% indicating 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 from the baseline method. Only a single operator conducted the experiment so additional testing is needed to confirm reproducibility.

Table 18. Variance components from the optimized method

Component	Variance Component	Percent of Total
Sample	0.0428	95.10%
Within	0.0016	3.70%
Other	0.0006	1.20%
Total	0.0450	100.00%

5.3.4 Comparison of the Headform Test Methods

The data from the optimized method was compared to the previous baseline method in Figure 52. Mean TFE and standard deviations for earlier data can be found back in Table 14. The medical masks in earlier chapters had their ear loops tied to improve their fit. They were analyzed with the adjusted medical masks from the current study for a more realistic comparison. A two-way ANOVA test was used to comparatively analyze the effects of sample, method, and their interaction. All three were identified as statistically significant with $P < 0.0001$. Across the data set, the optimized method had an average decrease of 9% TFE from the baseline method. All twelve samples saw a drop in TFE and narrower standard deviations using the new method.

However, these lower TFE values generally overlapped or fell within the wider data spread of the baseline measurements. From Tukey's HSD test, the pairwise comparison showed nine of the samples had statistically significant differences across the two methods where $P < 0.0001$. The lowest detectable change in TFE was around 7% in one of the knit face coverings (B-e). Only the N95 respirator control (R-a) and two of the barrier face coverings (B-h and B-b) did not have notable differences in mean TFE at $0.3\ \mu\text{m}$.

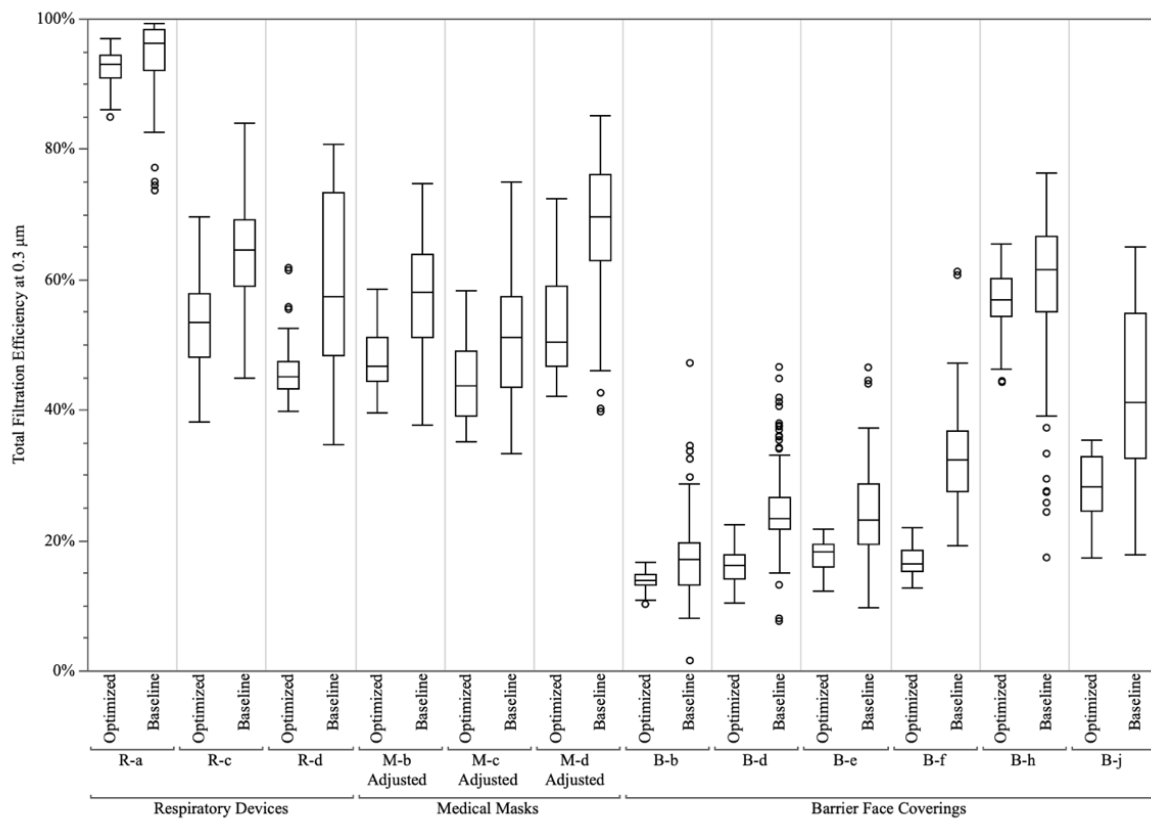


Figure 52. Box plot for TFE at $0.3\ \mu\text{m}$ comparing the optimized and baseline headform test methods by sample

5.4 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 a light workload. A combined test protocol was created to consolidate the segments and eliminate the need to remove the sample and reset the environment. Most significantly, the headform was moved into an environmental chamber which allowed the test conditions to be controlled. All samples were preconditioned and tested around 20°C and 65% relative humidity. These changes considerably reduced the standard deviation for each sample. However, high humidity has been shown to influence the filtration efficiency of hydrophilic materials [60]. It can agglomerate particles and impact their charge [4]. There did not appear to be improved filtration in the fabric samples. 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.

The optimized headform test method was able to differentiate between a wide range of products from three different categories with a difference in means of 2% TFE or more at 0.3 μm . The N95 respirator control was able to maintain TFE between 93-97% across particle sizes as expected of a certified respirator designed to seal to the face. The lower filtration at 0.3 μm may be the result of fit or high humidity conditions impacting the electrostatic filtration. However, performance remained consistent through movements 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 advanced headform.

Similar to the baseline results, TFE increased as a function of particle size for almost all of the samples with a few notable exceptions. The hybrid barrier face covering (B-j) saw a significant drop in performance at the 2 μm range. Another barrier face covering (B-d) had a smaller decrease in TFE. Typically, lower efficiencies at higher particle sizes can be attributed to

leakage due to poor fit since these particles are more easily captured by filtration mechanisms. The data each minute actually reported some negative values which indicated more 2 μm particles were measured inside the sample than there were in the environment. This could suggest something was coming off of the material, possibly fabric shedding that was picked up by the particle counters over the course of the test and might be harmful if inhaled. More research is needed to confirm there was no instrumental or experimental error. However, the consistent performance of the remaining products suggests this may be related to the specific properties of these samples.

The analysis predominantly focused on TFE at the most penetrating particle size, 0.3 μm . This size is used to describe the most difficult particle size to capture with traditional filter mechanisms, an important metric used in several standards to evaluate the worst case scenario. Outside of the N95, only three of the products including the flat fold KN95 (R-c), an adjusted medical mask (M-d), and one of the hybrid face coverings (B-h) were able to achieve the ASTM F3502-21 level 2 classification of filtration efficiency at or above 50%. An additional seven samples including the other style KN95 (R-d), the rest of the regular and adjusted medical masks (M-b, M-c, and M-d), and the other hybrid barrier face covering (B-j) were able to reach level 1 performance at or above 20% efficiency. The remaining knit and woven barrier face coverings all fell below these filtration efficiency levels.

The method was able to statistically differentiate between 90% of all possible sample pairs. There were statistically and clinically significant increases in TFE at 0.3 μm for all three medical masks that were tested as received and then adjusted. This demonstrated that improving the fit of these pleated masks by tightening the ear loops has the potential to improve their filtration efficiency up to 8%. The two styles of KN95s were also considered statistically and

clinically different with the flat fold able to achieve a better fit on the current headform. The difficulty 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 together 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 only marginal differences between the four knit and woven samples, while the two hybrid samples with nano materials were able to achieve higher filtration with similar designs. This illustrates the importance of material selection in addition to fit.

The impact of movement was reevaluated with the optimized protocol that contained sections of static and dynamic breathing. These results were quite different from the baseline method. There was no statistical difference between static and dynamic TFE across the data set. Only two of the adjusted medical masks showed a statistical difference between sections. Analyzing the four different types of movements across the data set found TFE only varied marginally by 2-3% from the bite. The pairwise analysis found more significant changes in mean TFE for most of the medical masks before and after the ear loops were adjusted along with the more traditional flat fold KN95. For these nonwovens, the bite was found to have notably higher TFE than other movements. This was surprising as this jaw movement previously shifted the positioning on the headform, reducing efficiency. It may be pulling the material tighter to the face as the mouth opens and giving it a larger surface area to pull the particles through. It could also be a limitation of the printed mouthpiece that does not change shape with the mouth cavity.

The first and last two minutes of stationary breathing were compared to see if TFE changed over the duration of the test as observed with the baseline method. There was a

statistical difference between the beginning and end of the test across the entire data set, but this 3% change was not clinically significant. Visually, TFE decreased over time across all of the nonwoven samples but only two samples were found to have significant differences between means. There was no clear change among the barrier face coverings which may suggest the changes in TFE were more closely related to movement. Movement only appeared to influence the medical masks and KN95s. These products were difficult to consistently don and achieve reasonable fit. The multiple layers of nonwoven polypropylene have a high filtering capability, but if a good fit is not achieved or maintained, the particles will go around rather than through the material. Movement may have introduced gaps around the perimeter, increasing leakage.

A comparison of the two headform methods showed improvements with the optimized test. The CVs all fell below 20% at 0.3 μm . The variability analysis gave a strong indicator that the new method was able to more repeatably evaluate different products. Sample type made up 95.10% of the method variability with a small within value of only 3.70%. This test was performed by a single operator and could not yet determine reproducibility. New variance components were determined for the earlier baseline test method data at the single 16 L/min flow rate. Sample type still made up the majority of variance at 82.30% with a higher inherent variability or within of 13.10%. The interaction between sample and operator was low at only 2.10% indicating good reproducibility. The optimized method successfully reduced the method variability and the inherent error. The ten replicates can likely be reduced due to the improved sensitivity of the method. Some degree of variation from the mean is still expected for the system-level test due to the variability of fit incorporated in the measurement.

The optimized headform test was able to repeatably and reliably evaluate the efficacy of different products available to the general public on an animatronic headform with breathing and

movement capabilities that can more realistically simulate daily wear. There are still some limitations to the current setup. 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 testing under the worst case scenario. 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 levels of activity. Completing ten replicates of the current ten-minute protocol was a long test to run. Other adjustments may include shortening the protocol and reducing the number of replicates to improve testing efficiency.

5.5 Conclusions

The optimized headform test method was able to differentiate between twelve different products across three categories with a range of filtration efficiencies from 14-93% at 0.3 μm . TFE was influenced by a combination of the material, fit, and design. This was evident in the KN95s that had moderate TFE despite their high material performance due to difficulty maintaining a seal to the face. The performance of the medical masks significantly improved by tightening the ear loops with cord locks. Meanwhile, the hybrid barrier face coverings appeared to improve filtration by incorporating nano materials into their products.

The most significant change in the optimized method was the controlled environmental conditions. Other testing parameters had less of an influence on TFE than previously observed. There were no significant differences between the static and dynamic sections. However, the bite showed higher efficiency than the other movements for several of the medical masks and a

KN95. TFE decreased over the course of the ten-minute test for the same group of samples, although the overall drop was not clinically significant. The comparison between the baseline and optimized methods found the optimized method had lower TFE and smaller standard deviations across all twelve products. The variance components confirmed that sample type was responsible for the majority of the variance with low unexplained error in the method.

The optimized method is a repeatable test that can more realistically evaluate the total filtration efficiency and inward leakage of these alternative products. There is still room for further development. The ASTM F3502-21 standard requires both filtration and breathing resistance measurements. A differential pressure sensor was connected to the mouth cavity of the headform during the optimized method and set to sample every five seconds. The data for each sample was recorded but fell outside the current project scope. This data could be compared to other measurement techniques to determine the accuracy of sampling on the headform. Ultimately, the optimized headform method should be able to evaluate both filtration and breathability in one protocol. A validation study with another operator is also needed to determine the reproducibility of the proposed method. The current method is designed to evaluate inward leakage. The reverse, generating particles from the inside to quantify outward leakage and determine the relationship between the two, remains important. Future studies could explore the relationship between TFE and facial features using the five different sized ISO headforms small, medium, large, narrow, and wide.

CHAPTER 6: Final Conclusions and Future Work

This work demonstrated that the total filtration efficiency of barrier face coverings could be realistically measured on an advanced animatronic headform. The baseline test method was able to clinically and statistically differentiate between samples with a difference in means of 5% or more. The statistical analysis of experimental parameters found that flow rate, operator, movement, and the testing duration all contributed to the overall variability in filtration efficiency. The variance components confirmed that sample was the largest contributor to variability, demonstrating good repeatability in the baseline method. Good reproducibility was confirmed by the relatively low variability contributed by the operator. The method was also able to evaluate inward leakage and assess fit by sealing the samples to the headform and comparing the filtration across particle sizes, respectively. This confirmed that leakage did significantly reduce performance.

The data was compared to the particulate filtration efficiency and breathing resistance tests run at a third-party lab using the recent ASTM F3502-21 Standard Specification for Barrier Face Coverings. This introduced an unexpected challenge as different labs were shown to have statistically different results for the same product because the tests were carried out using different flow rates. Both approaches were technically reasonable based on the standard. However, the use of a 10 cm/s face velocity with variable flow rates verses a constant 85 L/min flow placed barrier face coverings in different performance levels within the standard. More research is needed to confirm that these differences are solely the result of variable flow rate. The results from the first lab were compared to the headform. Overall, the filtration efficiency was lower on the headform as expected due to the incorporation of leakage into the total filtration efficiency value. However, this was not consistent across every sample with some

variability evaluating the barrier face coverings across the two methods. They did generally agree on the performance classification levels for 75% of the products.

The final optimized test method moved the headform into an environmental chamber to control the temperature and humidity during testing. The condensed protocol was still able to clinically and statistically differentiate between samples. The experimental parameters were found to be less influential in the new method. Additional research is needed to confirm the influence of movement and time on the total filtration efficiency. The mean total filtration efficiency and the sample standard deviation also decreased from the baseline method for all products. Future testing at a lower humidity should be able to confirm if this decrease is due the environmental control in the chamber. The variance components confirmed that the unexplained error in the optimized method was considerably reduced, and sample type remained the most important cause of variability. This demonstrated that the optimized method was more repeatable. A future validation study using the new method can be conducted by another operator to confirm the reproducibility of the method.

Future work may include the incorporation of a breathing resistance measurement into the headform method by simultaneously measuring the differential pressure across the sample. The proposed method is currently only used to evaluate inward leakage. In the future, the direction of particle generation may be reversed to quantitatively assess outward leakage as a better indicator of source control. This data could be further validated with a human wear study to correlate the human response to the headform data. Additional testing incorporating headforms of different facial shapes and sizes could expand the understanding of the influence of fit on the total filtration efficiency.

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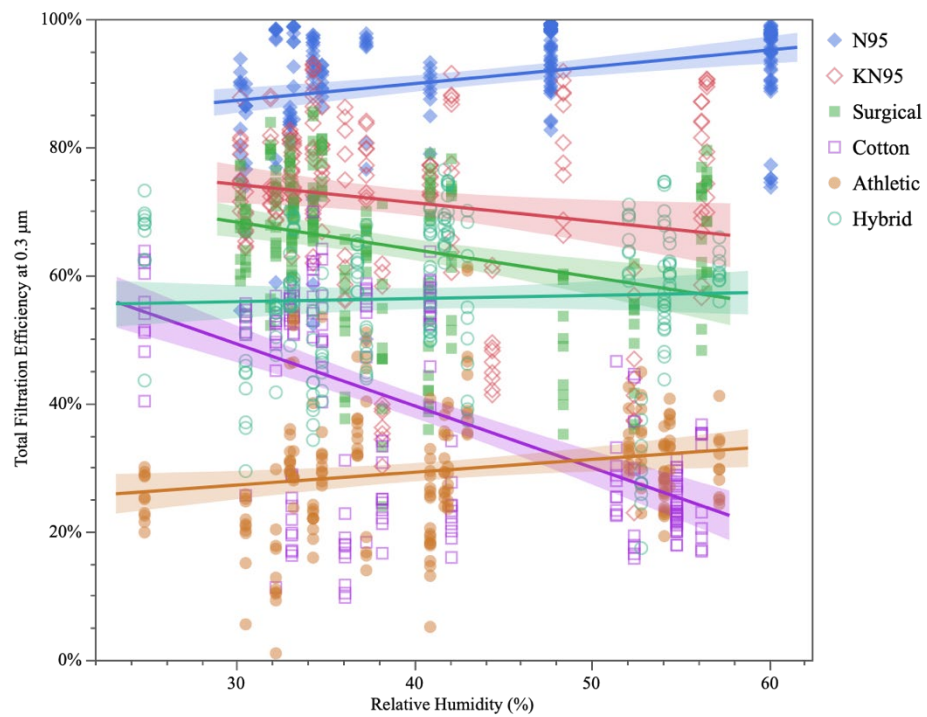
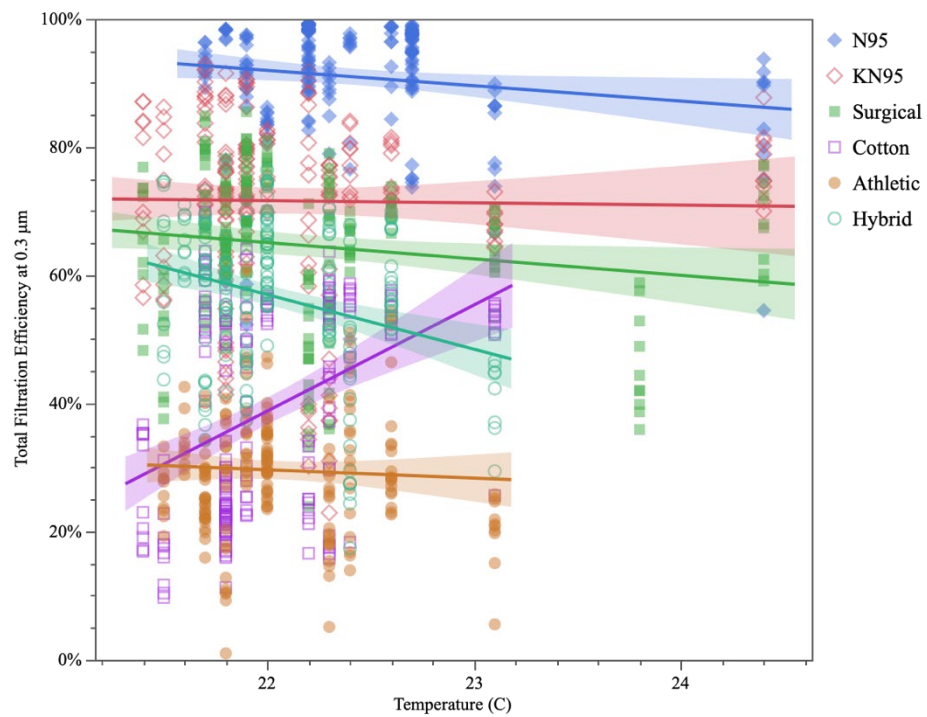
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APPENDICES

Appendix A: Observed Environmental Conditions in the Baseline Test Method



Appendix B: Sample Characteristics

ID ^A	Sample ^B	Material	Structure	Design	Layers	Retention	Nose Clip	Certification
R-a	N95 Respirator ³⁻⁵	Polypropylene	Nonwoven	Cup Shape	4	Head Straps	Metal	NIOSH 42 CFR Part 84
R-b	N95 Respirator ⁴	CoolSAFE®	Nonwoven	Flat Fold	4	Head Straps	Metal	NIOSH 42 CFR Part 84
R-c	KN95 Mask ⁴⁻⁵	Polypropylene	Nonwoven	Flat Fold	4	Ear Loops	Metal	GB 2626-2019
R-d	KN95 Mask ⁴⁻⁵	Polypropylene	Nonwoven	Tri-Fold	4	Ear Loops	Metal	GB 2626-2019
R-e	KN95 Style Mask ³⁻⁴	Polypropylene	Nonwoven	Flat Fold	3	Ear Loops	Plastic	-
M-a	Surgical Style Mask ³⁻⁴	Polypropylene	Nonwoven	Pleated	3	Ear Loops	Metal	-
M-b	Surgical Style Mask ⁴⁻⁵	Captur®	Nonwoven	Pleated	1	Ear Loops	Metal	ASTM F3502-21 Level 2
M-c	Surgical Mask ⁴⁻⁵	Polypropylene	Nonwoven	Pleated	3	Ear Loops	Metal	ASTM F2100-21 Level 3
M-d	Surgical Mask ⁴⁻⁵	Polypropylene	Nonwoven	Pleated	3	Ear Loops	Metal	ASTM F2100-21 Level 2
M-e	Procedural Mask ⁴	Polypropylene	Nonwoven	Pleated	3	Ear Loops	Metal	ASTM F2100-21 Level 1
M-f	Procedural Mask ⁴	Polypropylene	Nonwoven	Pleated	3	Ear Loops	Metal	ASTM F2100-21 Level 2
M-g	Procedural Mask ⁴	Polypropylene	Nonwoven	Pleated	4	Ear Loops	Metal	ASTM F2100-21 Level 3
B-a	Cloth Face Covering ⁴	Polyester and Cotton	Woven and Mesh	Cone	3	Ear Loops	None	-

ID ^A	Sample ^B	Material	Structure	Design	Layers	Retention	Nose Clip	Certification
B-b	Cotton Face Covering ⁴⁻⁵	Cotton	Woven	Cone	3	Adjustable Ear Loops	Metal	-
B-c	Cotton Face Covering ⁴	Cotton	Woven	Tri-Fold	2	Adjustable Ear Loops	Metal	-
B-d	Cotton Face Covering ⁴⁻⁵	Cotton	Woven	Tri-Fold	3	Adjustable Ear Loops	Metal	-
B-e	Cotton Face Covering ³⁻⁵	Cotton	Knit	Pleated	3	Ear Loops	Plastic	-
B-f	Athletic Face Covering ³⁻⁵	Polyester, Polyurethane foam, Nylon/Elastane	Knit with Foam Spacer	Fitted	3	Ear Loops	Metal	-
B-g	Athletic Face Covering ⁴	Polyester and Elastane	Knit	Cone	2	Ear Loops	None	-
B-h	Hybrid Face Covering ³⁻⁵	Polyester and Nylon	Woven, Mesh, Nano fabric	Fitted	4	Adjustable Ear Loops	Metal	-
B-i	Hybrid Face Covering ⁴	Polyester and Nylon	Woven, Mesh, Nano fabric	Fitted	3	Adjustable Ear Loops	Metal	-
B-j	Hybrid Face Covering ⁴⁻⁵	Nanotech and Cotton	Woven and Nonwoven	Fitted	3	Adjustable Ear Loops	Metal	-
B-k	Hybrid Face Covering ⁴	Polyester with Inner Filter Layer	Woven and Nonwoven	Pleated	3	Ear Loops	Metal	-
B-l	Cloth Face Covering with Filter ⁴	Nylon, Polyester, Spandex with Polypropylene Filter	Knit and Nonwoven Filter	Dome	5	Adjustable Ear Loops	Metal	-

^A Product group R for respiratory device, M for medical mask, and B for barrier face covering

^B Number indicates the chapters referenced