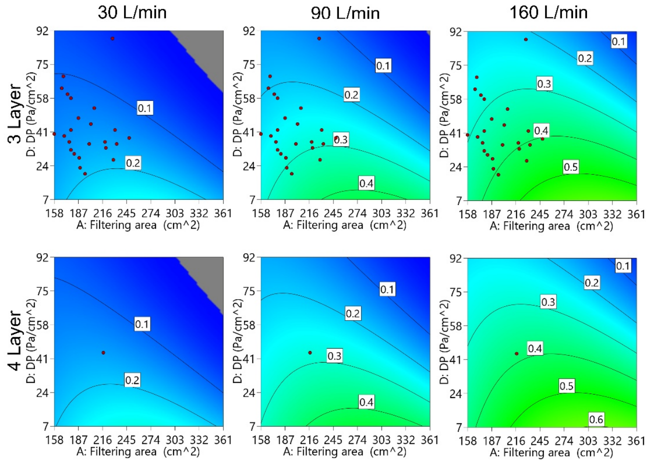

Fig. 11. TFE values predicted by the RSM model for a mask with a meltblown layer in the filter, but no nosepiece. Results are shown at three different flow rates (30, 90, and 160 L/min). Experimental datapoints are represented with red dots.

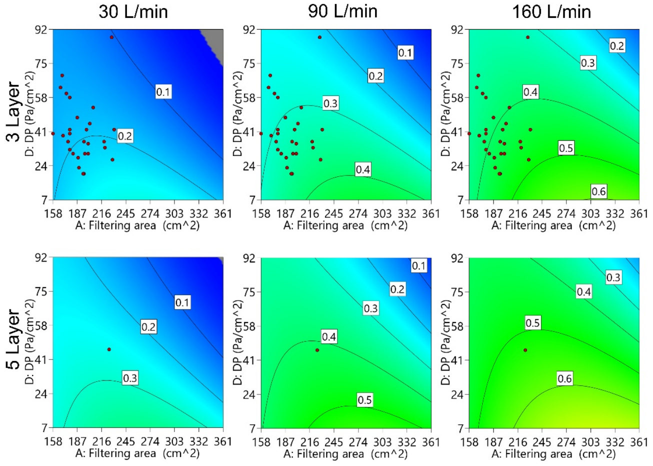

Fig. 12. TFE values predicted by the RSM model for a mask with a meltblown layer in the filter and a nosepiece in place. Results are shown at three different flow rates (30, 90, and 160 L/min). Experimental datapoints are represented with red dots.

factors for the correlation. These observations are compatible with our results regarding the trend and the spread of TFE data with respect to material breathability and BFE although a straight comparison between collection efficiency and TFE is improper. Since the former is a direct measure of aerosol filtration, the latter is an estimate from mask leakage and BFE, where the effects of inertial impaction and different aerosol size are not considered.

Computational fluid dynamics (CFD) simulations [38], [61] have been conducted to study the airflow pattern around a worn mask during breathing and coughing, evidencing how misfitting a mask create leakage through gaps compromising its efficacy [61], and that leakage correlates with lower filter porosity because of the increased DP of the filtering materials [38]. All these results corroborate the recommendation for a tight fitting and a breathable material, and the necessity of identifying comprehensive performance metrics which include the effect of leakage, such as the TFE defined in this study.

To further investigate the role of the seal, we tested the subgroup of 26 masks marketed with a nosepiece also after removing the nosepiece. We found that the presence of the nosepiece positively correlated with TFE at all three flow rates. The type of the nosepiece also affected the results, with an MW strip associated with a much better efficiency at reducing the leakage than a PO. This finding may be ascribed to the better pliability of metal when adapting the nosepiece to the user's nose ridge and its capability to maintain the shape. The surface response model confirmed the importance of the nosepiece in improving TFE performance, differentiating according to the presence of a meltblown layer, where the effect was more pronounced. These results underline the importance of the nosepiece in mask design, especially with filtering materials which offer a lower breathability, and are consistent with studies performed on human subjects [20] and with computational simulations [38], showing that air escaping from the gaps around the nose is more critical than lateral leakage.

The role of other parameters involved in mask design (mask area, the number of layers, and the presence of the meltblown) on the TFE was also investigated. While the analysis of the single factors did not detect any significant correlation with TFE apart from DP, the surface response model evidenced an influence of several factors on TFE. There was a minor negative quadratic variation of TFE with the mask area, with a maximum in the middle range. This trend could be ascribed to the fact that only the mask surface region around the mouth was involved in air filtering, while exceeding tissue wrapped toward the ears and under the chin offered a poor contribution. Concerning the design of tissue material, i.e., the number of layers and meltblown, while they improve material FE, they also worsen filter breathability, canceling out any benefit for masks with a poor seal. However, the surface response model showed that increasing the number of layers (up to 3) can enhance performance when a nosepiece is present, i.e., when the seal of the mask is good enough to contain the leakage due to an increase in DP.

The uncertainty associated with experimental TFE measurements might suggest a more extensive use of CFD simulations. Despite the interesting possibility to visualize the behavior of flow and particles through mask and face-seal leaks, its exploitation has been hindered by several factors. The typical approach is based on fixed geometries of the masks, thus neglecting the fluid-structure interaction between flow and mask (which is instead inherently reproduced in the laboratory test). It is well-known that inward and outward flows have very different effects on the protection offered by the mask [24]. On the one hand, inhalation generates a low pressure on the inner side of the mask, thus sealing or at least reducing perimeter leaks. On the other hand, exhalation increases the internal pressure, inflating the mask and increasing the perimeter leakages. This phenomenon is further amplified in the case of coughing and sneezing.

Another aspect worth to be mentioned is the impact of leak area on the amount of leaked flow and ultimately on the FE. CFD studies showed that gap heights greater than 0.2 mm can generate a total inward leakage larger than 2%, thus making ineffective even an filtering face piece 3 (FFP3) mask, while, for a 1 mm height, more than 70% of flow can be leaked unfiltered [58]. Xi et al. [61] performed CFD simulations with an SM geometry reconstructed by images of an SM and studied the impact of variable face-seal gaps on the amount of leaked flow. Interestingly, they observed that even a small gap of 0.5 cm^2 leads to a 9% leakage. Considering that 3-D optical scanners have hardly a resolution <0.1 mm (unless choosing very expensive products and small measurement volume), this makes the comparison between numerical studies and experimental tests very challenging. In fact, even a small error on the 3-D reconstruction of the face-mask assembly can return a significant misprediction of the leaked flow. This is also confirmed by the very limited validations of the CFD results, considering, at best, a benchmark in terms of velocity at a point and associated with large error bars [61].

Despite these limitations, numerical investigations by Solano et al. [38], Solano and Shoele [62], and Xi et al. [61] confirmed that a high-porosity mask (i.e., with higher breathability) reduces the edge leakages, especially in the presence of small gaps. These findings not only confirm the validity of the conclusions highlighted in this work, but suggest that an optimum tradeoff can be identified in terms of porosity and safety.

Overall, these considerations make more convenient and reliable to perform this kind of investigations with the two-phase method developed in [23] and applied in this work.

A. Study Limitations

The experimental method to determine TFE of face masks was based on the measurement of the fraction of exhaled air leaking at the face seal and the fraction of exhaled air passing through the mask filter. Two assumptions were made. First, the volume of air passing through the filtering material of a mask is subjected to FE equal to the BFE measured according to the EN 14683:2019 standard. Second, the fraction of air leaking at the face seal moves from the mouth to the external environment without undergoing any change in the amount and size distribution of the aerosol generated by the mask wearer. Under these circumstances, the measured TFE does not consider impaction filtration mechanisms that could be active in reducing droplet amount both for the fraction of air passing through the mask filter and that passing at the face seal. Therefore, TFE values determined according to the presented method represent a worst-case scenario; defining the lower value of filtration performance, a mask can show when only fine aerosol (<5 μm) is exhaled by the wearer. The existence of different processes for blocking particles than through-mask filtration has been observed by Lindsley et al. [35], ensuing from a collection efficiency in the same cases larger than the material FE. Cappa et al. [20] conducted an in-depth analysis of aerosol concentration in mask leakage exhaled during talking and coughing in human subjects. While air leakage reduced mask performance (from >90% to 70% for talking), particle concentration in leaked air was lower than in the original source, implying the effect of an impact mechanism on the inner surface of the mask, especially for larger particles [20]. This observation suggests that SMs can significantly reduce emission of large particles even in the presence of unfiltered leaked air. Even though the TFE may not represent an absolute measurement of mask performance in relation to COVID-19 transmission because of this bias, it is still informative to assess the relative performance among different masks and to detect correlations with constructive and fitting parameters that may guide mask design to improve its efficacy.

A second limitation of the proposed measuring methods is related to the nonnegligible uncertainty associated with the TFE measurement. Although the repeated experiments resulted in a good measurement repeatability in most of the cases, u_B(TFE) was markedly higher than u_A(TFE), due to the propagated uncertainty generated by the accuracy of the FM and the manometer we used. Type B uncertainty may include residual systematic biases which are not corrected by the manufacturer calibration and not accounted in Type A uncertainty, which was obtained by repeated observations performed with the same instrument. This aspect can be improved by using instrumentation with higher accuracy across the whole range of interest of DP and volumetric airflow.

Other than this, variability among masks from the same production batch was previously evidenced in [42] and [63], possibly impacting on ΔP measurement repeatability more than other sources of uncertainty.

Other limitations of the setup were previously identified [27] and were mainly related to the smooth and rigid surface of the head form, different from the skin. Elasticity and compliance of human skin can result in a better face fit and face seal [64]. In this case, our experimental conditions may cause the TFE to be underestimated. Nevertheless, the proposed methodology remains safely applicable for comparative TFE measurements between different masks.

V. CONCLUSION

The performance of SM and CM in terms of TFE is strongly affected by the mask filter breathability, recommending the selection of highly breathable materials in mask design to decrease air leaking, besides maximizing user comfort and compliance in wearing the face mask. When multiple filter layers are required and a lower breathability is obtained, TFE should be improved by focusing on mask fit and applying a metallic nosepiece. The same recommendation applies when a meltblown layer is present, given the nonnegligible impact of this layer on the filter breathability. On the other hand, providing that only layers with high breathability are used, CMs may offer an acceptable efficacy, in the context of their intended use, without requiring the inclusion of a nosepiece in their design.

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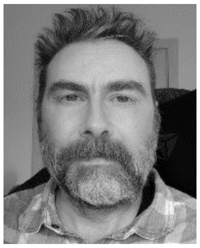

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Since 2009, he has been a Researcher with the Laboratory of Biophysics and Biosignals, Department of Physics and the Department of Industrial Engineering, University of Trento. He collaborated to projects in the field of cardiac arrhythmias, interventional cardiology, diagnostic radiology, reconstructive dentistry, histology, robotic surgery, and health and safety science. His research interests include bio-signal processing, medical image processing, segmentation and registration of multimodal data, 3-D computer guided surgery, numerical methods for computational simulations, and medical prototyping and validation.

Luca Benedetti has been a Laboratory Technician with the Department of Industrial Engineering, University of Trento, Trento, Italy, since 1991. He works in the field of materials characterization and in particular in the study of the degradation and protection of materials and coatings through accelerated aging techniques and electrochemical tests. He gained a consolidated experience in the field of metallic and organic coatings for industrial use and biomaterials, in particular implantable prostheses, stents, and heart valves. Since March 2021, he has been a part of the LASS-TN-Covid-19, a Joined Laboratory between the University and the Provincial Heath Trust of Trento for testing safety and performance of personal protection devices and other technologies against SARS-CoV-2 virus.

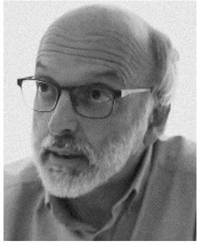
Luca Borro was born in Velletri, Rome, Italy, in 1986. He received the degree in architecture sciences from the Sapienza University of Rome, Rome, in 2013, the degree in biological sciences from the University of Urbino "Carlo Bo," Urbino, Italy, in 2019, and the bachelor's degree in biomedical engineering from UNICUSANO, Rome, in 2021. He is currently pursuing the master's degree in health biology with the University of L'Aquila, L'Aquila, Italy.

Since 2015, he has been working as a Technical Manager with the 3D Laboratory, Bambino Gesù Children's Hospital, Rome, where he is responsible for 3-D design for biomedical applications, 3-D printing of patient-specific anatomical parts for preoperative planning in surgery, and 3-D bioprinting for regenerative medicine. He has collaborated with several Italian and European scientific institutions on various research projects. He worked with the Santa Lucia Research Institute, Rome, on a project involving the in vitro construction of biological constructs for the study of amyotrophic lateral sclerosis using 3-D bioprinting. He also collaborated with the San Raffaele Institute, Milan, Italy, on a project involving the study of pancreatic beta cells using 3-D printing and bioprinting. He has authored or coauthored several publications in scientific journals and conference proceedings. His previous research interests included the development of nanocomposite scaffolds for tissue engineering.

Lorenzo Mazzei was born in Prato, Italy, in 1987. He received the bachelor's degree in mechanical engineering, the master's degree in energy and nuclear engineering, and the Ph.D. degree in industrial engineering from the University of Florence, Florence, Italy, in 2009, 2011, and 2015, respectively. His Ph.D. thesis focused on computational fluid dynamics (CFD) methodologies for the estimation of thermal loads in gas turbine combustors.

He continued the academic experience at the University of Florence, as a Post-Doctoral Researcher until the end of 2018 and as an Adjunct Assistant Professor at the University of Florence, since 2019, supporting the activities in the master course "Gas Turbine Power Plants," where he teaches CFD for heat transfer applications. Since 2017, he has been working with Ergon Research, Florence, former spin-off of the University of Florence devoted to the technology transfer to the industry. He has authored more than 55 conference papers and more than 35 journal articles, mostly in the fields of gas turbine combustion and heat transfer, thermal management, and fluid dynamics.

Dr. Mazzei is an ASME Member and contributes constantly to the activities of the ASME IGTI K-14 Gas Turbine Heat Transfer Committee, and an Associate Editor of the *Journal of Turbomachinery* and a Session Organizer of the ASME Turbo Expo conferences.



Giandomenico Nollo is currently an Associate Professor of Bioengineering with the Department of Industrial Engineering, University of Trento, Trento, Italy. He has conceived and led numerous national and international research projects aimed at the development and application of advanced health technologies, in collaboration with academia, industries, and health facilities. The analysis of biological signals for the modeling of the interaction processes between physiological systems, digital health, and the characterization of interface processes between implantable medical devices and tissues, functional performance, and safety of medical devices are the principal items of his research. He has authored over 220 scientific publications (HI-Scopus: 40).

Mr. Nollo served as a member of the Scientific Committee and the president of national and international workshops and conferences. He is currently the Deputy Vice-President of the Italian Society of Health Technology Assessment (SIHTA).

Alessio Bucciarelli received the M.Sc. degree in material science from the University of Venice, Venice, Italy, in 2013, and the Ph.D. degree in material, mechatronic, and system engineering from the Industrial Engineering Department, BIOTech Research Center, European Institute of Excellence on Tissue Engineering and Regenerative Medicine, University of Trento, Trento, Italy, in 2019.

During his Ph.D., he collaborated with several research groups, including the Bio-Nano Laboratory, Virginia Commonwealth University, Richmond, VA, USA, working on silk-based photoresist, and the Gilson Laboratory, Jeonbuk National University, Jeonju, South Korea, working on silk-based photoresin in the context of the Research and Innovation Staff Exchange (RISE) Marie Curie Project (REMIX, https://r1.unitn.it/remix/) on tissue engineering. In 2019, he joined the Microsystem Technology Group, Fondazione Bruno Kessler (FBK), Trento, to work on an industrial project within the Italian Polygraphic Institute and State Mint, Rome, Italy, working on inkjet and aerosol processes for the development of conductive layers. In FBK, he was the Main Instructor of a Ph.D. level course in design of experiment for the optimization of processes. He worked with the National Italian Council of Research (CNR-Nanotec), Lecce, Italy, to work in the development of photocrosslinkable biopolymer based bioinks and the process development of 3-D printed organ-on-chips devices. He is currently working with the Rizzoli Orthopedic Institute, Bologna, Italy. His research interests are mainly related to the use of statistical methods to optimize and standardize processes in the biomedical field.

Francesco Tessarolo the master's degree in biomaterials, and the Ph.D. degree in materials engineering from the University of Trento, Trento, Italy, in 2002, 2005, and 2006, respectively.

From 2006 to 2009 and from 2009 to 2013, he was a Post-Doctoral Research Fellow with the Department of Physics and the Biotech Center in Biomedical Technologies, University of Trento, respectively, having the role of Co-Investigator or Principal Investigator in several biomedical applied research projects and clinical investigations. He then moved to Bruno Kessler Foundation, Trento, for six years, joining the Healthcare Research and Innovation Program and participating in H2020 EU projects on radically new technologies to help older adults living independently at home. Since 2019, he has been with the Department of Industrial Engineering, University of Trento, where he currently holds a researcher position focused on innovative technologies for the multisensors real-time monitoring of processes and services in health care. Since March 2021, he has been technical responsible for the LASS-TN-Covid-19, a Joined Laboratory between the University and the Provincial Heath Trust of Trento for testing safety and performance of personal protection devices and other technologies against SARS-CoV-2 virus. He has authored more than 70 journal articles on peer-reviewed journal and more than 180 contributions at national and international conferences. His main research interests cover the fields of biomaterials and materials for medical applications, microbial biofilm and device-related infections, disinfection and sterilization, and information and communication technologies for the healthcare and wellbeing.

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