

Informing the Public's Unassisted Use of Diverse Facepieces Designed to Form a Seal: Quantitative, Comparative Testing Using the ASTM F3502 Leakage Assessment Test Method

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ABSTRACT

Introduction: A National Academies of Science study details the need for respiratory protection for the public. However, assistance with facepiece selection, fit, and use, is rarely available in the community resulting in suboptimal use of facepieces. This study evaluated filtering facepiece respirators (FFR) and a barrier face covering in a setting where neither professional guidance nor assistance were available.

Objective: This study compares the effectiveness of various facepieces at blocking aerosols during unassisted use, using the ASTM F3502 Leakage Assessment—a modified version of the ASTM F3407 fit capability test.

Methods: An ASTM F3502-2021 *Standard Specification for Barrier Face Coverings* Leakage Assessment was conducted with a TSI PortaCount 8048, for facepiece models worn by participants given no coaching or assistance. The ASTM F3502 method follows *ASTM F3407 Standard Test Method for Respirator Fit Capability* but with modifications to account for unassisted facepiece use outside of a respiratory protection program. The performance target, a Leakage Ratio (LR) of 10, would reflect 90% blocking of particles. Two FFR models and a reusable barrier face covering in a tubular form were studied. There were 59 participants.

Results: The facepieces performed above the target performance level, indicating, on average, more than 90% protection. One FFR achieved 93% protection with a LR of 15.0 (SD=5.5%), another FFR achieved 92% protection with a LR of 12.2 (SD=12.6%), and the reusable tubular facepiece achieved 93% protection with a LR of 14.2 (SD=4.3%) after 110 laundering cycles.

Conclusion: Disposable respirators and reusable face coverings can be compared quantitatively using the Leakage Assessment test method in ASTM F3502, which provides a critical tool for understanding and improving unassisted use of facepieces by the public.

KEYWORDS: Unassisted, Leakage, Fit Capability; Product Test, Fit Test, Filtering Facepiece Respirator, Barrier Face Covering, Source Control, Reusable, Gaiter, Tubular

INTRODUCTION

There is a need for facepieces designed to protect individuals from inhalation hazards in the community and in unregulated workplaces (NAS, 2022), where use occurs without training or assistance. Studies of filtering facepiece respirators (FFR) and other facepieces indicate lower performance during unassisted use and, as a consequence, suggest a need to minimize risk to both naïve and expert wearers when no assistance is available (Hannum, 1996; Cummings, 2007; Lee, 2008; Oberg, 2008; Brosseau, 2010; Rembialowski, 2017; Yeung, 2020; Chen, 2022; Wang, 2024).

This study's aim was to test and compare the effectiveness of diverse facepieces in blocking aerosols during unassisted use. Two international consensus standards were the basis for the testing approach. *ASTM F3407, Standard Test Method for Respirator Fit Capability* (ASTM 2021a) has a product test method relating to facepiece fit. *ASTM F3502 Standard Specification for Barrier Face Coverings* (ASTM 2021b)

adopts provisions of ASTM F3407, with some modifications designed to model unassisted donning. This study employed ASTM F3502's Leakage Assessment plus relevant provisions of ASTM F3407, as directed by ASTM F3502. In contrast to facepiece fit testing, which assesses individuals in the workplace under a Respiratory Protection Program (RPP), these two methods evaluate a product's capability prior to its purchase and use. Performance levels developed by the National Institute of Occupational Safety and Health (NIOSH) help in the interpretation of product testing results.

Facepieces intended for unassisted use have requirements that are distinct from facepieces designed for occupational RPPs. For example, unassisted use relies on the wearer's recall of instructions (Chen, 2022; Yeung, 2020) as well as the wearer's intuition when they don an unfamiliar facepiece (Chasco, 2023). In RPPs, experts assist the wearer with facepiece selection and fitting, and workplaces implement environmental and administrative controls to manage risks. (OSHA 1998; Zhuang 2005; Zhuang, 2007; Zhuang, 2008; Zhuang, 2017; Chen, 2009; NIOSH, 2024). RPP controls also include intentional evaluations of technology to support RPP improvement (Chapman, 2024). RPPs drove development of methods for testing the fit capability of facepieces (Zhuang, 2017), resulting in ASTM F3407 (Coffey, 2021).

Section 1.1 of ASTM F3407 states its provisions apply to the testing of air-purifying, half-facepiece respirators, e.g., FFRs. The precise term for an ASTM F3407 fit capability test is "Respirator Fit Capability (RFC) test", which is defined in ASTM F3407. The term for the output of the RFC test is "subject RFC result", per section 3.1.6. Section 1.6 cautions that having the desired fit capability does not guarantee that (in subsequent fit testing under an RPP) a given wearer will be able to achieve the required "fit factor" when wearing a particular manufacturer's model. Fit testing focuses on finding the right facepiece model for a given wearer, as may be indicated by the fit factor achieved during fit testing (Regli, 2021). ASTM F3407 cautions that wearers "must always be given the opportunity to try other models or other manufacturers' respirators." ASTM F3407 is to be used in testing air-purifying, half-facepiece respirators. To help manufacturers address fit and leakage issues when developing other types of facepieces, ASTM F3502 adopted the ASTM F3407 test method by directly importing its terms, with some modifications.

In contrast to ASTM F3407, ASTM F3502 addresses the design, testing, manufacture, and supply of facepieces intended for unassisted use, such as in the community, where no training or fit testing is available. ASTM F3502 anticipates that manufacturer instructions will be the main form of assistance to the wearer, aided by product design. By comparison, during product testing under ASTM F3407, section 14.2, a test administrator can take the actions needed to achieve an optimal fit to an individual's face. Examples of such actions include familiarizing the wearer with donning, doffing, and seal check procedures; helping them to adjust the facepiece; re-explaining procedures after a failed seal check; and directing repositioning and repeat of the seal check. ASTM F3502's Leakage Assessment, while derived from ASTM F3407, anticipates the use of facepieces outside of RPP controls (Brosseau, 2022; Nicas, 2024; Brosseau, 2024).

ASTM F3502's section 8.3 describes its Leakage Assessment as a standard approach to assessing leakage through the entire facepiece, including the filter, face seal, seams, etc. According to Note 26 of the standard, Leakage Assessment is a "fit capability test" but is termed a "Leakage Assessment" to clarify its broader scope, which may include facepieces intended for use outside of a workplace, such as with children and general community use. In ASTM F3502, Leakage Assessment is optional, unlike filtration efficiency and breathing resistance testing, which are both required.

The Leakage Assessment output, a LR, has the same function as ASTM F3407's "subject RFC result" (the output from ASTM F3407's fit capability test). With respect to unassisted fit, ASTM F3502 section 8.3.5 directs that during the Leakage Assessment testing, "Test subjects shall don the barrier face covering sample without assistance from the test coordinator", and, "Test subjects shall receive donning and doffing training only from reading the user instructions or watching video versions of the instructions as provided by the manufacturer...". This direction can be contrasted with the high level of assistance and training that is available per section 14.2 of ASTM F3407.

While ASTM F3502 provides the Leakage Assessment as a test method for the fit of a facepiece, it does not set a minimum performance requirement for the resulting LR. NIOSH has articulated LRs of 5 and 10 as suitable for comparing the performance of ASTM F3502 barrier face coverings, whose presumed use is

in unassisted settings. (CDC, 2024; Brosseau, 2022). By comparing LR_s, wearers can gauge the suitability of a facepiece for use (e.g., in the community), when unassisted by the expertise and controls of an RPP.

METHOD

Ethics

Ethical approval for the project, inclusive of quantitative and qualitative studies, was granted by the University of the West of Scotland, School of Health and Life Sciences Ethics Committee (ref no:20956).

Performance target

An ASTM F3502 LR reflects the average of all results for all facepieces of a given size, per ASTM F3502 section 8.3. The objective is to determine the mean LR value for a given size facepiece.

ASTM F3502 does not articulate a LR performance level, but NIOSH has defined two performance levels which pertain to facepieces tested under the ASTM F3502 Leakage Assessment: Enhanced Performance, a level based on achievement of a LR of 5, and Enhanced Performance Plus, for a LR of 10 (CDC, 2024; Brosseau, 2022). For this study, NIOSH Enhanced Performance Plus (i.e., 10) was adopted as the mean LR target for each group of participants.

Table I presents the target and other LR_s alongside the corresponding level of effectiveness in blocking particles, in terms of percentage blocked. The following discussion of the values presented helps explain the target performance level.

The ASTM F3502 LR is a non-linear function. An LR is equal to $\frac{1}{\% \text{ leakage}}$, creating a non-linear hyperbolic function which has a vertical asymptote at zero leakage. To average the LR for a group of results, these values need to be converted back to a leakage percentage, a linear function. From these converted values, the average of the results can be calculated, which can then be converted back to a LR. The LR, percentage particles blocked, and the exposure level have the relationship depicted in Table I. Facepieces attaining the target LR of 10, would block at least 90% of particles, including particles that penetrate the filter and leak through all other sources. Use of a quantitative respiratory fit tester in N99 mode should measure penetration of all particle sizes within the range of the instrument (20 nm – 1 µm). This approach would provide a measure of Total Inward Leakage rather than a fit factor (which is designed to measure only particle leakage through the facesal). In following the ASTM F3502 standard, the present study used this approach.

This approach is in contrast to ASTM F3407, in which the fit test mode is selected to ensure that only minimus penetration occurs through the filter element. Selecting a mode appropriate for a filter's presumed filtration efficiency enables focused attention on the facesal rather than total particle penetration. For example, the filters for N95 and N99 FFRs capture test particles very effectively. As a result, developers of the ASTM F3407 methodology can assume that any particles measured occur from leakage (not filter penetration) and therefore are useable as an indicator of the level of fit.

ASTM F3502, was developed to test a wide range of facepieces with unknown filter types with widely variable abilities to withstand particle penetration. ASTM F3502 was also designed to extend to future innovations which may be developed to align with the standard's provisions. As such, ASTM F3502, through its Leakage Assessment provisions, seeks to measure all particles from all sources, providing an indication of a facepiece's as-worn performance. The exposure reduction and protection levels available from a facepiece model can be inferred from the degree of particle reduction achieved by the facepiece under unassisted use referencing the manufacturer instructions. A target of 10 aims for no more than 10% exposure to the wearer of the product, as anticipated under NIOSH Enhanced Performance Plus.

Table I. Chart depicting ASTM F3502 LR values and the degree of effectiveness they reflect in terms of percentage of particles

ASTM F3502 LR (Sample benchmarks at this level)	Percentage of particles blocked	Exposure level (all sources)
1	No particles blocked	Full exposure
2	50%	50%
5 (NIOSH Enhanced Performance)	80%	20%
10 (NIOSH Enhanced Performance Plus)	90%	10%
15+ (FFP2)	Minimum 93%	Maximum 7%
17+ (N95)	Minimum 94%	Maximum 6%
20	95%	5%
50	98%	2%
100	99%	1%

Note: The LR and percentage values in Table I are presented to enable comparisons. In addition to different LRs, it provides information on the corresponding degree of effectiveness that these LRs would reflect, in terms of percentage of particles blocked. LRs of 5 and 10 reflect enhanced performance levels for fit (CDC, 2024; Brosseau, 2022) adopted in a NIOSH framework. LR values of 15 to 20 approach the exposure reduction capability of FFRs sometimes used in the community, such as FFP2s and N95 respirators. A LR value of 50, while notional here and not found in an existing framework, derives from work by other investigators on respirators for public health uses (FDA 2007). Finally, 100 is the ASTM 3407 fit capability performance level for facepieces, e.g., FFRs, designed for use in a Respiratory Protection Program (when the test is set up to ensure filter penetration is negligible). It bears repeating that the ASTM F3502 Leakage Assessment test method uses N99 mode, and therefore the percentage particles blocked encompasses all forms of leakage including leakage through seams, at the face seal, and by filter penetration. It is also worth noting that filter penetration testing, reported in percent efficiency, uses constant air flows, to model breathing, at rates which are higher than those typically achieved by a study participant carrying out exercises under a Respiratory Protection Program fit test. The values for the FFP2 and N95 benchmarks account for edge leakage (1%) and filter penetration (5%), hence the 1% lower benchmark (94%) for an N95 FFR.

Selection of facepieces for study

Three facepiece models were chosen (Table II). Two models were FFRs certified to FFP2 under EN149, and therefore tested previously to a 94% filtration efficiency: 3M 8810, a cup shaped FFR, and 3M Aura 9320+ a tri-fold FFR. Both FFR models have two head straps, a “one-size-fits-most” design, and reported results for respirator fit-testing (Berger, 2022; Manninen, 1988; Williams, 2023a; Zhang, 2023; Derwein, 2024). Two versions of a tubular facepiece model (facegaiter, manufactured by tensARC, Stirling, UK) were used. Both are available in four sizes: Small (S), Medium (M), Large (L), and Extra-Large (XL). One version has a warp knit polyester fleece filter (“Filter A”) and the other a non-woven polypropylene microfiber filter (“Filter B”). Each participant wore the Filter B version in two conditions: one sample was laundered once, the condition for first wear; the other sample had been laundered at least 110 times. As reported previously (Baglin, 2022), the tubular facepiece with Filter B performs at ASTM F3502’s highest performance level for breathing resistance (<50pa; 5 mm H₂O) and exceeds ASTM F3502’s highest performance level for filter efficiency (50%), achieving 94% reduction in particle concentration.

Table II. All facepieces tested in this study.

Facepiece information					
Type	Filtering Facepiece Respirator (FFR)		Reusable tubular facepiece		
Model (Version and/or SizeTs)	3M 8810 (one size fits most)	3M Aura 9320+ (one size fits most)	facegaiter (Filter A version / Sizes S, M, L, XL)	facegaiter (Filter B version / Sizes S, M, L, XL)	
Condition when tested	New in package	New in package	Laundered once (as at first wearing)	Laundered once (as at first wearing)	Laundered a minimum of 110 times

Note: All facepieces were tested, as required (per the manufacturer), in their condition at first wearing by ASTM F3502 7.3.2.1. Also, ASTM F3502 7.3.2 and 8.3.2 require further testing, after the maximum number of launderings indicated by the manufacturer for a given performance level. The manufacturer's instructions for the reusable tubular facepiece direct the wearer to launder the facepiece before the first wearing; and the two versions of the tubular facepiece were tested after one laundering. Only the tubular facepiece with Filter B, however, was laundered further and tested in the resulting condition after 110 launderings. For the FFRs, their condition was only as found when new and in their packaging.

Instrumentation selection and proficiency

The instrumentation selected for performing the ASTM F3502 Leakage Assessment test protocols was the TSI PortaCount 8048 (Grinshpun, 2020). This model calibrates automatically at the session start. One team member was trained and certified by Fit2Fit (Hempstead, UK) as a fit-test administrator (Baxter, 2024) in the month prior to data collection. This individual fulfilled the role of "test administrator" under ASTM F3407 and "test coordinator" under ASTM F3502.

Target participants

The target number of participants was 60, and the desired profile was educated individuals who were non-expert and/or "naïve" as to fit-testing.

The study's source of volunteers were students and staff at two campuses of the University of the West of Scotland, School of Health & Life Sciences. Potential volunteers were recruited through university-wide electronic notices and posters, by in-person visits to classrooms, and through one-on-one conversations at each of two campuses. Some participants were offered a £10 Amazon gift card by way of compensation, after amendment of the Ethics protocol.

Some considerations in establishing the sample size included the following. The study sought participants who would wear (a) at least one "one size fits most" FFP model and (b) one of four sizes of the tubular product, in at least one version in two conditions. As noted, the tubular product conditions reflected two reprocessed states, 1 or 110+ launderings. The provisions of ASTM 3502's Leakage Assessment require testing 10 participants for each facepiece size of a given model. While the FFP models had one size, the tubular product's four sizes required a participant count of at least 40 (10 participants x 4 sizes). Participants were not sized prior to attendance, and given the risk of cancellations by prospective participants, 50% more than 40 were estimated as needed, so a target of 60 participants was set.

The study design could not rely entirely on methodologies found in the respirator and FFR literature. The single head dimension which sizes the tubular facepiece is not among the measurements commonly employed in anthropometric studies. It would not be represented in any bivariate panel established (consistent with existing rules and protocols) to assess FFRs. As a result, recruitment strategies were important to the study. When conducting study recruitment in-person, the research team's health sciences

lead, in some instances (to identify prospective participants who may size as a Large or Extra Large), made a subjective and non-invasive observational assessment of the prospective participant.

Preparation

Participants were told that they would need to refrain from smoking, eating, or drinking within one hour of their Leakage Assessment appointment. The tubular facepiece's manufacturer instructions recommend use of clothing that maintains its "tuck-in neck seal" when bending over. Therefore, participants were asked to wear to their appointment a high neck top, such as a crew neck t-shirt; sweatshirts were available for use by a participant with a top that was not suitable. There was no requirement to be cleanshaven. Cleanshaven wearers cannot be presumed in the community, so ASTM F3502 provisions do not mitigate facial hair's risk to the seal in its protocols.

On a test day, one of the two FFR models was randomly assigned to the day's participants.

A laptop was provided in the test area, enabling the participant to view the video instructions for the cup model FFR, the tri-fold model FFR and the tubular facepiece. The written instructions for each were also provided.

Consent

At their Leakage Assessment appointment, the participant read and signed a consent form permitting use of their data as needed for the project, subject to university requirements and the General Data Protection Regulation (GDPR) as instituted in the UK.

Data collection from research participants

Each appointment was 90 minutes in length, of which 20-30 minutes was devoted to collection of personal data from research participants. After consent was confirmed but prior to the Leakage Assessments, the test administrator created an ID number and Participant Profile, which recorded the exclusionary data, demographic data, including the presence of facial hair, prior FFR use, and sex (selected as either "male" or "female"). Anthropometric data were collected from the participant and recorded. In addition to face width and face length, required for ASTM F3502 and ASTM F3407, the following were measured: jaw width; nose length; nose protrusion; lip length; head circumference; and neck circumference. Images were taken to later approximate face depth and the nose gap area. Also taken was the measurement used to size a facegaiter: tubular facepiece seal circumference.

Conduct of a Leakage Assessment for each facepiece model

Data collection on the facepieces, employing ASTM F3502 the Leakage Assessment test method, typically ran 60 minutes per participant, within the 90-minute appointment. All Leakage Assessment tests were sequential, with only one participant tested at a time. Because the tubular facepiece was reusable, it needed to be tested in two conditions, as first worn (laundered once) and after the maximum number of launderings claimed by the manufacturer. The first facepiece to be tested was an FFR, randomly assigned in similar numbers. The participant was asked to sit at the laptop with the written and video instructions for the FFR to be tested. The participant was asked to study its instructions before donning the facepiece and following the seal check specified by the manufacturer. Per ASTM F3502, neither the test administrator, nor any other study team member, answered questions arising from a facepiece model's instructions nor assisted participants as they donned a facepiece. Testing different versions of the same product with the same participant did not require an additional review of wearer instructions.

The exercises performed by the participant were those required by ASTM F3502 (listed in ASTM F3407 section 14.2.7): normal breathing; deep breathing, turning head side to side; moving head up and down; talking; grimace; bending over; normal breathing. Each is performed for one minute, with the exception of the grimace, which is performed for 15 seconds. At the end of the test, the test administrator would review

the PortaCount 8048 result. Per provisions of the standard, if the test administrator thought the results were low and the facepiece poorly fitted, the test administrator could request the participant to review the instructions and repeat the test once using the same protocol.

The study design permitted testing two FFRs for each participant, in addition to the multiple versions of the reusable tubular facepiece before and after extensive laundering. At the start of data collection, after seven instances of conducting Leakage Assessments on both FFR models (along with the other data collection), it was determined that testing two FFRs in an appointment was too demanding on the participant inside the 90-minute time limit.

For each participant all FFR testing was completed before the tubular facepiece testing began. For the tubular facepiece, the same manufacturer instructions applied to Filter A and Filter B models, so as noted the instructions were studied only once. The correct tubular facepiece size was supplied based on the tubular facepiece seal circumference, which is a facial dimension listed among the others noted in the subsection entitled "Data collection from research participants." The participant then carried out further adjustment following the written and video instructions. When a participant had finished reviewing the written and video instructions for the tubular facepiece, as with the FFR, the test administrator observed but did not assist in donning nor in the seal check. Once the participant donned the model, completed the seal check, and said they were ready to proceed, the testing started.

Each participant was provided first with a Filter B model which had one laundering cycle. The same procedure was then repeated for the Filter B tubular facepiece with at least 110 laundering cycles. In some instances, the tubular facepiece subsequently was reprocessed, consistent with its instructions and prior study findings (Mackay, 2025), and used with a later participant. When time permitted, the same procedure was repeated for a Filter A tubular facepiece which had been put through a single laundering cycle.

Calculation of the LR for each facepiece

Under a ASTM F3407 RFC, individual exercises with a particular respirator are averaged using the harmonic mean, as carried out by the PortaCount equipment. Under ASTM F3502, even as informed by the ASTM F3407 provisions which it adopts, there are no explicit instructions to use the arithmetic or harmonic mean. Use of the arithmetic mean could create a bias wherein high performing individuals (outliers) within the group cause a significant increase in the result for the group. Under the study method, both the arithmetic and harmonic means were calculated to understand the extent of this bias.

RESULTS

Data were analyzed and visualized using Microsoft Excel (Redmond, Washington, USA). The analysis produced descriptive statistics, which are presented here, and inferential statistics to be reported in the future.

Participant data

There were 59 participants, of which 55 completed testing of the reusable, Filter B tubular facepiece and at least one FFR. For the reusable tubular facepiece version with Filter B, these 55 participants were tested twice, once wearing a sample of a version laundered a single time and once wearing a sample of a version laundered 110 or more times, as described in Table II. Given time constraints, a smaller number of participants, 27, were tested wearing the tubular facepiece with Filter A after one laundering cycle. Of 37 females, 35 completed testing and comprised 63.6% of the 55 participants. Participants ages ranged from 19-66.

Facepiece data, including LRs

The results for particles blocked for all participants, for each facepiece model, are shown in Figure 1

including the low performance outliers. The FFRs had wider ranges of results, while the tubular facepiece had narrower ranges, suggesting more consistency in values across participants.

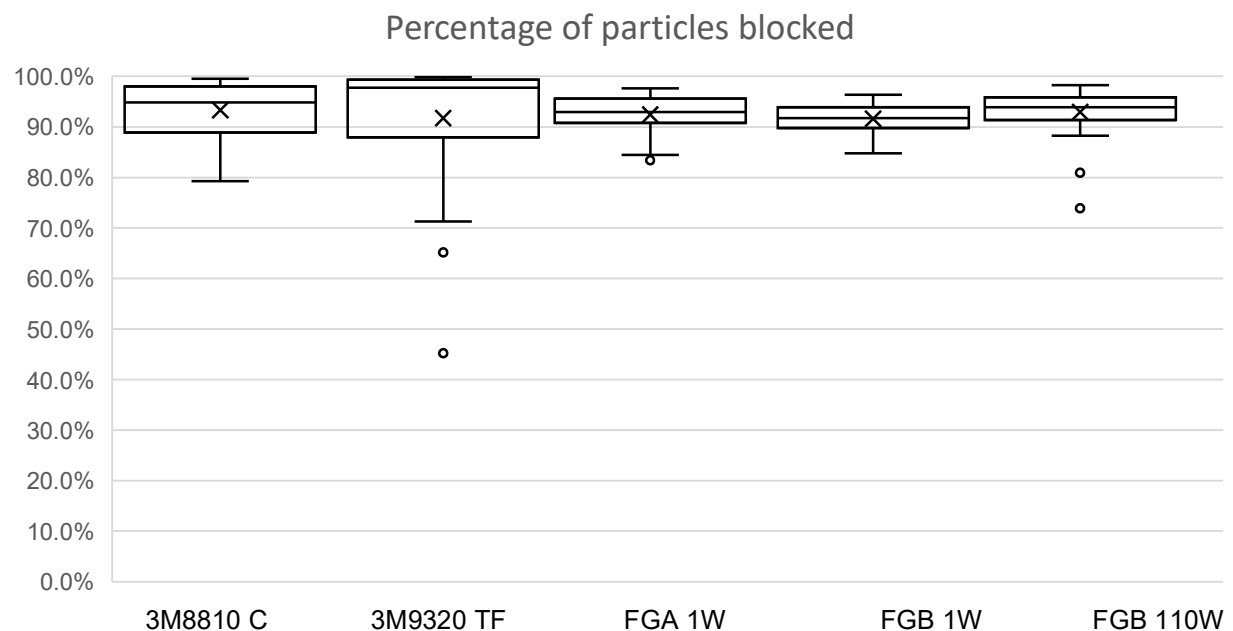


Figure 1. Percentage particles blocked based on LR value, by facepiece. Note: Tests were conducted on four versions of three facepiece models, with one version having two conditions based on the number times laundered: FFR - 3M 8810 cup-shaped (3M8810C); FFR - 3M 9320 tri-fold (3M 9320TF); reusable tubular facepiece - facegaiter Filter A with one laundering (FGA1W); reusable tubular facepiece - facegaiter Filter B with one-laundering (FGB1W); reusable tubular facepiece - facegaiter Filter B with 110 or more launderings (FGB110W). In the box plot, the box represents upper and lower quartile, box line is median, the cross is mean, and the individual points are outliers.

For each facepiece model, the average LR results exceeded the target performance level of 10, indicating more than 90% blocking of particles during typical conditions of wear. Table III presents each facepiece's Leakage Assessment results. The reusable tubular facepiece model referred to as the Filter B tubular facepiece was tested in two conditions, therefore results for both are presented.

Table III includes calculations of the average LR (for each facepiece version) by arithmetic mean. The results of the tri-fold respirator illustrate the difference between arithmetic mean and harmonic mean calculations: its LR was 94.3 by the arithmetic mean, and 12.2 by the harmonic mean. The tubular facepiece had the highest percentage of participants achieving the target and therefore the greatest consistency in results.

Table III. ASTM F3502 Leakage Assessment results reported as LR.

Results by facepiece and their LRs for individuals tested	N =	Average LR calculated by arithmetic mean	Average % of particles blocked (Standard deviation)	Average LR calculated by harmonic mean	% of participants achieving ≥ 10 LR (target level)
3M 8810 Half facepiece (cup)	32	38.4	93% (5.5%)	15.0	75%
3M 9320+ Half facepiece (tri-fold)	34	94.3	92% (12.6%)	12.2	74%
facegaiter Filter A after 1 wash	27	16.6	92% (3.6%)	13.2	81%
facegaiter Filter B after 1 wash	55	13.5	92% (2.8%)	12.0	80%
facegaiter Filter B after 110 washes	55	18.9	93% (4.3%)	14.2	89%

Table IV presents information on participants with self-reported facial hair and the LR for the facepieces they wore during testing. The results for the cup model FFR indicate superior performance over the tri-fold model. The results for the tubular facepiece Filter B in the 110 laundering condition indicate it was the most consistent, with 12 of the 13 participants achieving the target level. Note that the sample sizes for Filter A and the tri-fold were smaller, and the results may be different if tested on a larger group.

Table IV. ASTM F3502 Leakage Assessment results reported as LRs, for facepieces worn by male participants with facial hair (self-reported stubble or beard). Sample size may not be representative of the adult male population.

Results by facepiece and their LRs for individuals with facial hair (stubble or beard) tested	N =	Average LR calculated by arithmetic mean	Average % of particles blocked (Standard deviation)	Average LR calculated by harmonic mean	% of participants achieving ≥ 10 LR (Target level)
3M 8810 Half facepiece (cup)	11	51.9	95% (5.2%)	20	82%
3M 9320+ Half facepiece (tri-fold)	5	26.6	85% (13.1%)	6.8	40%
facegaiter Filter A after 1 wash	5	10	90% (2%)	9.8	60%
facegaiter Filter B after 1 wash	13	12.6	92% (1.9%)	11.9	85%
facegaiter Filter B after 110 washes	13	14.7	91% (5.7%)	11.4	92%

Figure 2 presents the distribution, by facepiece type, of LRs within specific ranges, or bands, of performance. It provides a comparative view of their propensity to leak and their effectiveness in blocking particles under the test conditions. For all Leakage Assessments run, 97.5% resulted in a LR of more than 5. The most common LR was between 10 and 20.

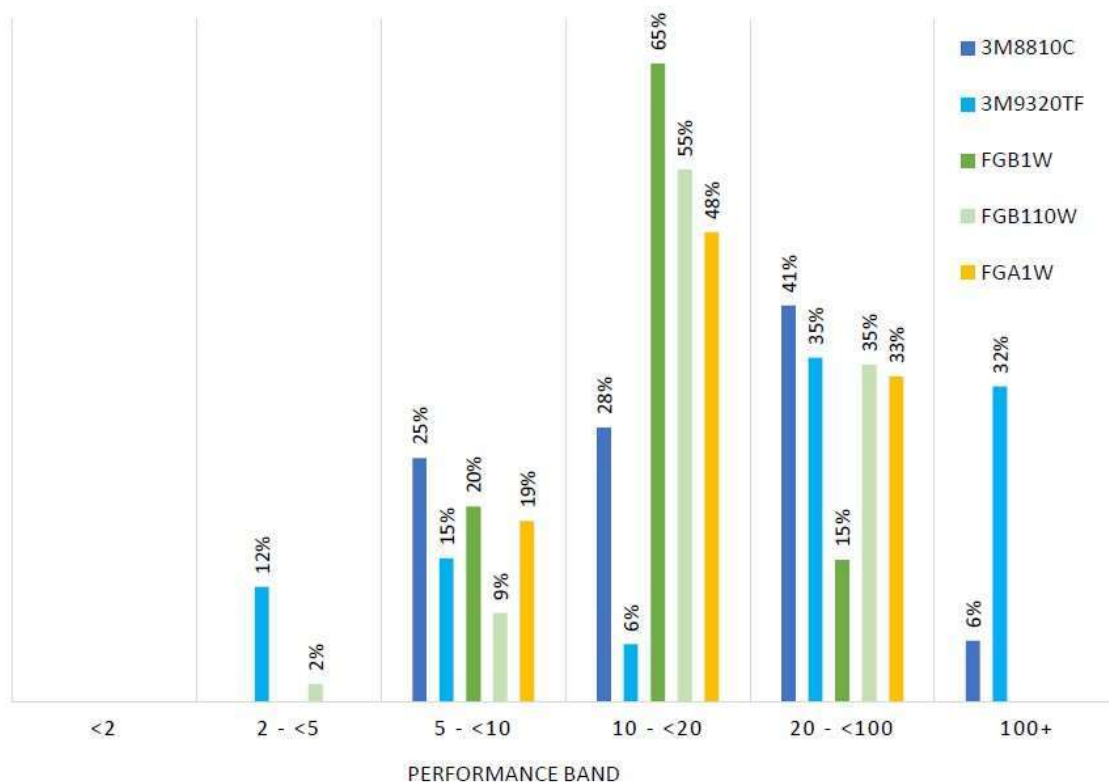


Figure 2. ASTM F3502 Leakage Assessment results, reported as LRs presented in a distribution by performance bands. Note: Leakage Assessment results are presented by facepiece LRs collated into performance bands. See Figure 1 key for full names of facepieces.

Figure 3 provides a cumulative view of each model's performance, by the percentage achieving the minimum LR specified, i.e., at or above 2, 5, 10, 20, or 100. The FFRs achieved the study target of 10 (or more) at a percentage of 75% of participants (24 of 32) for the cup shape and 74% for the tri-fold (25 of 34). Similarly, 80% of participants (44 of 55) wearing the Filter B tubular facepiece with one laundering met the target, while 89% of participants (49 of 55) wearing the 110-wash Filter B tubular facepiece met the target. For the band meeting or exceeding a LR value of 5, the lowest performing facepiece was the tri-fold FFR, yet this facepiece was also the highest performer with respect to achieving average LRs of 20 (or more) and 100 (or more).

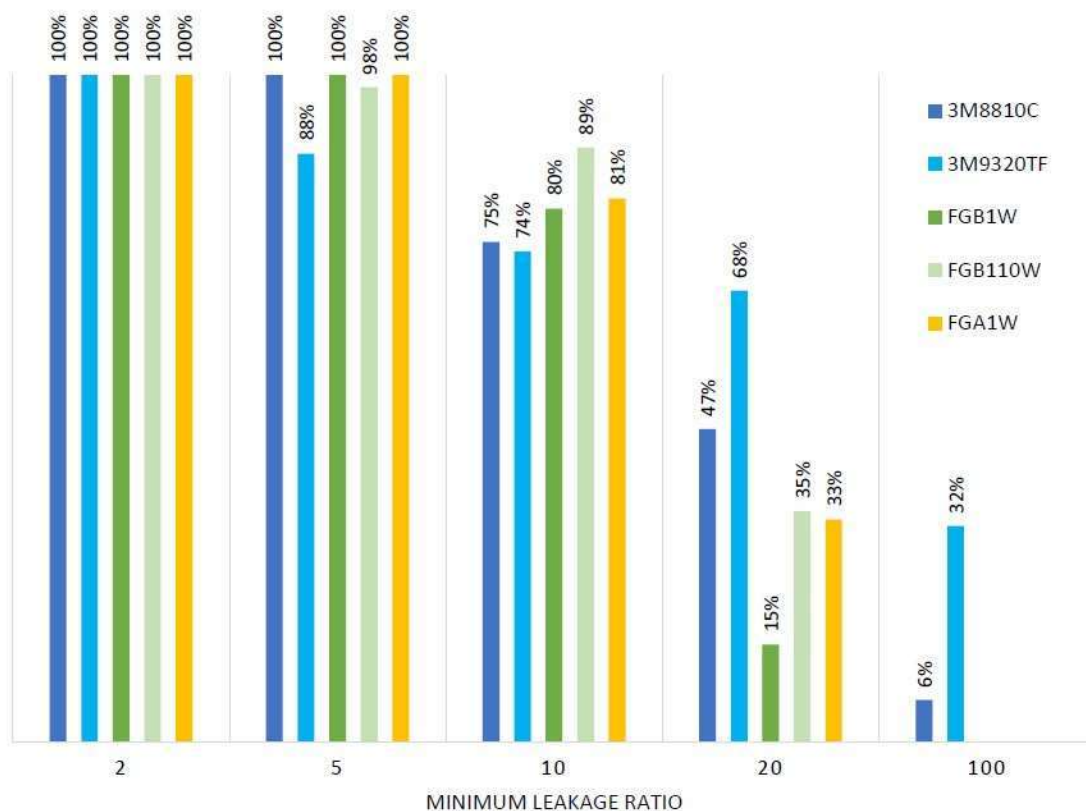


Figure 3. ASTM F3502 Leakage Assessment results showing the percentage of participants achieving LR at or above 2, 5, 10, 20, or 100. *Note: This cumulative view indicates the percentage of the facepieces achieving a LR of 2 or more, 5 or more, 10 or more, 20 or more, and 100 or more. For example, a facepiece achieving a performance level of 20 will be counted in each of the set of bars labelled “2+”, “5+”, “10+”, and “20+” but not further. See Figure 1 key for full names of facepieces.*

Figure 4 presents data for the reusable tubular product with Filter B, for samples worn after a single laundering, per instructions for first wear, and after at least 110 laundings. The LR increases by an average of 5 with most participants' LR seeing an improvement, as indicated by the number of values above the dotted line. The nonlinear nature of the LR means the increase will have a larger impact on the lower end of performance outcomes. For example, a LR of 5 which increases by 5 to 10, moves from blocking 80% to blocking 90%, while a LR of 15 which increases by 5 to 20, improves from 93.3% to 95%.

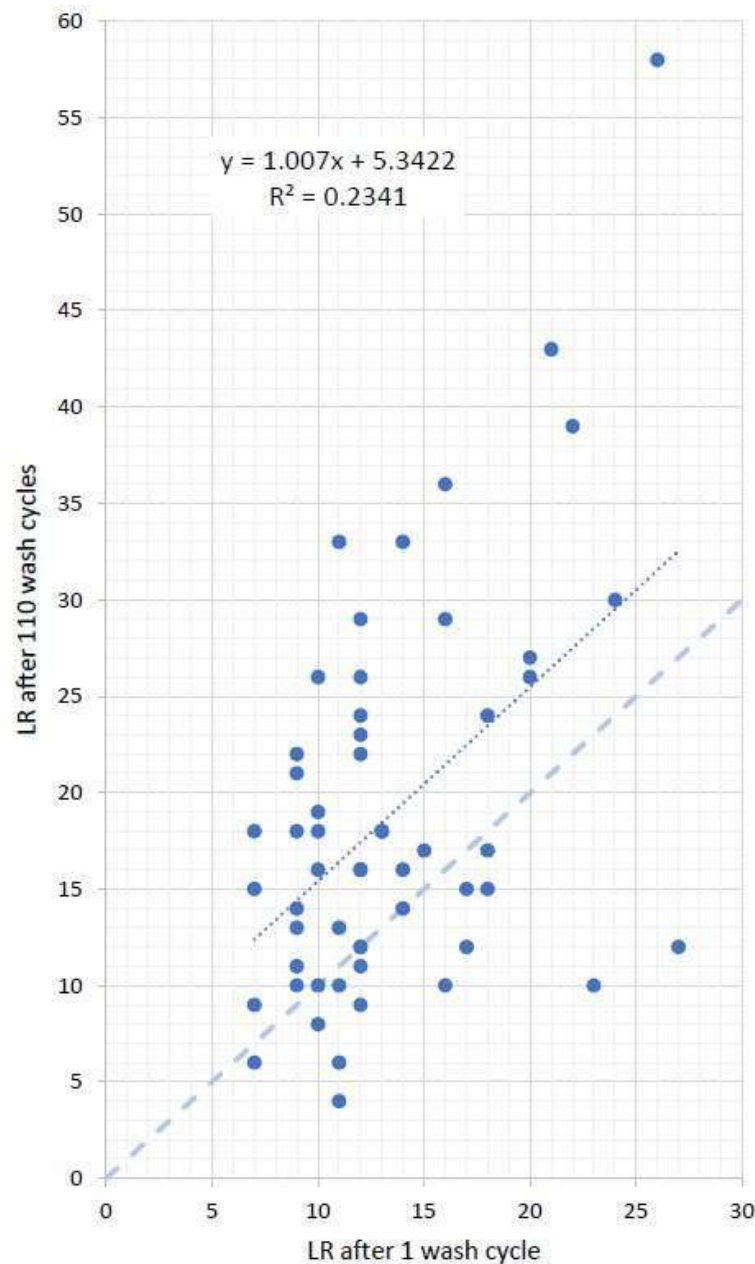


Figure 4. Comparison of LR after 110 wash cycles vs. 1 wash cycle for the reusable tubular facepiece with Filter B. *Note:* This graph depicts leakage for the reusable tubular facepiece with Filter B, as indicated by the LR, with a higher LR value indicating less leakage. The LRs for individual participants ($n=55$) are each represented by a blue dot. The dashed line represents a theoretical equal performance before and after 110 laundering cycles. The dotted line indicates the average change in performance, showing an overall improvement in performance after repeated laundering cycles. Actual values above the dashed line show improved performance after extensive laundering, while the values below the dashed line show decreased performance; some of the changes would be due to variability in donning. Samples tested after 1 laundering and after 110 or more laundering cycles were not the same samples.

Cross-tabulation of dimensions for bivalent panel and tubular facepiece sizing

To aid in improving fit, reducing leaks, and mitigating exposure to hazards, FFRs have been studied to determine key facial dimensions, but tubular facepieces have not. The following is a brief analysis of the anthropometric measurements taken in this study and test method outcomes. Analysis can identify trends in the relationship between the tubular facepiece and the two commonly required measurements, face length and face width. The relationship between individual results and individual facial dimensions will be explored in a follow-on paper.

Figure 5 plots the results for the facegaiter sizing dimension – the tubular facepiece seal circumference – for all participants against the bivalent panel dimension, face length. This plotting depicts the relationship between these two dimensions. As seen, there is a weak correlation between the tubular facepiece size and face length. There is a slightly stronger but still fairly weak correlation between the tubular facepiece size and face width, as seen in Figure 6. The lack of a clear relationship has implications for sizing. Sizing seeks to predict the most suitable facepiece for the wearer prior to its selection and acquisition. Outside of an occupational setting, there is very likely no fit testing system in place for the wearer. In this study, the tubular facepiece designed for unassisted settings performed well compared with half facepiece FFRs designed for assisted settings. However, it must be asked whether current dimensions (face length and face width) can be used to predict sizing and fit sufficiently for tubular solutions, as currently required under ASTM F3502.

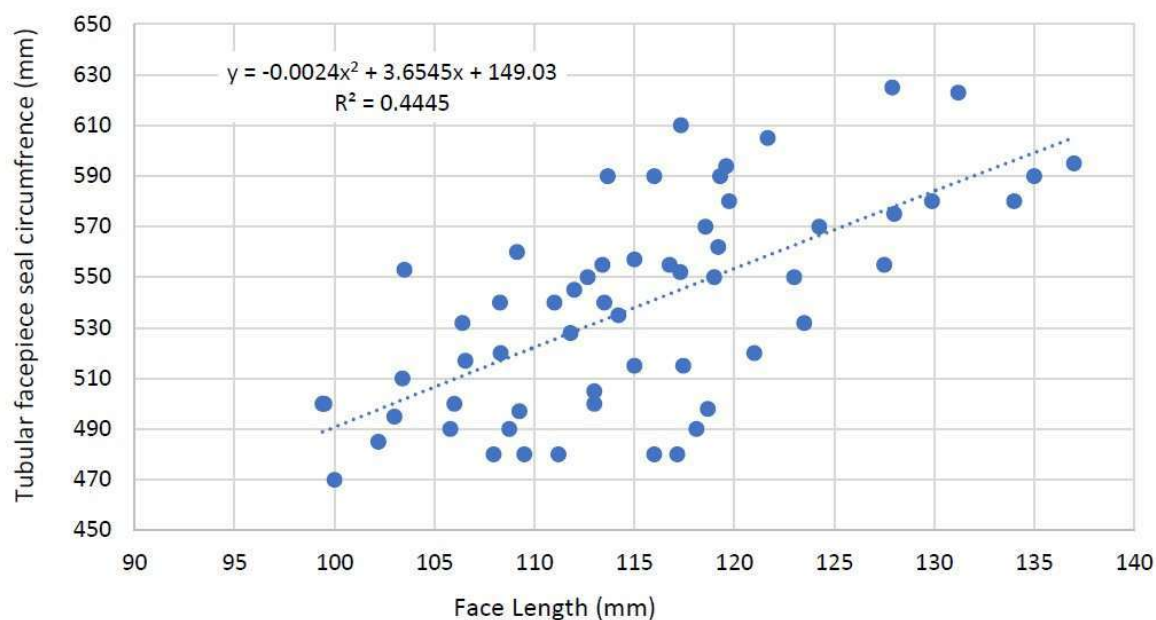


Figure 5. The relationship between participant face length and tubular facepiece seal circumference. *Note: The data in this graph reflect measurements of facial dimensions from all 59 study participants. Face length is a required measurement under ASTM F3407, and therefore required under the ASTM F3502 section 8.3 Leakage Assessment. The tubular facepiece seal circumference is the anthropometric measurement used in this study for sizing the tubular facepiece, as directed in the manufacturer instructions of the model chosen for study.*

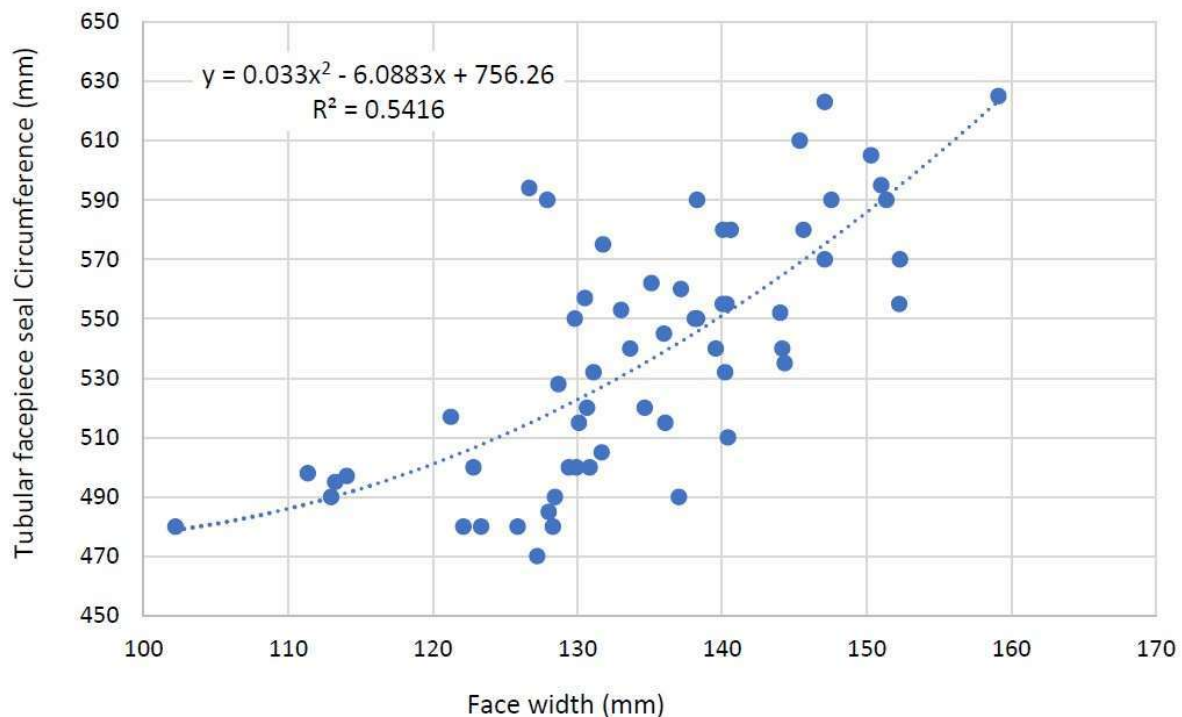


Figure 6. The relationship between participant face width and tubular facepiece seal circumference. *Note: The data in this graph reflect measurements of facial dimensions from all 59 study participants. Face width is a required measurement under ASTM F3407, and therefore under ASTM F3502 section 8.3 Leakage Assessment. The tubular facepiece seal circumference is the anthropometric measurement used in this study for sizing the tubular facepiece, as directed in the manufacturer instructions of the model chosen for study.*

DISCUSSION

Without assistance and by following only the supplied user instructions, wearers of the tested facepiece models achieved the NIOSH Enhanced Performance Plus requirement: a LR of ≥ 10 . While some individuals achieved LR's below 10, the average LR for all wearers wearing a given facepiece exceeded 10, meaning that each group (wearing a given facepiece) was protected from at least 90% of all particles. Table III provides details. On average, one version of the reusable tubular facepiece blocked 93%, while a cup FFR was at 93% and a tri-fold FFR was at 92%. Also, for the cup FFR and the tubular facepiece, facial hair was not an obstacle to achieving the target performance level, as was seen in Table IV. The ASTM F3502 Leakage Assessment helps illustrate the quality of reusable, alternative facepieces. It also suggests potential use as a tool to determine which facepieces are suitable for a given setting. Facepiece alternatives could be tested, including a NIOSH-certified N95; an "international" FFR such as FFP, KF94 or KN95 respirators certified under other country's standards (CDC, 2022); a "Wildland Firefighting and Urban Interface Firefighting Protective Face Covering" (NFPA, 2025); or a ASTM F3502 Barrier Face Covering. Using ASTM F3502's Leakage Assessment, these facepieces can be assessed with some rigor before wider distribution in the community. Facepieces could be assessed for possible use in unregulated workplaces (Dosman, 2000; Geng, 2024; NAS, 2022); in workplaces seeking to address wearer preferences (Aggarwal) such as mitigating the impacts of facial hair (Williams 2023b; Bhatia, 2022; Jung, 2023); or in the community (NAS, 2022).

Below are issues for consideration when adopting the use of a ASTM F3502 Leakage Assessment in product development, and in refining ASTM F3502 further.

Reporting of Facepiece Performance

Consideration should be given to confirming the intent to use the harmonic mean in reporting results under the ASTM F3502 Leakage Assessment. ASTM F3502 section 8.3.6 states that, for each size, one must report a calculation of the average LR. This calculation is for all bivariate panel cells for the stated product size (in the modified NIOSH bivariate panel used under ASTM F3502). Unlike ASTM F3407, ASTM F3502 does not specify what is meant by “average”, the arithmetic mean or harmonic mean; however, the term “average” will typically refer to the arithmetic mean. The ASTM F3502 LR and the ASTM F3407 RFC (Respirator Fit Capability) both describe non-linear relationships. Using the arithmetic mean will introduce an error when there are high performing outliers, which increase the reported average value incorrectly. This shift can be substantial, as seen in the results for the two FFR models in Table III. Using the harmonic mean allows the results for each wearer to be converted back to a value on a linear scale, averaged, then converted back to the correct LR for the group. This is the method used by ASTM F3407 in summing the individual results from each exercise in order to calculate the RFC for the individual. It is also the method used internally by the TSI PortaCount 8048. Use of the harmonic mean is particularly important where there may be a wide range of results in testing facepiece fit (Brown, 1992, Brown, 1995). ASTM F3502 should be revised to specify in explicit terms, and with appropriate qualifications, that the LR is to be calculated using the “harmonic mean.”

It also may be helpful to consider whether use of the harmonic mean itself is the most suitable approach for evaluating results from individual test subjects. A mean can signify that less than 50% of the test participants achieved the stated performance value. That outcome may be sufficient for testing respirators under ASTM F3407 (whose pass mark is 13 out of 25 participants wearing the product) because such respirators are designed for use in an RPP which also conducts individual fit testing on its participants. Specifically, an individual fit test determines which facepiece, among a range of possible products, meets the requirements and is suitable for the individual wearing it. However, there are situations outside of a regulated or RPP setting where an individual requires protection and could be largely reliant on the manufacturer's product capability test. Because such cases are foreseeable, it may be more appropriate to require that a large majority of fit capability test participants achieve the required performance level. An increased number or percentage performing as desired would suggest that the assessment more accurately represents wearer expectations. The results from Table III show that the products tested in this study achieved a pass mark of between 74% and 89% for a LR of 10. For a target LR of 5, 97.5% of test participants achieved this. Based on these findings, it might be reasonable to add a requirement that at least 75% or 80% of test participants meet a designated performance level.

Notably, the performance of the tubular facepiece product was not substantially influenced by face width or face length, which are the dimensions typically used in recommending a facepiece size to an individual. This finding and others will be reviewed in detail in a follow-up paper looking at the relative influence of anthropometric dimensions on fit as indicated by the ASTM F3502 LR.

Facepiece Fit Capability - Distinguishing Among Facepieces Designed for Unassisted Use.

Investigators use ASTM F3502 to compare the filtration and breathing resistance performance of diverse facepieces (Brochu, 2024; Hyun, 2023; Freeman, 2021). With respect to facepiece fit and overall protection performance when worn, ASTM F3502's Leakage Assessment also could inform the public's unassisted selection of various facepieces. A non-exhaustive list of key areas for review includes product types, anthropometric dimensions, and performance levels.

With respect to product type, ASTM F3502 does not restrict application of its test method to a particular facepiece type (e.g., half face design), thereby supporting innovation. As discussed, this study's facepieces included the tubular form factor. Product design experts note the benefits of the tubular form for facepieces (Brandel, 2020; DuPuis, 2022; Comeau, 2024; Bartoszek 2020; Aherleroff 2021; Schmitt, 2022), as do studies (Cooper; Mueller) and other documentation of professional judgment (Bhattacharjee 2020; Bothra 2020; Comeau 2020). These sources assess the tubular form's value to retention systems, leakage control, comfort, and other design parameters. ASTM F3502, sections 5.2.1 and 8.1.1.3, expressly anticipate a tubular form, permitting comparison to other facepiece types (Louie, 2022). However, studies which

compare the tubular form typically examine off-the-shelf versions designed for sun or wind protection (Lindsley, 2021) or certain improvised configurations (Pan, 2021; Lindsley, 2021; Cooper, 1983; Mueller, 2020). Few have studied the tubular form when intentionally designed for use by the general public as respiratory protection. Historically, there has been changeable guidance (Freeman, 2021; Freeman, 2022) and confusion about this facepiece type (Doron, 2023). In Figure 3, the data showed FFRs afforded the highest levels of protection, when fitted well to an individual participant, whereas participants wearing a tubular facepiece achieved the target performance at a larger percentage than those wearing either of the FFRs.

Study findings about the reusable tubular facepiece include the following. Firstly, the tubular form compares well to FFRs, as seen in Tables III and IV and in Figures 2 and 3. Secondly, although its filter material has a lower filtration capability than the Filter B version of the tubular facepiece (Baglin, 2022) and the FFR models studied here, the Filter A version performed at a high level. As such, the Filter A tubular facepiece reflects one promise of the tubular form: a strong seal yet an exceptionally low breathing resistance (1.7 mm H₂O; 17 Pa) (Baglin, 2022). In this study it showed high performance as worn, due to low leakage and enhanced filter performance at the lower operational pressures associated with normal breathing.

Thirdly, fabric construction can be a benefit. In the Results section, Table III, the LR for the reusable tubular facepiece with Filter B is compared before and after 110 wash cycles, with higher performance with more laundering cycles. In Figure 4, LR values were higher in the more heavily laundered version (110+ laundry cycles). The initially stiff Filter B material softens during the first few laundering cycles. This softening changes the hand of the material such that the fabric follows the contours of the face more closely, resulting in an improved seal and reduced leakage.

Fourthly, the location of where the tubular facepiece seals to the face is less variable than for other styles, indicating that this form may provide Near Universal Fit. The seal avoids areas problematic for half-face designs. The tubular facepiece in this study provided a consistent level of performance across a wide range of individuals. Such consistency is advantageous in settings outside of an RPP. For unassisted settings, however, the potentially wide range of performance parameters and testing outcomes call for a complex framing that is challenging to communicate. Also, a fragmented approach to assessing tubular facepiece performance reinforces the observation that there is no widely accepted method (Grozowska-Sobas, 2023).

The same issue arises when comparing the performance of alternative FFRs under unassisted use. For example, there is messaging in the community to use an “N95 or equivalent” but it is imprecise. KN95s have significantly more leakage than N95s (Duncan, 2021), partly due to ear loops (Caoili, 2020). However, there are examples of public health experts (Safarpour, 2022; Cahill, 2024; McGarity, 2024) treating KN95s and N95s as equal, even while CDC groups KN95s among “international” respirators which are certified under other countries’ rules (CDC, 2022). FFP2s and KF94s, certified to 94% filtration efficiency, routinely are equated with N95s, e.g., when distinguishing them from non-respirators (Lu, 2023; Tang, 2021; Dheda, 2021). However, KF94 fit issues produce more leakage than N95s (Park, 2021); and, where FFP2 models have ear loops, face seal leakage is more likely and they are much less effective (Baxter, 2024.). NIOSH has conducted extensive outreach to improve respirator use in the community, including a Respirator Fit Evaluation Challenge (Wehring, 2024) and Respirator Fit for All (Pollard, 2024). The aim of helping the public’s use could be supported by a common product test method to assess FFR performance, as worn under unassisted use, to better indicate the likely impact of different products as a personal or community wide intervention.

With respect to anthropometric dimensions, substantial scientific research, debate, and consensus (Zhuang, 2017) led to the adoption of two dimensions for sizing half face respirators: face length and face width. It is understood that the type of FFR (Manganyi, 2017; Fu, 2024) as well as the nose gap area (Griffin, 2024), nose protrusion (Khairul Hasni, 2023; Han, 2003), jaw width (Winski, 2019), and other features (Chopra, 2021; Manganyi, 2017) influence fit also. Unlike the half-face designs in the aforementioned studies, the tubular facepiece is not sized by those dimensions. Despite that, the tubular facepiece, tested under a ASTM F3502 Leakage Assessment in this study, performed well. Its results were comparable to an FFR’s. The tubular form’s performance also was more consistent than that of the FFRs, as seen in

Figure 1 and Table III, even after extensive laundering. This consistency suggests a more universal fit across participants by avoiding areas of the face to which it is more difficult to seal. For the tubular form, a sizing system based only on length and/or face width is not suitable and a new approach is required which more closely aligns to fitment requirements.

Finally, consideration might be given to ways to support the development of facepieces for unassisted use. There are several options.

One approach is the adoption of evidence-based performance levels. Table I provides a potential set of LR_s for gauging performance. As noted in the Methods section, NIOSH has defined two performance levels for facepieces tested under the ASTM F3502 Leakage Assessment: Enhanced Performance, based on achievement of a LR of 5, and Enhanced Performance Plus, for a LR of 10 (CDC, 2024; Brosseau, 2022). Performance standards would aid the public in discerning between facepieces, including FFR_s, for unassisted use. Adding the NIOSH values, 5 and 10, into ASTM F3502 would be an important step. Most LR_s for all models in this study were between 10 and 20, reflecting 90% to 95% blocking capability. Employing higher performance levels may be challenging, however. Evidence from this study would suggest a lower level than 20. Specifically, less than half of the cup and tubular models exceeded 20, but more than two thirds (68%) of the tri-fold did exceed 20, reflecting 95% blocking. These results suggest a level of 20 might be difficult to achieve consistently. Notably, NIOSH did not adopt a level of 20 despite expert reviews and recommendations for doing so (Brosseau, 2022).

Another option would be to increase the percentage of participants which must meet a designated performance level in product testing for this design parameter. As noted, this study's data suggest that a 75% or 80% figure might be useful and overcome reliance on a mean. Consideration, however, must be given to the cost to manufacturers who seek to develop and test their innovations in this area. High costs could see the continued reliance on improvised solutions by the public. There are other ways to support the development of facepieces for unassisted use. These approaches include developing requirements for specific user populations and better tailoring user information, e.g., manufacturer instructions, to unassisted conditions. Study data on the latter topic will be reported in a follow-up paper.

All of these approaches are complementary and can strengthen the already high value of the ASTM F3502 Leakage Assessment.

CONCLUSION

ASTM F3502 helped standardize facepieces across a range of designs, quality, and performance. Under it, a reusable facepiece in a tubular form can demonstrate consistent, high-level, and sustained performance after repeated launderings, across a range of wearers and sizes. Also, ASTM F3502's test methods enable comparisons of product performance, across facepieces, outside of an RPP. In particular, it is possible to compare the performance of facepieces designed for occupational settings yet extended to unassisted use in the community (e.g., N95s and international respirators such as KN95s, FF94s, etc.) with facepieces intentionally designed for unassisted use outside of an RPP. Targeted changes to ASTM F3502 could enhance the standard for such purposes.

Limitations

Like some other particle-counting instruments, PortaCount 8048 is known to underreport particles within the facepiece. The reason is that it samples continuously during the full breathing cycle, rather than just during inhalation. Another limitation is that facial hair was self-reported; future studies could adopt an objective method (Floyd, 2018). Also, it was not possible to have the same participant use the same sample for each test. Two different sets of the reusable tubular facepiece with Filter B were laundered (for a different number of cycles) to test each condition in the same session on the same participant. Finally, recruitment occurred in a university setting which may not reflect the general population.

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