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Transforming safety for the future: Introducing cutting-edge aerodynamic endonasal filtration innovation in a post-pandemic era

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Abstract---Is there a solution missing for personal respiratory protection that is user-friendly, suitable for everyday use, and offers low visual and physical intrusion while safeguarding against a broad spectrum of threats, including airborne pathogens, specifically fine and ultrafine particles? Reflecting on recent challenges, during the SARS-CoV-2 pandemic, occupational safety devices like filtering face masks were repurposed for the general population. However, these devices, designed for controlled work environments, revealed limitations when used extensively in daily life, including issues with comfort, compliance, and compatibility with various activities. This necessitates a shift in perspective, emphasizing overall daily life effectiveness over isolated efficacy. Nasal filters emerge as potential solutions, yet their systematic definition as devices and products is lacking, underestimating the complexity required for optimal performance. This paper draws insights from the pandemic experience to propose systematic product specifications and characterization methods for an innovative respiratory protection device, addressing the limitations associated with endonasal applications and advocating for technological advancements.

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Introduction

In response to the SARS-CoV-2 pandemic, devices designed for occupational safety, such as filtering half masks, were repurposed for widespread use among the general population [1]. While these devices are effective in controlled work environments with known risks, their application to protect against potential airborne threats in daily life presents distinct challenges. Unlike occupational settings, where risks are localized and known a priori, the general population faces potential threats distributed over time and space, making respiratory protection necessary for extended periods. This extended use introduces challenges related to comfort, compliance, and compatibility with daily activities. Notably, prolonged use of face masks in everyday settings can compromise their efficacy due to issues such as discomfort and inadequate compliance. Addressing these shortcomings requires a new perspective that prioritizes protection in the diverse conditions of daily life while maximizing tolerability and minimizing visual and physical intrusion.

Endonasal filters emerge as promising solutions, having been proposed for protection against allergens, particulate matter, and airborne pathogens. However, the lack of a rigorous technical and scientific approach has hindered their development and evaluation. This paper aims to derive systematic product specifications and characterization methods for an effective endonasal respiratory protection device, taking into account the challenges associated with miniaturization and the need to filter fine and ultrafine particles.

Usage Prospects of Nasal Filters

Potential Advantages

Threats to the respiratory tract, such as allergens, particulate matter, and aerosols carrying pathogens, are well-documented and studied. The upper airways, particularly the nose, play a crucial role in breathing and offer a conducive environment for microbial growth. Protecting the nasal route from external aggressors has been a longstanding consideration, given that 90% of breathing occurs through the nose. However, the efficacy and effectiveness of nasal filters remain understudied due to the absence of standardized methodologies for their evaluation [2].

Allergic rhinitis, linked to pollen emission, poses a significant health concern. The average size of pollen particles ranges from 10 to 100 µm. Addressing this threat requires a filter capable of capturing particles of a few microns. Sensitization to dust mite allergens affects a substantial portion of the global population. Mite allergens are associated with particles >10 µm in diameter, with an average size of 20 µm. An effective mite allergen filter should filter particles with a diameter between 1 and 20 µm.

Airborne droplets, emitted during coughs or sneezes, are potential carriers of pathogens, including viruses. Droplets vary widely in size, with 95% falling between 2 and 100 μm. The SARS-CoV-2 pandemic has highlighted the need to address aerosol transmission, emphasizing the importance of effective filtration systems capable of blocking particles as small as 0.3 μm. Particulate matter (PM) includes coarse, fine, and ultrafine particles. PM 10, PM 2.5, and PM 1 are categorized based on their aerodynamic diameters, with sizes < 10 μm, < 2.5 μm, and < 1 μm, respectively. Efficient endonasal filters must account for these different size classes to provide comprehensive protection.

Particle size plays a crucial role in determining their potential health impacts. Particles smaller than 2.5 μm in diameter pose the highest risk, as they can penetrate deep into the lungs and potentially enter the bloodstream. This has led to a global focus on protection from PM 2.5 and PM 1. Both the International Agency for Research on Cancer (IARC) and the World Health Organization (WHO) classify PM as highly carcinogenic. Numerous scientific studies link particulate matter exposure to respiratory and cardiac diseases, contributing to premature deaths. WHO estimates that air pollution causes 4.2 million premature deaths worldwide.

More than half of fine particle air pollution (PM2.5) and most primary organic particulate matter result from combustion processes. Urban environments, such as Shanghai and Guiyang, show anthropogenic particles primarily from motor vehicle exhausts and other combustion processes, with sizes ranging from 0.2 to 1.4 μm. Preliminary tests have explored the correlation between atmospheric particulate matter concentration and the spread of SARS-CoV-2, suggesting that particulate matter might aggregate to droplets and act as carriers. Preventing emissions from combustion processes, a major source of PM 2.5 and PM 1, conflicts with economic development and represents a long-term goal. Immediate protection of the population is vital, especially in conditions of instantaneous risk, detectable through distributed particle measurement systems.

Given the definitions of PM1 and PM2.5, establishing an endonasal filter characterization methodology does not impose a minimum size limit for included particles. Nanometric particles (approximately 0.001 to 0.1 μm) need different treatment due to Brownian-type transport phenomena. Direct sampling provides particle size distribution values (0.2 to 1.4 μm), allowing the assumption of two reference size classes with different protection efficacies: Class 1 (0.02 to 1.0 μm) achievable by NaCl aerosol generators, and Class 2 (0.3 to 1.0 μm) as a minimum challenge through particles with certified sizes. Endonasal filtering presents a technological challenge due to miniaturization, but it significantly extends usage time and circumstances, providing extensive user protection [3-7].

Critical issues for effective endonasal filtration

A filter medium's design balances three antagonistic parameters (filtration efficiency, device size, and breathability) to achieve optimized performance. Endonasal application introduces unique constraints, primarily dictated by the nostril's size, as opposed to face masks. Endonasal application requires a very different set of constraints than other personal protective equipment, such as face

masks; nasal application is dominated by the size, equal to that of the nostril, which constraints the other properties (see Table 1).

Table 1
Envelope of requirements for personal filtration systems

Parameter	Endonasal	Face mask
Filtration efficiency	As high as possible	As high as possible
Device size	Fix	As low as possible
Breathability	Fix	Fix

Principles of fibrous filter design and application to nasal filters

Fibrous filter media, common in air filtration systems, rely on five mechanisms: impact, interception, diffusion, electrostatic, and sieving. These principles, foundational in HEPA filters and personal filtration devices, contribute to efficient particle capture. Optimizing endonasal filters for fine and ultrafine particles necessitates maximizing the diffusivity capture effect, achieved by lowering transit velocity through the filter. This requires increasing the filter's cross-sectional area and size to reduce pressure drops.

Respiratory filters' efficiency in capturing ultrafine particles decreases with increasing air speed. Applying these principles to a filter within the nostril, which faces varying air speeds in different sections of the upper airway, presents challenges. The external nostril, with a flow speed of 2-3 m/s, and the nasal valve, with speeds up to 12-18 m/s, demand a unique design. Conventional flat fibrous filters would face flow velocities in the order of m/s, losing the diffusion mechanism's capture contribution, increasing pressure drops, and compromising breathability. A planar fibrous filter in the nostril is unsuitable for capturing ultrafine particles under these conditions.

Demand for innovative technological solutions arises in the quest to place a filter within or overlapping the nostril aperture area, capturing fine and ultrafine particles (<2.5 µm) while ensuring sufficient breathability. This endeavor doesn't represent a mere variation of existing filtration technologies but introduces a novel and complex application. Air filtration relies on physical capture phenomena such as impact, interception, diffusion, electrostatics, and sieving. Diffusion emerges as the most suitable for halting ultrafine particles, requiring air speeds on the order of cm/s or less. However, within the nostril, air speeds reach the order of m/s, overpowering diffusive motion. Additional filtration structures within the nostril would increase air speed, moving further away from conditions conducive to diffusive transport.

The control of airspeed within the filter device involves designing the filter housing, filter medium, and related components. To enhance diffusion-based capture, airflow velocity decreases through the filter medium, allowing more time for particle diffusion and collision with the filter material. However, due to nostril size constraints, conventional mesh filter design solutions are impractical. The

cross-sectional area cannot be increased to reduce air speed to the required levels for ultrafine particle capture.

Three-dimensional and non-planar nasal filters, incorporating new technologies, present an alternative. However, their high surface/volume ratio, looped, and convoluted designs do not effectively decrease air speed, and their capture mechanisms based on sieving raise concerns about pressure drops and durability. Experimental testing of a nasal filter model based on conventional technologies yielded penetration values >80% of PM1, contrasting with the declared value of <10%, and breathability issues unsuitable for prolonged use. Achieving endonasal filtration of fine and ultrafine particles compatible with human respiration proves extremely challenging due to the nostril's small size and limited inlet area, setting insurmountable upper limits to air speed. Mesh filters may not be viable, and novel solutions are imperative.

An alternative aerodynamic filtration approach, developed and independently tested by some authors, demonstrates efficacy in filtering fine and ultrafine particles <2.5 µm, exceeding 90% across the size spectrum of 5.0 ÷ 0.5 µm, with low resistance to flow. The macroscopic effect of the aerodynamic filter involves generating diffusive-like vigorous mixing, ensuring ultrafine particles impact a specific filter section without inducing high dissipative generalized turbulence flow [3-7]. A graphic representation of the different effects is shown in 1.

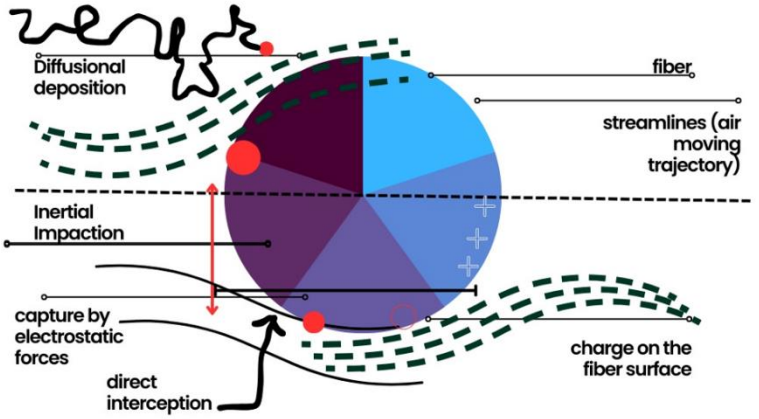

Figure 1. Capture mechanisms of fibrous filters

Figure 2 shows a graph well known in the technique, which clarifies the contributions to the capture of particles of different diameters by the different filtration mechanisms occurring in a filter made up of micrometric fibres arranged in a weave (mesh).

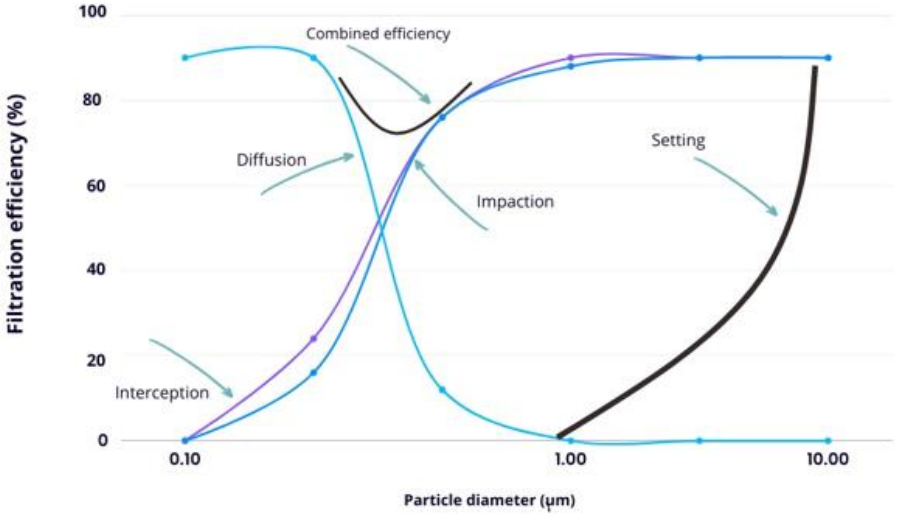

Figure 2. Filtration efficiency as a function of aerodynamic particle diameter due to different filtration mechanisms

The sars-Cov-2 pandemic

A review of literature on physical phenomena potentially associated with airborne pathogen transmission reveals eight key conclusions. The spread of human-derived aerosols through speech is more significant than anticipated, extending beyond sneezing or coughing. Speech droplets generated during talking contribute to aerosol saturation in inadequately ventilated spaces, with the epidemiological implications yet to be fully understood. Identifying concentrated risks (coughing, sneezing, contact) is insufficient; defense against diffuse risks, arising from particles persisting in the environment, is crucial. Relational settings, where speech generates persistent aerosols, pose potential risks. Speech, as a tool for societal value creation, faces challenges, especially concerning limitations on relationships.

Balancing economic productivity and health protection poses difficulties for policymakers. During emergencies, protective equipment designed for professional use (surgical masks EN14386, filtering face masks EN149) was utilized for the general population. Continuous, widely usable protection systems with modulated degrees of protection are needed. Evidence suggests that the nasal cavity is a preferred site for SARS-CoV-2 entry and proliferation, emphasizing the importance of protective measures in this area [8.-14] To meet the demands of the current situation, four key directions for innovation are proposed, focusing on a personal protective device designed for continuous and non-invasive use. A nasal filter emerges as a potential solution, possessing intrinsic properties such as compatibility with the nostril, extended tolerability, protection against various particles, easy compliance, and minimal environmental impact. These properties make it suitable for everyday use, even in seemingly low-risk environments, without affecting speaking skills or generating social stigma.

Table 2 provides a comprehensive comparison of the desirable properties for a protective device for the general population, emphasizing the unique characteristics of a nasal filter. The short perimeter to seal, aided by the expanding nostril, contributes to effective protection with fewer materials compared to traditional face masks.

Table 2
Desirable properties for a protective device for the general population and comparison with the characteristics of a nasal filter

	1. Protects the nose, preferred site of access and proliferation of exogen microorganisms	2. It is well tolerated and can be used for long time	3. Protects in everyday life, even in seemingly risk-free environments	4. It does not affect speaking skills and relational activities
NASAL FILTER	*Intrinsic*	*If compatible with the nostril and with good breathability, it is more tolerable than a filtering mask over time*	*Increased tolerability multiplies the time of use*	*Intrinsic*
	5. It protects vs. liquid aerosols and droplets nuclei	**6. Easy compliance limits misuse**	**7. Low EOL environmental impact**	**8. Small, or not visible at all, it does not generate stigma or alarm**
NASAL FILTER	*Required Property for Some Application Classes To be verified through ad hoc tests*	*Short perimeter to seal The nostril helps the seal by being slightly expanding, compressing the perimeter of the filter*	*Less materials than face masks Absence of spun polymers that release microplastics into the environment at the end of their life []*	*Intrinsic*

Performance Specifications

Moving beyond qualitative properties, the discussion delves into defining performance and product specifications for nasal filters, crucial for ensuring their efficacy. Classes of harmful inhalable particles and associated protection specifications are detailed in Table 3, guiding the development of filtration classes. Filtration efficiency, characterized by the percentage of trapped particles, is proposed with a minimum threshold of 90% for each filtration class. A flexible test system, incorporating HEPA filters, particle generators, mixing chambers, optical particle counters, and a breathing simulator, is suggested for comprehensive performance testing against different filtration classes.

The respiratory resistance (Rf) is proposed as a critical factor for nasal filter evaluation, with an index adherent to nasal breathing physiology. A quality factor (Qf), considering filtration efficiency and breathing resistance, serves as a holistic performance indicator. The potential inactivation of captured pathogens by the filter system is acknowledged, with the need for specific microbiological testing methodologies. Given that nasal filters are placed inside the human body, stringent regulatory requirements, particularly in terms of microbiological quality, are outlined. Compliance with European Pharmacopoeia standards is essential, and Table 4 summarizes the regulatory requirements for nasal filters.

Conclusion

Airborne allergens, diverse particles, and pathogens pose a constant threat to the human respiratory system, varying in size from pollen (10 µm to 100 µm) to anthropogenic environmental pollution particles (PM1, <1 µm). The necessity for protecting against fine (<2.5 µm) and ultrafine (<1 µm) particles has led to the exploration of nasal filters. Although studies indicate that individuals predominantly breathe through their noses, the widespread adoption of nasal filters has been hindered by the absence of standardized measurement systems and limited clinical validations.

Existing endonasal filters, predominantly utilizing fibrous filter technology developed in the 1970s, face critical challenges. The requirement for low flow velocity through the filter to entrap particles conflicts with the need for a compact filter size, especially in applications like endonasal filtration. Fibrous filters, effective in environmental filtration, become impractical for personal air filtration, where the large surface area needed for adequate flow rates is constrained by compactness requirements. In endonasal applications, the nostril's size constrains the cross-sectional area, resulting in airflow velocities that exceed the capabilities of fibrous filters. At higher velocities, fibrous filters lose efficiency below 10 µm and introduce substantial breathing resistance. Therefore, fibrous filter technology is deemed unsuitable for filtering fine and ultrafine particles in nasal filters, necessitating the exploration of new technologies.

The ongoing SARS-COV-2 pandemic has heightened interest in endonasal filters for trapping ultrafine particles due to the airborne nature of speech aerosols, the persistence of potentially infected aerosols in relational contexts, and the need for protection in seemingly low-risk environments like restaurants. The existing gap

in respiratory protection devices for everyday life emphasizes the need for a nasal filter with specific properties: protection of the nose, long-term tolerability, effectiveness in various contexts, non-interference with daily activities, aerosol protection, enhanced compliance, low environmental impact, and minimal visibility.

While certain properties are inherent to nasal filters, others require individual validation. Aggregated product specifications from scientific literature, focusing on filtration efficiency, breathing resistance, and quality factor, serve as performance indicators. Additionally, mass production considerations highlight the necessity for automated facilities ensuring microbiological compliance. Biocompatibility tests and adherence to European Pharmacopoeia standards, particularly EP5.6 - 2.6.12, underscore the stringent requirements for nasal filters placed within the human body. In conclusion, effective nasal filters for fine and ultrafine particle filtration demand innovative technologies and rigorous adherence to performance specifications and regulatory standards.

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