Demonstration of a Reusable Mask in a Tubular Design that Provides Universal Fit and Protection from Respiratory Hazards

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ABSTRACT

Background: There is a well-documented need for a reusable, high-performing face mask for use by the public as a barrier to respiratory hazards.

Objective: This utility validation study sought to assess the functionality of a tubular-shaped, textile-based solution to enable the simple manufacture of a reusable face mask designed to minimize leakage and to achieve high levels of community protection from respiratory hazards.

Methods: We used a mechanistic approach to design, develop, and combine engineered components into an integrated tubular solution. To ensure the desired features were optimized when integrated, after reprocessing we tested the entire mask, as worn, for physiological impact, comfort, filtration efficiency, and leakage. For several features, the novel design and tubular shape required in-house design and manufacture of new test equipment. We tested fabrics, prototypes, and reprocessing protocols in-house and with academic partners. Independent testing for certain features was available (e.g., EN14683 Medical Face Masks, ASTM F3502-21, Standard Specification for Barrier Face Coverings) and was used to confirm performance.

Results: The tubular shape, special seals, unique harness, and three-layers of fabrics with distinct functions and composition work together to minimize leaks and ensure durability after repeated laundering. In-house testing indicated that designing a textile-based, tubular-shaped face mask optimized for source control with minimized leakage also resulted in wearer protection properties, even after hundreds of laundering cycles. Independent testing of one filter choice (Filter B) after 50 laundering cycles confirmed low breathing resistance (4.9 mm H_2O/48 Pa) and high filtration efficiency (96%) to ASTM F3502-21.

Conclusion: This utility validation study concludes that a reusable, tubular-shaped, textile-based face mask is capable of a universal fit as well as filtration efficiency and breathability performance levels that are similar to those for a disposable filtering facepiece respirator.

Keywords: Reusable mask, Filtration, Universal fit, Leakage, Breathability, Barrier face covering, Source control, Filtering facepiece respirator, Gaiter, Tubular face mask.

INTRODUCTION

Reusable face masks that are used to reduce risks from respiratory hazards must address many physical and human factors in their design, fabrication, use, and care. A solution should avoid

negative impacts from wearing and reuse; and such impacts can include adverse physiological effects (Spang et al, 2021) and health effects (Keri et al, 2021). Filtration, breathability, fit, seal, and comfort must meet desired performance levels (NASEM, 2022; Cloet et al, 2022). Often, key parameters do not work together: good filtration may mean poor breathability (Freeman et al, 2021; Payne et al, 2022). A solution balancing these factors, such as a filtering facepiece respirator, may have - in use - a poor fit or broken seal (Koh et al, 2022), and experimentation shows that even small gaps can produce leaks that undo the benefits of an efficient filter (Lai et al, 2012).

Because of the COVID-19 public emergency when the project began in 2020, respiratory transmission of the virus was a primary concern to the researchers, as was the question regarding how long the pandemic (including masking by the public and supply chain disruptions) might persist. Guiding principles initially were (a) stopping transmission at the source ("source control"); (b) accommodating supply chain issues through easily understood and replicated design, sizing, materials, manufacturing, and reprocessing; (c) accounting for biocompatibility of materials; and (d) ensuring durability and convenience, to encourage compliance with masking policies. As the project progressed into 2021, we planned to identify benchmarks from standards in the areas of source control and personal protection, such as the Barrier Face Covering provisions issued by ASTM International in February 2021 and adopted for occupational settings by the US Occupational Safety and Health Administration (Brosseau et al, 2022). In seeking to optimize source control as a design parameter, the research took an early focus on leakage. Existing solutions are not adequate for some head sizes and face shapes (Chopra et al, 2021; Solano et al, 2021), nor even for standard NIOSH head forms (Stannard et al, 2021). After prolonged use in a day, options that pass a fit test may cause discomfort or abrasions which are a disincentive to use (Cloet et al, 2022). Common conditions, e.g., dry eye (Fan et al, 2022), individual circumstances, e.g., facial hair (Bhatia et al, 2022), or other factors can mean options that perform well for some do not perform well for others.

Assessing breathability helps, in part, to determine the impact of various factors (e.g., seals, airflow through the filter) on leakage. Breathing resistance during inhalation leads to a feeling of wearer burden. Keeping airway resistance at 6.5 mm H_2O/L sec^{-1} (4.6 mm H_2O at 85 L/min) or below renders the burden less perceptible (Shaffer et al, 2014). On exhalation, the build-up of CO_2 within the mask can trigger a higher breathing rate and feelings of breathlessness. Breathability quantifies the effort to breathe when worn, with lower values more easily tolerated. Improving air flow through the filter also reduces the volume of leakage through any gaps at the edges following temporary or permanent failure of the seal. Adding space at the mouth, or plenum (Pan et al, 2021), can distribute and slow air flow through the filter, potentially reducing resistance also. The impact of the dead space observed in filtering facepiece respirator use was a well-studied issue of interest (Zheng et al., 2022). Given the potential for CO_2 build-up within the plenum, human subject tests were run to compare this effect with that of a filtering facepiece respirator. Physiological changes at rest, light, and moderate exercise were measured. Maximum CO_2 was about 3% for the benchmark respirator and 3.5% for the first prototype. While testing with the first prototype produced a slightly higher level of CO_2 than the respirator, there was no discernible impact on heart rate, blood oxygen saturation, or feelings of breathlessness. These results confirmed the safety of the novel design before conducting independent testing to filtration efficiency and breathing resistance standards.

Reusable solutions also should be durable for prolonged or intermittent wear over a long lifetime (Allison et al, 2021), across diverse conditions e.g., dust, smoke, pathogens (NASEM, 2022), with availability (Allison et al, 2021) and adjustability (Ipaki et al, 2021) to protect many wearers and wearer types. There is no universal system for fitting the public with face masks (NASEM, 2022), and research would need to address fit as a key parameter in developing a reusable textile-based face mask to aid individual and societal resilience to respiratory hazards.

A utility validation study (Weng et al, 2022) describes those factors which can be assessed to a standard for the purpose of comparison (Borkow et al, 2010). A utility validation study could design for, then assess, filtration efficiency and breathing resistance factors, as observed under independent testing of performance to existing international standards.

METHODS

A multi-disciplinary team provided expertise in engineering, textile science, physiology, microbiology, infection control, and public health. A mechanistic approach was used in design and development to ensure all air flowed only through the filter and did so consistently for all potential wearers. We conducted in-house testing and testing by independent laboratories. There were three steps.
Step I. Minimize leakage by design (and provide simpler sizing, fitting, and instructions)
Step II: Assess reusability and performance
Step III: Assess final prototypes' performance as worn and under independent testing

Step I. Minimize leakage by design (and provide simpler sizing, fitting, and instructions)

We designed an in-house apparatus to test outward and inward mask leakage. There is no consensus approach for measuring outward leakage (Bagheri et al, 2021; Koh et al, 2022; Lindsley et al, 2021). Only in-house inward leakage test results are included here, to explain the development of prototypes combining multiple design parameters.
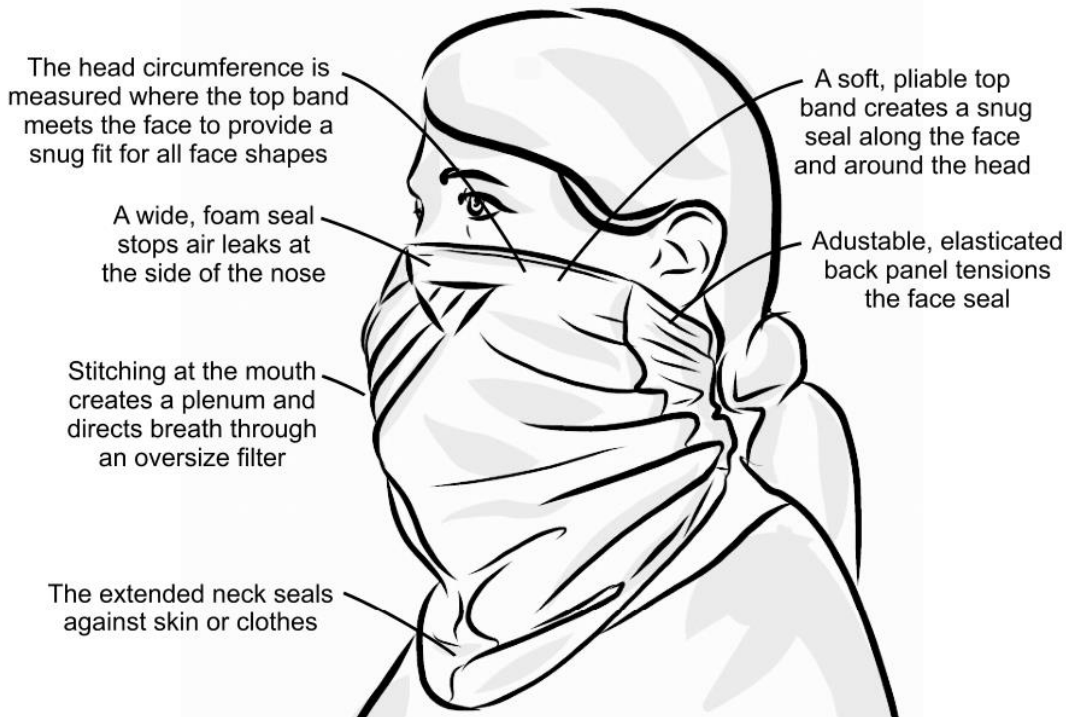
A tubular shape could locate seals away from jaw movements (e.g., talking) and away from the complex, variable contours of the mouth. Avoiding this area also could avoid other issues arising from use of half face masks, such as slippage during speech. Pliable fabrics were needed to follow the facial contours to create the seal on the tubular product. A wide range of fabrics yarns and construction were evaluated for filtration, flow resistance, robustness, and durability. Warp knit fabrics were chosen for their strength, dimensional stability, and their ability to drape well (Billings et al, 1970) and so contribute to a seal with the skin. The fabrics we tested are known for their biocompatibility from their use in other applications, and this attribute was confirmed by reference to emerging standards related to fabric masks, such as the fabric types listed as suitable by the American Association of Textile Chemists and Colorists in Table A1 of its Guidance and Considerations for General Purpose Textile Face Coverings: Adult (AATCC, 2020).

As noted, an added space at the mouth, or plenum (Pan et al, 2021), could distribute and slow air flow through the filter. Creating space in front of the mouth with seals at the upper and lower edges meant that an oversized filter could be utilized. Also, because the seals are formed away from the mouth and jaw, the embedded filter and plenum mechanism could be optimized to enhance filter performance during low velocity respiratory activities; during high velocity events, e.g., coughing and sneezing, the same mechanism would reduce the risk of seal failure and leaks. Figure 1 presents a schematic showing features of the tubular mask solution which is the subject of this utility validation study.

Convenience as a design parameter suggested that a face mask should have a familiar look to a potential wearer and should be easily accessible for the wearer. A tubular shape can rest on the shoulders (as with a snood or buff) and can be pulled up quickly as soon as needed, thereby reducing potential fomite transmission to other surfaces. Local accessibility requires the ability to manufacture locally with commonly available equipment and resources, e.g., fabrics that are easy to source, assemble, and clean. The solution's design and manufacture were created to be easily reproducible by others at small or large scale.

In addition to addressing these physical mechanisms, we converted certain human factors into design parameters. First, an embedded foam nose seal deforms to the nose shape to prevent leaks around the nose bridge. For convenience and compliance, it needs little user interaction, only alignment to the nose bridge. The nose seal is held in place by a band at the top of the fabric tube, which also creates a positive force on the seal. Second, only a single measurement around the perimeter of the head determines the wearer's size, and fit is not affected by other variations in face size or shape. After this simple sizing exercise, the design permits each wearer to achieve a consistent and high level of fit. An adjustable strap in the back was added to reduce the range of sizes presented to the wearer and enhance comfort. Also, personalization of masks can encourage masking (Palcu et al, 2022); the outside layer of fabric selected for the solution easily permits aesthetic choices (from an infinite palette given that

the outer layer is a printable textile) to complement diverse hair and skin tones and to provide neutral and accent hues, while a range of patterns can blend with work, dress, or leisure wear.

The head circumference is measured where the top band meets the face to provide a snug fit for all face shapes

A wide, foam seal stops air leaks at the side of the nose

Stitching at the mouth creates a plenum and directs breath through an oversize filter

The extended neck seals against skin or clothes

A soft, pliable top band creates a snug seal along the face and around the head

Adustable, elasticated back panel tensions the face seal

Figure 1. Schematic of reusable mask in a tubular design that provides universal fit and protection from respiratory hazards.

The tubular style facilitates simpler manufacturing, sizing, and care. The tubular solution was designed to hold its shape after many washings, with no rigid or semi-rigid parts to distort during handling, use, or washing. During wear, the seal would be less likely to fail because it rests in an area of the face with little to no movement; and, as result, slippage is avoided, performance is more consistent, and instructions to wearers can be simpler. Prototypes with this combination of features were tested for performance before and after reuse.

Step II: Assess reusability and performance

Two key design parameters for the filter were (A) product reuse after repeated laundering and (B) meeting performance levels required for the solution's intended uses.

Regarding reuse after repeated laundering, reusability parameters included (1) durability to meet desired performance levels after reprocessing; (2) the ability for domestic laundering which results in a product that can be worn again safely. For durability, both the filter fabrics and the fabric for the entire face mask required dimensional stability, to allow for prolonged storage or use. Warp knits are highly durable, and selection of this fabric construction is expected to contribute to the extended reusability of the solution, with minimal fraying from wear and laundering over time. The minimum target level was set at 100 wash cycles with "whole" mask filtration performance as worn maintained within 5% of the values when new. For domestic laundering, we carried out two assessments of cleanliness after reuse. Under the first, effective decontamination was defined as an absolute reduction in bioburden to the levels permitted for single use medical face masks (30 cfu/g) using BS EN 14683. The second assessment

involved seeding samples with bacteria, laundering, and observing survival levels; this second inquiry is still ongoing and not reported here.

Regarding meeting performance requirements, this parameter addresses the impact of fabric composition on intended use. In addition to being highly durable, dense, finely knitted fabrics made from multifilament yarns offer very good filtration. They do so by creating long and complex flow paths with relatively low flow resistance and, hence, good breathability (Chiera et al, 2022). The choice of yarn had to enable wicking to prevent moisture accumulation (Rogak et al, 2021) and minimize abrasion, e.g., as can occur from micromovements during use.

We used the parameters above to engineer a reusable solution to meet performance standards (which we identified as filtration efficiency and breathability, among others) after repeated laundering. Standards require that a textile meet desired performance levels after re-processing, as called for in ASTM D3938-18, Standard Guide for Determining or Confirming Care Instructions for Apparel and Other Textile Products. Our re-processing test method involved an in-house durability assessment on 5 samples. Samples are sized and adjusted to fit a breathing manikin and tested as they would be positioned on an individual when worn ("as worn").   Samples are washed in a front-loading UK domestic washing machine using a standard laundry cycle at either 40 ^{o}C or 60 ^{o}C and using a regular powder detergent. After washing, the samples are dried using a UK domestic tumble drier on a low heat setting. In-house testing occurs before laundering and after 1, 5, 10, 20, 30, 40, 50, 60, 80, 100, 125, 150, 175 and 200 wash cycles. In-house testing assessed total inward leakage (edge leakage and filter penetration) using an artificial breathing device described below and depicted in Figure 2. For reasons detailed further below, two alternative models (with Filter A and with Filter B) were laundered and tested in-house. The same re-processing protocol is followed for the samples for independent testing to EN14683 and ASTM F3502-21.

When independently validating filtration and other performance requirements, we found that the tubular shape introduced some complexity in testing. Existing mask standards call for certain test apparatus and instrumentation, and the testing parameters often presume the product being tested has the shape, seal, and composition of a typical half face filtering facepiece respirator. To mediate the conflicting requirements among different parameters, our method included the development of two filter alternatives, Filter A and Filter B. Our method therefore included an additional demonstration of whether the use of alternative filters was possible within the tubular style platform while maintaining high performance when each is embedded.

Prototypes and benchmarks (e.g., FFP2 respirator (N95 equivalent), Type IIR medical face mask to EN 14683) were tested in-house with a specially developed, artificial breathing device with source and susceptible manikins, seen in Figure 2 (not in a testing configuration); test cabinet; particle counters; and other equipment. This equipment would be validated under Step III, through independent tests.

Given that the solution was for source control, we considered group transmission dynamics and set the minimum "as worn" performance requirement as follows: the reduction of expelled (wet) particles, at a size greater than 1 µm, by 80% (including any edge leakage). During in-house testing of performance when worn for source control, results showed that high levels of smaller particles were being filtered, indicating that a degree of wearer protection when worn could also be achieved. We set the performance for wearer protection at least 80% for dry ambient aerosols >0.3 µm, which is significantly more difficult to meet. For both source control and wearer protection, we set breathability at <50 Pa at an inhalation rate of 30 L/min tidal (average healthy adult undertaking light activity) so the solution would limit pressure on the seals and burden on the wearer. Prototypes of the filter mechanism were constructed and tested in-house to determine if these levels would be met.

Filter A was constructed of three layers (Rogak et al, 2021), each from a different three-dimensional warp knit fabric. The properties of the inside layer (touching the face) help take up moisture, wick, and protect the middle layer; the middle layer captures the smallest particles; the outer layer protects the middle layer and serves as an added particle barrier on inhalation. The three layers of fabric would be selected to create trilobal charging, helping to attract very small particles moving through the face mask. Finally, the strategic spacing of the three layers is designed to influence flow resistance and filtration, with stitching through the layers using multi-filament thread to clamp the layers close together. This stitching stiffens the assembly and increases flow resistance to provide better structure and shape to

the filter itself, directing more flow to areas away from the nose and mouth, improving overall filtration, and leveraging the plenum and oversized filter's surface area to enhance overall breathability at high levels of filtration performance. In this way, the tubular fabric face mask and its embedded filter materials comprise the overall filtration solution, as an integrated assembly with several functional components.
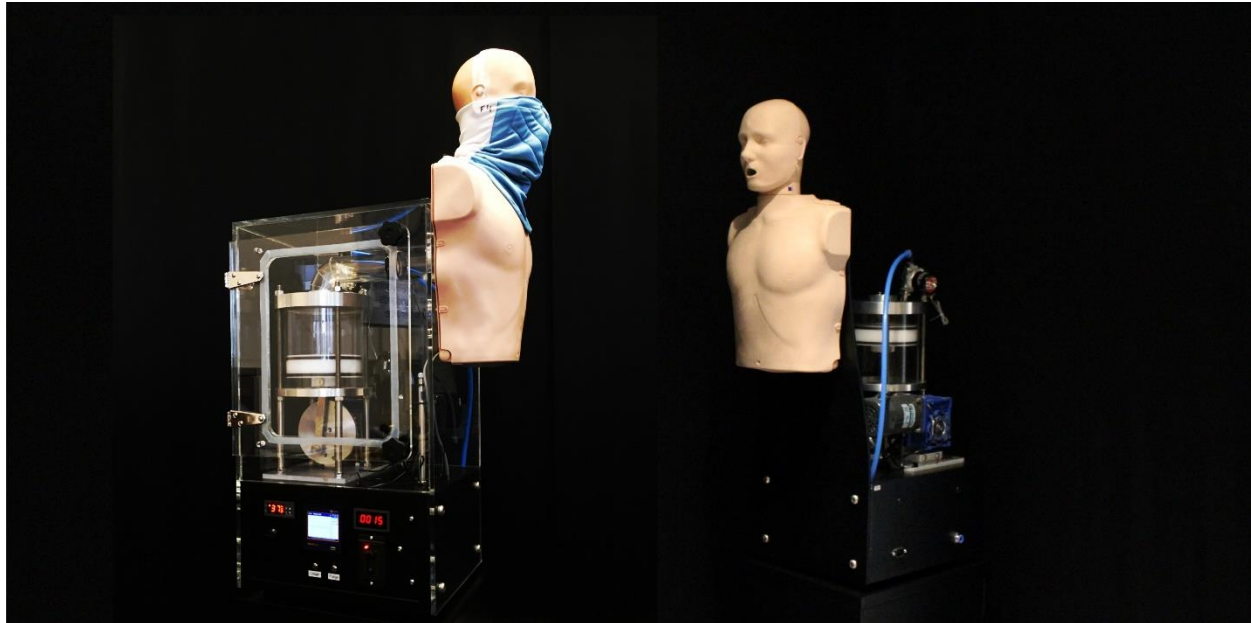
Figure 2: Source and susceptible manikins capable of tidal breathing and constant flow. The source manikin has 10 Hz pressure sensors to track flow resistance in the breathing cycle, is heated to ensure correct buoyancy of exhaled air, and has a secondary containment chamber to prevent leakage of source aerosol.

In developing the filter mechanism, layer by layer, the filter performances of each potential/candidate fabric for Filter A were assessed individually, as well as when combined and layered as simple quilts. Filters with peak pressures >110 Pa and filtration performance <80% (0.3-10 µm) were deemed unlikely to be suitable. Down-selecting to a final configuration covered a range of fabrics with multiple yarns and construction types. To create Filter B, Filter A's middle layer was replaced with a non-woven fabric, to make the solution more suitable for testing under the existing standards for face masks and the associated test apparatus.

Testing for filtration efficiency was run in-house after laundering across multiple sessions, using the framework provided in existing standards for testing for performance after processing.

Step III: Assess final prototypes' performance as worn and under independent testing

Our method called for testing the two filter constructions described in Step II. The original, Filter A, has three layers of knitted fabric and was optimized for testing the entire integrated solution as worn under use conditions such as coughing and tidal breathing. Filter B, with a nonwoven filter between two knitted layers, was designed to perform under the constant flow conditions and the aerosol specific to respirator testing; the relevant standards utilize broad performance requirements and do not directly seek to reproduce in-use conditions.

Common measures of face mask effectiveness, e.g., breathability and filter performance, were the primary methods by which Filters A and B were gauged and compared to benchmark solutions. However, the overall design – a tubular shape as enhanced by a plenum (formed by unique stitching), an

oversized three-layer filter, and engineered seals - was conceived as an integrated solution whose whole is potentially better than the sum of its parts. Therefore, a key part of the method was assessing the performance of the entire face mask "as a whole" and "as worn", as referenced earlier.

To assess "whole mask" performance, as worn, the tubular face mask (with Filter A) and two benchmarks, a respirator, and medical face mask, were first tested in-house for wearer protection on the breathing manikin having a plastic head form covered by firm, silicon skin, as seen in Figure 2.   The manikin was placed within a 400-liter test chamber; there were two challenge aerosols: 12% NaCl dried particles (not discharged to Boltzman equilibrium) and DEHS liquid particles (which have zero charge). All samples were first tested 'naturally fitted' to determine Total Inward Leakage (TIL) then re-tested with the edges taped to prevent all edge leakage, to directly measure filter penetration. Edge leakage was then calculated as TIL minus Filter Penetration and the protection factor was calculated as 1 divided by TIL.   Testing for TIL and total outward leakage used airflow conditions typically experienced when worn (i.e., tidal breathing over the range of 15-45 L/min) under challenges with diverse aerosols, e.g., with variations by type and particle size.

To validate "whole mask" results, independent tests (Textile Protection and Comfort Center, NC State, USA) of whole mask performance were run on the tubular face mask (Filter A) with a NIOSH-approved N95 respirator (Gerson, USA) control, as reported in Results, relating to whole mask performance as worn. The TPAAC (Textile Protection and Comfort Center) test manikin, seen in Figure 3, has softer, silicon skin as well as dynamic head movement. These independent tests would gauge whether there was consistent "whole mask" performance as worn.

Figure 3. Dynamic head form having silicon skin, with control on left (N95) and the tubular face mask (Filter A) on right, utilized to gauge whether there was consistent "whole mask" performance as worn.

As noted in Step II, our tubular style product does not have the shape, seal, or composition anticipated by the provisions of relevant standards. In addition, analysis during prototyping showed there was little difference between Filter A (composed only of common textiles) or Filter B (with a non-woven middle layer similar to those used in single use respirators) under in-house testing for performance as worn; however, tests for performance of the mask, as worn, are not yet included in relevant standards. As part of our method, we therefore sought external review and validation of in-house results. Accordingly, the solution, incorporating Filter A or Filter B, was sent for independent testing to existing mask standards to confirm key performance values.

RESULTS

The following are results for the testing and benchmarking of the tubular face mask against a filtering facepiece respirator and medical mask. All results are from testing of three specific products: a tubular face mask commercially known as facegaiter™, the filtering facepiece respirator (3M Aura™ 9320, EN149:2001 FFP2 NR D CE2797, Minnesota, USA), and a medical face mask (EN14983:2019 Type II R, Zhejiang Quzhou Rongbo Medical Instrument Co., Ltd, Quzhou, PRC).

1. Results Summary: Breathability

In-house breathability tests results illustrate how the facegaiter (Filter B) is substantially more breathable than a respirator or medical face mask, as seen in Figure 4. Breathability values for the facegaiter with Filter A (not shown in Figure 4) further improved on benchmark levels, with its results being just under half of those for a facegaiter with Filter B. These resistance levels, which are close to or below 4.6 mm H_2O indicate there may be no discernible breathing resistance for a healthy average adult engaged in light activity (Shaffer et al, 2014).

In contrast, for the medical face mask, a lack of edge seals meant that up to 50% of the air bypassed the mask filter, producing much lower values than when the edges of the medical mask were sealed by taping. Only the medical mask had its edges sealed with tape; the filtering face piece respirator and the facegaiter form natural edge seals and were not taped. Figure 4 shows only the data for the medical mask when the seals were taped; it indicates that the medical mask style is more breathable than a respirator when both are fully sealed, but both are less breathable than the Filter B facegaiter. This difference from the benchmarks may be partially explained by the facegaiter's larger filter area, which is approximately three times the surface area of benchmark filters.

Independent tests (Nelson Laboratories, Salt Lake City, USA) on breathability to ASTM 3502-21 yielded values of 1.7 mm H_2O (17 Pa) for Filter A and 4.9 mm H_2O (48 Pa) for Filter B, under positive flow (exhalation) at 85 L/min (approx. 27 L/min tidal).

2. Results Summary: Filtration Efficiency

As noted in the Methods section, several fabrics were tested individually and as integrated into the overall solution. The following are results for Filter A and Filter B, under both in-house and independent testing. Table I shows Filter A's final composition, with the performance of each layer and as assembled; Table II shows a >99% BFE for five samples of the facegaiter face mask incorporating Filter A (4ward, UK, EN14683) after 100 laundering cycles. Table III shows a consistent >96% PFE after 50 laundering cycles of the facegaiter face mask (Filter B), for ASTM 3502-21 (Nelson Laboratories, Salt Lake City, USA).
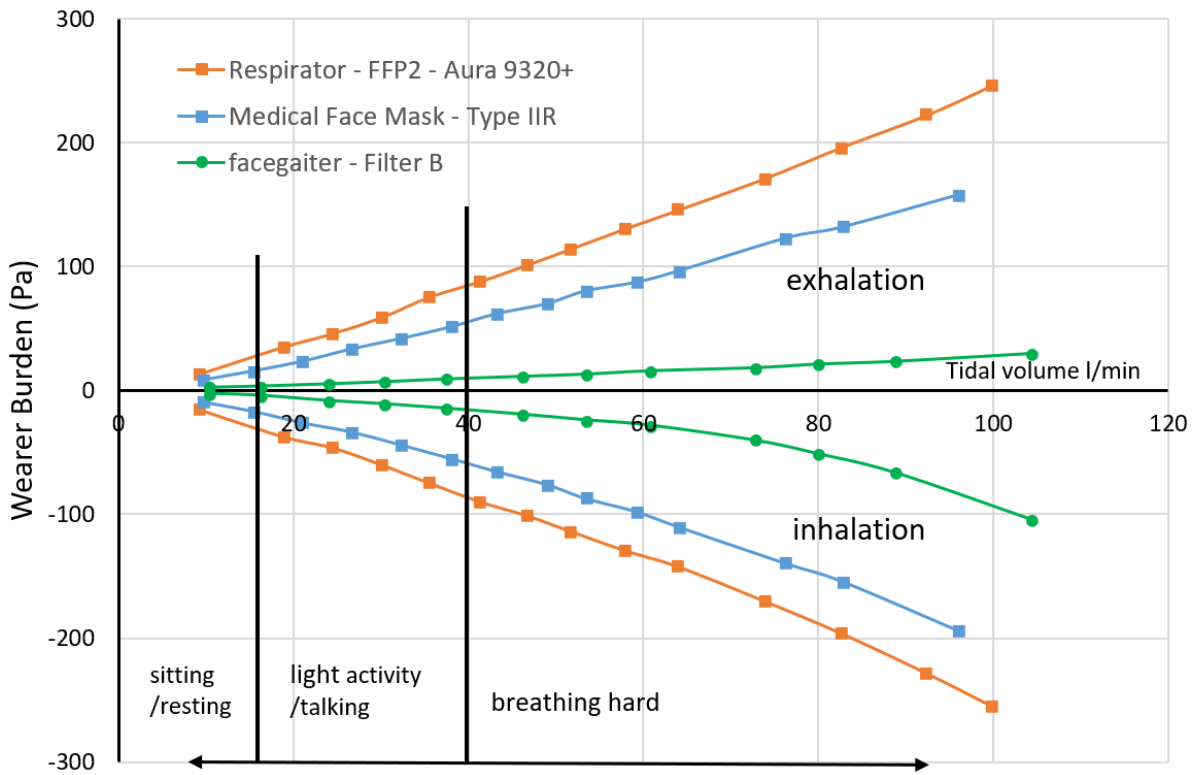
Figure 4. Graph of inhalation and exhalation resistance at different breathing rates. All values are maximum pressure at peak flow for masks as worn on a manikin.

Table I. In-house Tests of Filtration and Peak Pressure for Components in Filter A and Filter A as Assembled (Tested Unlaundered, under a Tidal Flow of 15 L/min on a 150 mm Diameter Sample Holder; Peak Velocity approximately 10 cm/s; Test aerosol 12% NaCl sample and aerosol not discharged)

Filter types	Peak Pressure Pa	Filtration	
		Mass 0.3-10um	Count 0.3-0.5um
Benchmark filters			
Respirator (FFP2 - Aura 9320+)	107	99.8%	98.6%
Medical face mask (Type IIR)	78	99.8%	99.0%
facegaiter filter layers (filter A)			
Inside layer (warp knitted nylon)	8	58.0%	32.2%
Middle layer (warp knitted polyester fleece)	21	91.0%	73.1%
Outside layer (warp knitted polyester)	10	49.9%	25.2%
facegaiter 3-layer filter A (as assembled)	47	99.7%	97.5%

Table II. Independent BFE test results (EN14683, 4ward, UK) for 5 facegaiter face masks (Filter A) after 100 laundering cycles (40 °C and tumble dried). On seam test includes standard stitching. EN14683 assesses survivability of *staphylococcus aureus* using a wet aerosol and cascade impactor, size range 0.65 μm – 7.0 μm, mean particle 3.0 um, velocity 9.6 cm/s

facegaiter (filter A) after 100 wash cycles	Sample 1 (off seam)	Sample 2 (off seam)	Sample 3 (off seam)	Sample 4 (on seam)	Sample 5 (on seam)	Threshold (EN14683)	Result
Bacterial filtration efficiency (BFE) %	99.64	99.7	99.37	99.85	99.91	≥ 98	Pass

Table III. Independent test results (Nelson Laboratories, Salt Lake City, USA) for 10 samples of the facegaiter face mask (Filter B) after 1 and 50 laundering cycles (60 °C and tumble dried), for ASTM 3502-21 with a TSI 8130 automated filter tester, using a sample holder to allow positioning of whole mask with positive clamping around the edge of the 3-layer filter at or inside of the seal positions. Flow rate = 85 L/min, test aerosol NaCl, 50% of the test aerosol by mass is <0.27 μm and 50% by count is <0.075 μm

Number of wash cycles	Test filter B	Sample Number									
		1	2	3	4	5	6	7	8	9	10
1	Filtration %	94.14	96.00	95.36	94.13	94.31	96.68	96.53	95.00	94.69	95.05
	Airflow Resistance (mm H_2O)	3.9	4.0	4.0	3.4	3.9	3.9	3.9	4.0	3.8	3.8
50	Filtration %	98.22	97.68	98.38	98.27	98.43	97.16	97.21	96.49	98.56	97.53
	Airflow Resistance (mm H_2O)	4.8	4.2	4.9	4.5	4.5	4.2	4.2	4.4	4.8	4.2

3. Results Summary: Whole Mask Performance as Worn

Testing and benchmarking the tubular face mask against a respirator (FFP2) and medical face mask produced the results in Table IV. These in-house testing results are arranged to show, ultimately, the protection factor for a susceptible wearer to two aerosol types across a range of particle sizes.

Table V presents the results from independent testing of whole mask performance, with the lowest average performance being 86% (14% TIL) for the facegaiter tubular solution at the smallest particle size with that test set up.

4. Results Summary: Reusability

Reuse requires the ability to clean and re-process the solution. Independent testing results indicate effective cleaning through a domestic washing and tumble-drying process, meeting the cleanliness requirements of BS EN14683, <30 cfu/g, (4ward, UK).   Reuse also requires durability and effectiveness over time. Results demonstrate that breathability and filtration performance are maintained after re-processing, including, as reported in Results Summary: Filtration Efficiency, under independent tests occurring at 50 and 100 laundry cycles. Further in-house filtration testing has shown that, after 200 washes, Filter A exhibits a 2% drop in filtration (when washed and tumble dried in-house at either a 40 °C or 60 °C setting); based on the consistently high performance, it is expected that Filter A might be serviceable for up to 500 washes. Ongoing, in-house tests of a facegaiter with Filter B (60 °C setting plus tumble drying) currently show continued high-performance (at or above initial values) after 150 laundering cycles.

Table IV. In-house, "whole mask" testing: filter efficiency plus leakage for facegaiter (Filter A) after 100 laundering cycles (40 ºC and tumble dried), and benchmarks

	particle size	FFP2 Aura 9320+		Medical Face Mask Type IIR		facegaiter filter A	
		DEHS	NaCl	DEHS	NaCl	DEHS	NaCl
Filter Performance	0.3	97.6%	98.0%	90.3%	96.6%	81.8%	93.1%
	0.5	98.3%	98.7%	95.1%	98.4%	89.5%	94.8%
	1	98.6%	98.9%	96.8%	98.9%	93.4%	96.7%
	2	98.9%	99.1%	97.6%	99.3%	96.0%	97.8%
	5	99.4%	99.4%	98.9%	99.4%	98.3%	99.6%
	overall by mass	99.0%	99.1%	97.8%	99.2%	96.1%	98.0%
Filter Penetration	0.3	2.4%	2.0%	9.7%	3.4%	18.2%	6.9%
	0.5	1.7%	1.3%	4.9%	1.6%	10.5%	5.2%
	1	1.4%	1.1%	3.2%	1.1%	6.6%	3.3%
	2	1.1%	0.9%	2.4%	0.7%	4.0%	2.2%
	5	0.6%	0.6%	1.1%	0.6%	1.7%	0.4%
	overall by mass	1.0%	0.9%	2.2%	0.8%	3.9%	2.0%
Edge Leakage	0.3	14.5%	7.0%	69.1%	33.1%	-0.5%	-0.1%
	0.5	11.3%	6.2%	67.0%	32.2%	-0.5%	0.1%
	1	9.5%	5.2%	63.5%	30.9%	-0.5%	0.7%
	2	8.6%	5.1%	59.8%	29.3%	-0.2%	0.7%
	5	7.0%	2.9%	50.1%	23.2%	0.0%	1.3%
	overall by mass	8.3%	4.7%	57.3%	28.1%	-0.2%	0.8%
Total Inward Leakage	0.3	16.9%	9.0%	78.8%	36.5%	17.7%	6.8%
	0.5	13.1%	7.5%	71.8%	33.8%	10.0%	5.3%
	1	10.9%	6.4%	66.6%	32.0%	6.1%	4.0%
	2	9.6%	6.1%	62.2%	30.0%	3.8%	2.9%
	5	7.6%	3.5%	51.2%	23.8%	1.7%	1.6%
	overall by mass	9.3%	5.6%	59.5%	28.9%	3.7%	2.8%
Protection Factor	0.3	5.9	11.1	1.3	2.7	5.6	14.7
	0.5	7.7	13.4	1.4	3.0	10.0	18.9
	1	9.2	15.7	1.5	3.1	16.5	24.9
	2	10.4	16.4	1.6	3.3	26.0	34.3
	5	13.1	28.4	2.0	4.2	57.5	60.9
	overall by mass	10.8	18.0	1.7	3.5	27.1	35.1

Table V. Independent testing (Textile Protection and Comfort Center, NC State, USA) of one facegaiter (Filter A), after a single laundering cycle (40 °C and tumble dried), fitted and tested three times on an experimental, animated head and shoulder manikin having a range of motions mimicking human movements and pliable artificial skin. The number of ambient particles was increased as required using artificially generated NaCl following the standard fit test protocol. Animation was continuous, with a 1-minute sample time for each motion.

Motion type	Filtration efficiency % (0.3-0.5um)			
	N95	facegaiter - filter A		
	Control	test run 1	test run 2	test run 3
Still	94.5	92.8	93.8	91.6
Still	94.3	92.5	93.3	91.5
Head Nod	93.5	88.0	86.9	86.9
Head Shake	93.5	85.5	82.8	85.3
Jaw Up & Down	92.9	86.5	84.7	88.4
Head Wobble	90.8	84.7	81.3	85.1
Still	89.9	85.9	83.5	86.6
Average	92.8	88.0	86.6	87.9

CONCLUSIONS

Our objective was to design, develop, and test a reusable, high-performance, tubular-shaped face mask with a focus on eliminating edge leakage, and the results indicate the benefits of the tubular solution.

• Under testing to ASTM 3502-21, the facegaiter tubular solution (Filter B) achieved breathability of 4.9 mm (48 Pa) and filtration efficiency of >96%. This independent test result and others showed high performance for filtration and breathability.

• Reducing the resistance to air being directed through the filter allows effective edge seals to be created more easily and reduces the volume of air flowing around the filter if there is a partial seal failure. Total inward leakage was used to assess overall wearer protection and was an indicator of overall mask performance for both wearer protection and source control. Results show that edge leakage is a critical factor in performance of masks as worn and suggest that assessing face mask performance by testing isolated filter specimens will not address other relevant mechanisms influencing functionality for the control of respiratory hazards.

• Engineered enhancements to a basic tubular style – including the creation of a large plenum, use of a multi-layer warp knit fabric filter, development of effective edge seals away from the mouth, and use of an oversized embedded filter - work in an integrated way to achieve the demonstrated performance.

• A tubular solution with engineered enhancements has a universal fit, adjustability, low wearer burden, and robust, bio-compatible fabrics that together treat each wearer equally well and offer an alternative for underserved populations, e.g., those with small faces, facial hair, or face types whose dimensions are not fully addressed under existing protocols.

• The project's research and documentation of filtration performance over hundreds of washes contributes to the state of practice for reusable face masks.

Limitations. There will be some limitations on the in-house testing set-up. For example, silicon skin is less pliable than a human face so it is possible results are lower than those that may be achieved using human test subjects.

Next Steps. Our next steps include the following: conducting independent testing for filtration efficiency after increased numbers of laundering cycles; publishing details on the in-house apparatus including a comparison of its test data in relation to independent test results, as well as outward/inward leakage testing; publishing data related to decontamination, e.g., tests conducted under alternate domestic laundering conditions; carrying out fit and leakage assessments across a large cohort of human subjects with varied facial features to validate universal fit, to include measurements of subjective comfort; assessing whole mask performance for wearer protection to specific environmental and work place hazards (including challenges relative to dust, ash, pollen, and other particulates and aerosols); and further developing the tubular solution as a platform for the assessment of new filter configurations optimized for various respiratory hazards.

Summary. A tubular shape can be leveraged to create a reusable, convenient, robust, highly breathable, face mask that minimizes leakage and provides an effective two-way barrier from respiratory hazards, with simpler sizing and a secure, universal fit.

Acknowledgments

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