Evaluation of the Outward Protection Efficacy of Masks and Respirators Against Viral Aerosols

Ying Shi [1, a], Yunyun Zhou [1, b], Yan Fang [1, c], Wencheng Hu [1, d], Guozhuo Gong [1, e, *], Shubin Jin [1, f], Ji Liu [1, g], Zhuowei Chen [1, h]

[1] Institute of Urban Safety and Environmental Science, Beijing Academy of Science and Technology, Beijing, 10054, China

[a] shiying09131001@163.com, [b] 1411066728@qq.com, [c] 292286385@qq.com,

[d] who518@126.com, [e] ggzhuo@163.com, [f] jinshubintc@sina.com,

[g] submarin@163.com, [h] czw@bmilp.com

Abstract. This study evaluated the outward protection performance of various masks and respirators against viral aerosol emission, considering factors like wearing style, sampling point, and breathing condition. Using a headform with cyclic breathing, we tested four variables: device type, wearing style, sampling point, and breathing situation. A split-plot design with 126 experiments was employed, and Fisher's LSD analysis ensured reliable data. Results showed significant differences in Total Outward Leakage (TOL) among devices, with the cup mask offering the best protection and FFP3 NR-valve the worst. Improper wearing styles, especially "pulled-down-to-nose-clip," increased TOL by 1.3 to 3 times. Sampling points and respiratory changes also affected TOL, with the nose clip area recording the highest leakage. The study highlights the importance of proper mask usage and device selection for effective outward protection.

Keywords: Source control; TOL; Masks and Respirators; Outward Protection Efficacy.

1. Introduction

Over the past two decades, public health crises such as tuberculosis, SARS, and COVID-19 have posed significant threats to global health. Numerous studies [1, 2] have shown that these respiratory infectious diseases can be transmitted through the inhalation of aerosols containing pathogens. Wearing masks has been proven to effectively protect individuals from environmental particulate matter, known as "respiratory protection" or inward protection efficacy, measured by total inward leakage (TIL)[3-5]. This aligns with the original design intent of masks [6]. However, the COVID-19 pandemic has highlighted that mask-wearing by infected individuals is equally critical in reducing viral load in the air and protecting healthy populations, a concept termed "source control" or outward protection efficacy, measured by total outward leakage (TOL) [7]. This is particularly evident in cases involving asymptomatic or pre-symptomatic carriers [8].

During the pandemic, the CDC recommended that healthcare professionals use respirators, surgical masks (SM), or cloth masks as source control devices to mitigate the dissemination of viral aerosols [9]. Empirical studies have shown that masks can alter the direction of aerosol dispersion, reducing the transmission of infectious aerosols. An experimental study using headforms to investigate source control versus respiratory protection found that applying masks or respirators on the "source" (source control) was significantly more effective than on the "recipient" (respiratory protection), highlighting the importance of source control [10]. However, while criteria for evaluating respiratory protection are well-established internationally [11-15], performance metrics for source control lack reliable indicators and standardized testing methods, indicating a need for further research.

A quantitative study using headforms has shown that medical and cloth masks can intercept 40%-60% of exhaled aerosol particles during coughing and breathing activities [10,16]. The relative positioning of the "source" and "recipient" affects aerosol concentration: during coughing, a "front-to-front" configuration of cloth masks reduced aerosol concentration by 92%, while a "side-by-side" arrangement was less effective. Conversely, during breathing, the "side-by-side" configuration was more effective. However, fiber shedding from cloth masks may complicate the assessment of their effectiveness in mitigating exhaled particle emissions[17].

Recent research [18] has demonstrated that the outward protective performance of N95 filtering facepiece respirators (N95 FFR) surpasses that of SM, blocking 99% of simulated cough aerosols compared to 59% for SM. A study evaluating the outward protective performance of masks under different sealing conditions (0%, 50%, and 100%) found that reducing facial seal leakage significantly diminishes TOL[19]. Additionally, masks with high breathability force aerosols to pass through the filtration material rather than leaking through the facial seal, indicating that higher air permeability can effectively minimize leakage[20].

Existing methods and research on respirator and mask testing have laid the foundation for developing standards governing non-medical masks for source control applications. This study employs a headform with cyclic breathing to compare TOL across various types of masks and respirators under different flow rates, wearing styles, and sampling points. The findings will serve as a pivotal reference for revising TOL standards and improving the evaluation of outward protection performance of masks and respirators as source control devices.

2. Methods

2.1 Test system and approach

The testing system designed to evaluate the outward protective performance of devices is illustrated in Figure 1. The TOL of various respiratory devices is assessed using a headform, which is positioned within a cubic chamber measuring 1m x 1m x 1m, referred to as the leakage chamber. Aerosols are vaporized in a corn oil aerosol generator (TSI SIX-JET ATOMIZER; MODEL 9306) and then channeled through a three-way valve that connects to an aerosol mixing chamber (20cm x 20cm x 20cm), the leakage chamber, and the mixing chamber. The horizontal port of the three-way valve is linked to the mixing chamber, while the vertical port is connected to the leakage chamber. Two fans within the mixing chamber ensure thorough homogenization of the aerosol, guaranteeing uniform distribution throughout the chamber. Additionally, a humidifier and heater maintain the relative humidity at 40% and the temperature at 25°C, thereby minimizing the influence of these parameters on particulate matter. To reduce aerosol loss during transport, the length of the connecting tubing is kept as short as possible.

The mixing chamber is connected via a one-way valve to a breathing simulator, which in turn is linked to the leakage chamber. During the inhalation cycle, the breathing simulator is configured to draw aerosol from the mixing chamber; during the exhalation cycle, the aerosol is expelled through the mannequin head wearing the respiratory device via the transport tubing. This process simulates the cyclic breathing of a human. A particle sampling instrument (TSI Model 8530) is employed to measure the concentration and size distribution of particles at the mouth opening of the headform and within the leakage chamber. The particle concentration in both the leakage and mixing chambers ranges from 0.3 to 20μm. All equipment is calibrated before conducting the tests.

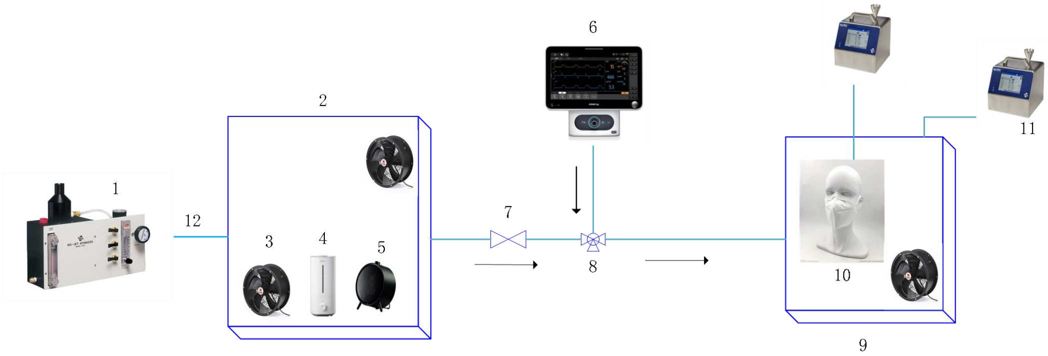


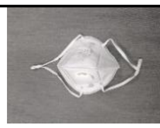
Figure 1 Schematic diagram of the testing system

1. Corn Oil Aerosol Generator (TSI SIX-JET ATOMIZER; MODEL 9306); 2. Mixing chamber; 3. Exhaust fan; 4. Humidifier; 5. Heater; 6. Breathing Simulator; 7. Unidirectional valve; 8. Three-way valve;9. Leakage chamber; 10.Headform; 11. Particle Sampling Instrument (TSI Model 8530); 12. Vacuum tub

2.2 Masks and respirators used in this study

In this study, five distinct types of masks were employed (Table 1). Mask A, a SM, is the most commonly utilized by the general public during public health emergencies. Mask B, a KN95-foldable respirator, is frequently adopted by individuals in densely populated settings. Mask C, a FFP3 NR-valve respirator, is typically worn by individuals engaged in strenuous labor or in hot and humid environments to mitigate air resistance. Mask D is a cup mask, and Mask E is a KN95-willow respirator.

Table 1 Information of devices tested

	Mask A	Mask B	Mask C	Mask D	Mask E
Name	SM	KN95-foldable	FFP3 NR-valve	Cup Mask	KN95-willow
Total Area（cm2）	161.5	166.5	141.4	189.2	154.7
Standard	YY0469-2011	GB2626-2019	EN149:2001+A1:2009	GB2626-2019	GB2626-2019
Filtration efficiency(%)	96.5%	99.3%	99.6%	99.8%	98.2%
Sample Photo					

2.3 Wearing styles used in this study

This study incorporated three distinct wearing styles to ascertain their impact on the outward dispersion of aerosols: (a)proper wearing, (b) pull down to the nose clip, and (c) cross on the cheek. The latter two wearing styles were designed to simulate common misapplications of mask usage.

Figure 2 (a) proper wearing; (b) pull down to the nose clip; (c) cross on the cheek

2.4 Points tested in this study

This study evaluated three sampling points to determine the TOL at these specific locations: (a) in front of the mask, (b) at the nose clip, and (c) on the side. These points were selected to simulate the most common leakage sites associated with mask usage.

Figure 3 (a) in front of the mask; (b) at the nose clip; (c) on the side.

2.5 Breathing situations used in this study

This study engineered three respiratory situations to simulate varying levels of physical exertion: (a)Flow 1: a respiratory rate of 20 breaths per minute with a tidal volume of 0.6 liters per breath; (b) Flow 2: a respiratory rate of 20 breaths per minute with a tidal volume of 0.8 liters per breath; and (c) Flow 3: a respiratory rate of 30 breaths per minute with a tidal volume of 1.2 liters per breath. These situations were designed to replicate low, moderate, and high levels of labor intensity, respectively.

2.6 Test procedures

Before the commencement of each test, corn oil aerosol is atomized within the generator. The atomized aerosol is subsequently conveyed through a transport tube to the mixing chamber, where it reaches a steady state. At the onset of the experiment, the breathing simulator is activated with specific activity parameters configured. The breathing simulator controls the respirator to inhale the gas mixture from the mixing chamber, which is then exhaled through a one-way valve into the headform placed within the leakage test chamber.

To ensure the accuracy of the experiment, a ventilation fan is activated at the beginning of each test to ventilate the leakage chamber, maintaining the background concentration within the chamber below 0.005 mg/cm³. For the stability of the data, the aerosol concentrations inside the mask, within the respirator, and outside the headform are continuously measured until a stable level is achieved.

To calculate TOL according to the given formula (1):

$$\text{Total outward leakage} = \frac{\text{Cout}-\text{Cbg}}{\text{Cin}} * 100\% \qquad (1)$$

Cout: Average concentration of aerosol outside the headform reaching steady state within 30 seconds; Cbg: Average concentration of data points inside the leakage test chamber reaching steady state within 30 seconds; Cin: Average concentration of aerosol inside the mask and respirator reaching steady state within 30 seconds.

2.7 Experimental design and statistics analysis

The dependent variable is the TOL, while the independent variables include the wearing style, device type, sampling point, and breathing situation. All equipment underwent 30 repeated tests under different experimental conditions, resulting in a total of 126 experiments.

A split-plot experimental design was employed, wherein the type of equipment was designated as the primary experimental unit, and the wearing style, sampling point, and breathing situation were considered secondary experimental units. The simplified linear model for this split-plot design is as follows:

$$yijklm=\mu+\tau i+\alpha j+ \tau\alpha ij+\beta k+\alpha\beta jk+\delta l+\alpha\delta jl+\beta\delta kl+\alpha\beta\delta jkl+\varepsilon m+\alpha\varepsilon jm+\beta\varepsilon km+\delta\varepsilon lm+$$

$$\alpha\beta\varepsilon jkm+\alpha\delta\varepsilon jlm+\beta\delta\varepsilon klm+\alpha\beta\delta\varepsilon jklm+\theta ijklm \begin{cases} i = 1,2,3 \ldots 30 \\ j = 1,2,3,4,5 \\ k = 1,2,3 \\ l = 1,2,3 \\ m = 1,2,3 \end{cases}$$

In the model, yijklm represents the observed value for a specific plot; μ represents the overall mean; τi represents the random error associated with repeated measurements; αj represents the effect of equipment type on TOL; ταij represents the random error associated with repeated measurements for the interaction between equipment type and other factors; βk represents the effect of wearing styles on TOL; δl represents the effect of sampling point on TOL; εm represents the effect of breathing scenario on TOL; αβjk、αδjl、βδkl、αβδjkl、αεjm、βεkm、δεlm αβεjkm、αδεjlm、αβδεjklm represent the interaction effects of these factors on TOL; Θjklm represents the random measurement error.

The factors that exerted significant influence were identified through Fisher's Least Significant Difference (LSD) analysis, and post hoc comparisons were conducted to determine the levels of impact. Tests for homogeneity of variance and normality of data were performed using residuals. All analyses were examined to ensure that the assumptions of the analysis were met, and any differences with a p-value < 0.05 were deemed statistically significant.

3. Results

Table 2 concludes the TOL of exhaled aerosols from various types of masks, as sampled at different locations, across three wearing styles and three breathing situations.

Table 2 Total outward leakage for different types of devices

Wearing styles	Mask types	Sampling points	Flow1	Flow2	Flow3
proper wearing	SM	in front of the mask	7.40	10.81	26.31
		at the nose clip	27.51	38.07	43.32
		on the side	22.97	32.70	37.92
	KN95-foldable	in front of the mask	2.50	2.16	2.23
		at the nose clip	9.77	7.43	8.08
		on the side	1.14	0.91	1.28
	FFP3NR-valve	in front of the mask	27.57	42.71	41.73
		at the nose clip	42.95	42.30	53.38
		on the side	13.79	29.97	28.98
	Cup mask	in front of the mask	1.32	1.70	3.07
		at the nose clip	2.93	2.31	2.80
		on the side	177	2.33	2.98
	KN95 willow	in front of the mask	2.76	3.07	4.13
		at the nose clip	4.22	4.89	10.83
		on the side	1.34	3.62	2.89
pull down to the nose clip	SM	in front of the mask	24.25	30.68	36.01
		at the nose clip	45.08	48.88	52.49
		on the side	34.57	37.84	50.04
	KN95-foldable	in front of the mask	2.90	2.59	3.74
		at the nose clip	9.42	8.49	8.22
		on the side	2.27	2.04	2.15
	FFP3NR-valve	in front of the mask	32.12	39.66	46.07
		at the nose clip	60.41	56.67	66.16

		on the side	25.78	19.98	34.03
	Cup mask	in front of the mask	2.35	3.09	3.60
		at the nose clip	5.15	4.73	5.03
		on the side	3.74	4.21	4.97
	KN95-willow	in front of the mask	3.34	3.69	5.13
		at the nose clip	6.92	6.09	7.80
		on the side	3.24	1.77	4.68
cross on the cheek	SM	in front of the mask	19.13	26.66	32.03
		at the nose clip	30.25	32.59	34.74
		on the side	23.70	35.74	38.90
	KN9-foldable	in front of the mask	4.65	8.87	7.09
		at the nose clip	10.06	10.10	10.16
		on the side	6.95	8.29	10.03
	FFP3NR-valve	in front of the mask	24.30	35.42	32.61
		at the nose clip	35.37	35.31	42.37
		on the side	33.65	38.31	25.30
	Cup mask	/			
	KN95-willow	in front of the mask	4.24	4.78	6.09
		at the nose clip	5.50	5.32	6.53
		on the side	3.58	3.86	5.37

Table3 Analysis of variance for TOL of different types of devices

Variable	Degree of freedom	F	Distinctiveness
Wearing styles	2	53.380	<0.001*
Device types	4	2708.681	0.000*
Sampling points	2	151.192	<0.001*
Breathing situations	2	53.378	<0.001*
Wearing styles * Device types	8	42.004	<0.001*
Wearing styles * Sampling points	4	23.475	<0.001*
Wearing styles * Breathing situations	6	6.382	<0.001*
Device types * Wearing styles	8	85.594	<0.001*
Device types * Breathing situations	8	25.891	<0.001*
Sampling points * Breathing situations	4	2.106	0.032
Wearing styles * Device types * Sampling points	16	15.002	<0.001*
Wearing styles * Device types * Breathing situations	16	4.743	<0.001*
Wearing styles * Sampling points * Breathing situations	8	1.556	0.097
Device types * Sampling points * Breathing situations	16	3.831	<0.001*
Wearing styles * Device types * Sampling points * Breathing situations	32	2.159	<0.001*

* In the “Variable” column, the asterisk “*” is employed to denote the interaction between the listed variables; in the “Significance” column, the presence of an asterisk “*” indicates a statistically significant difference.

The analysis of variance results presented in Table 3 reveals that wearing styles, device types, sampling points, breathing situations, wearing styles * device types, wearing styles * sampling points, wearing styles * breathing situations, device types * wearing styles, device types * breathing situations, wearing styles * device types * sampling points, wearing styles * device types * breathing situations, device types * sampling points * breathing situations and wearing styles * device types * sampling points * breathing situations have a significant influence on TOL.

Pairwise comparisons were conducted using Fisher's Least Significant Difference (LSD) method to assess the differences among various equipment types, with the results presented in Table 4. Among the five types of equipment tested, the FFP3NR-valve exhibited the highest leakage, followed by the SM. The KN95-foldable and KN95-willow demonstrated intermediate levels of protection, while the Cup mask achieved the best protective performance.

Table 4 The Fisher LSD comparison results in a pair of TOL between different device types.

(I) Device types	(J) Device types	Mean difference (I-J)	Standard error	Significance	Confidence interval	
					Lower limit	High limit
SM	KN95-foldable	26.931*	.470	.000*	26.010	27.853
	FFP3NR-valve	-4.593*	.469	<0.001*	-5.513	-3.673
	Cup mask	29.390*,b	.529	.000*	28.354	30.426
	KN95-willow	27.954*	.470	.000*	27.033	28.874
KN95-foldable	SM	-26.931*	.470	.000*	-27.853	-26.010
	FFP3NR-valve	-31.524*	.470	.000*	-32.445	-30.603
	Cup mask	2.459*,b	.529	<0.001*	1.422	3.495
	KN95-willow	1.023*	.470	.030*	.101	1.944
FFP3NR-valve	SM	4.593*	.469	<0.001*	3.673	5.513
	KN95-foldable	31.524*	.470	.000*	30.603	32.445
	Cup mask	33.983*,b	.528	.000*	32.947	35.018
	KN95-willow	32.547*	.469	.000*	31.627	33.466
Cup mask	SM	-29.390*,c	.529	.000*	-30.426	-28.354
	KN95-foldable	-2.459*,c	.529	<0.001*	-3.495	-1.422
	FFP3NR-valve	-33.983*,c	.528	.000*	-35.018	-32.947
	KN95-willow	-1.436*,c	.528	.007*	-2.472	-.400
KN95-willow	SM	-27.954*	.470	.000*	-28.874	-27.033
	KN95-foldable	-1.023*	.470	.030*	-1.944	-.101
	FFP3NR-valve	-32.547*	.469	.000*	-33.466	-31.627
	Cup mask	1.436*,b	.528	.007*	.400	2.472

3.1 The effect of wearing styles on TOL

It is anticipated that improper wearing styles will compromise the outward protective performance of masks. Figure 3 presents the mean TOL, standard deviations, and significance levels for each device across various wearing methods.

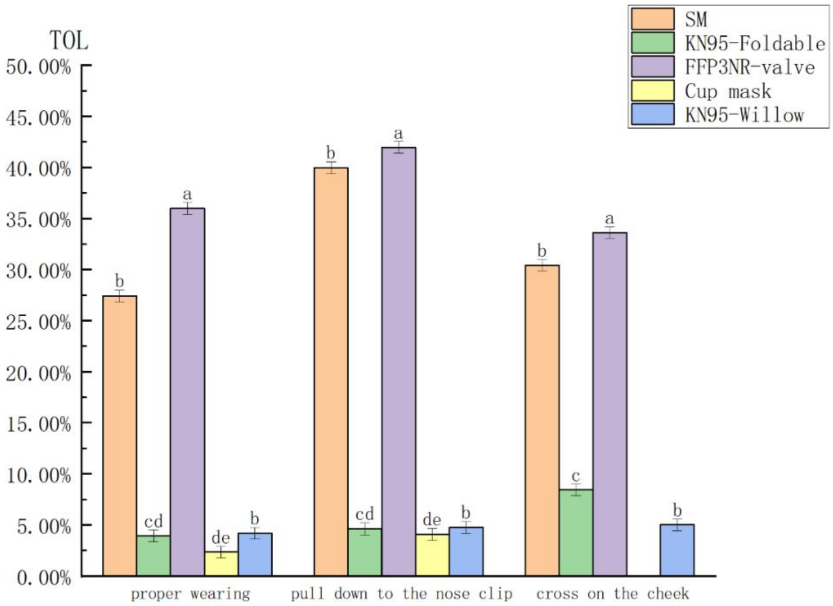


Figure 4 Wearing styles * Device types Interaction effect test

Among the three wearing styles, the FFP3NR-valve exhibited the highest TOL (36.007%; 41.988%; 33.633%), followed by the SM (27.440%; 39.985%; 30.427%). Both the FFP3NR-valve and the SM demonstrated the highest outward leakage rates when worn in the manner of "pulled down to the nose clip," with the FFP3NR-valve significantly exceeding the SM. This may be attributed to two factors: First, the FFP3NR-valve is equipped with an exhalation valve, which allows exhaled air to be expelled without filtration, thereby inherently causing a high outward leakage rate. Second, when these two types of masks are worn and pulled down to the tip of the nose, the leakage at the nose clip area increases significantly.

The KN95-foldable and the KN95-willow exhibited a significant difference only in the wearing style of "crossed on the cheek" (foldable type: 8.463%; willow type: 5.031%), with the leakage rate of the KN95-foldable being approximately 1.5 times that of the willow type. This discrepancy can be ascribed to the fact that the KN95-willow features an additional pleated design on the side, which enhances the fit along the edges.

Among the five types of masks, the cup mask demonstrated the most superior outward protective performance (2.357%; 4.097%; /), primarily attributable to its superior fit compared to the remaining four types of masks.

3.2 The effect of Sampling points on TOL

It is anticipated that the TOL will vary across different sampling points. Figure 5 presents the mean TOL, standard deviations, and significance levels for each device across various sampling points.

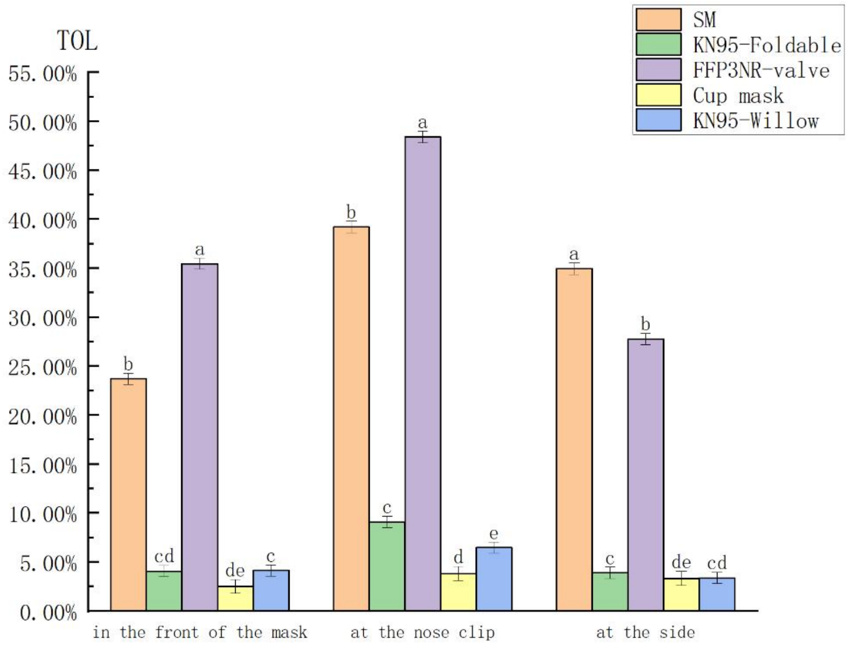


Figure 5 Sampling points* Device types Interaction effect test

Among the three sampling points, the TOL at the sampling point near the nose clip is the highest. For masks of the same type, the leakage rate at the nose clip is approximately 1.5 to 3 times higher than that at the front and side positions. The TOL at the sampling point in front and the sampling point at the side vary depending on the type of equipment.

For the FFP3NR-valve, the TOL at the nose clip is the highest (4n8.401%), followed by the front and side positions (35.468%; 27.760%). For the SM, the TOL at the nose clip is also the highest (39.208%), with the side and front positions following suit (34.943%; 23.700%). This is attributed to the relatively larger facial gaps between the nose clip and the cheeks when the SM is worn.

For the KN95-foldable and the KN95-willow, the TOL at the nose clip is the highest. The KN95-foldable (9.079%) exhibits a TOL approximately 1.5 times higher than that of the KN95-foldable (6.478%). The differences in TOL at the front (4.082%; 4.137%) and at the side (3.897%; 3.375%) are not significantly pronounced.

The cup mask exhibited the lowest TOL across these three sampling points (2.522%, 3.827%, 3.332%), with no significant differences observed.

3.3 The effect of breathing situation on TOL

It is anticipated that different breathing situations will influence the TOL, specifically manifested in the potential increase of TOL with elevated breathing flow rates and frequencies. Figure 5 presents the mean TOL, standard deviations, and significance levels for each device across various breathing situations.

The impact of these three breathing situations on the TOL of the cup mask and the KN95-foldable is not pronounced. This is attributed to the design of the cup mask and the KN95-foldable, which ensures a superior seal between the mask and face.

For the KN95-willow, the first two breathing situations do not significantly affect the increase in TOL. However, when the breathing flow rate and frequency are increased to a certain extent, a significant impact on TOL is observed. This may be due to the structural characteristics of KN95-willow, which is prone to deformation under high breathing flow conditions.

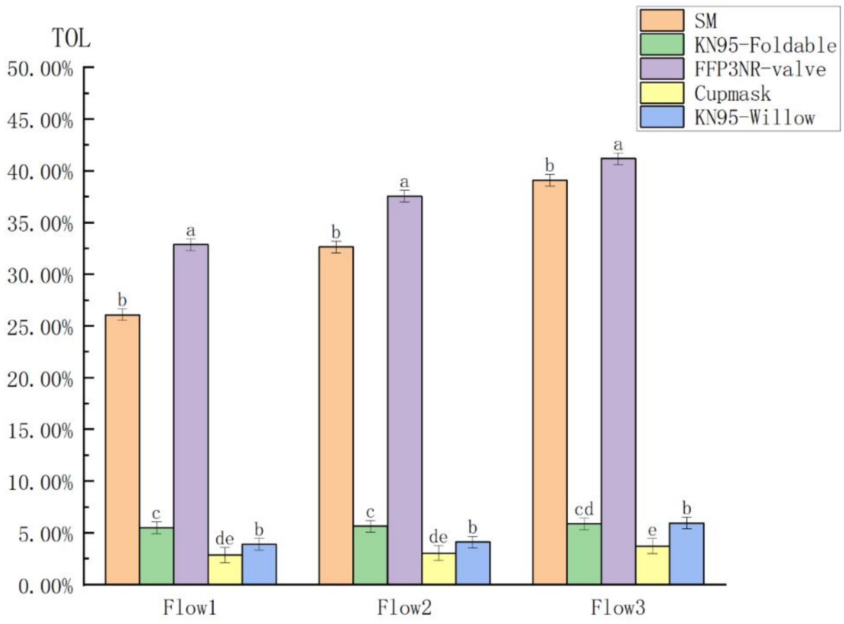


Figure 6 Breathing situations* Device types Interaction effect test

4. Summary

This study evaluated the outward protective performance of various masks and respirators, including SM, KN95-foldable, KN95-willow, FFP3NR-valve, and cup mask, using atomized corn oil aerosol to measure Total Outward Leakage (TOL). These devices serve as source control to prevent aerosol emissions during activities like breathing, sneezing, and coughing. The study assessed the impact of device type, wearing style, sampling point, and breathing situation on TOL.

Results showed that masks with exhalation valves (e.g., FFP3NR-valve) had the highest TOL (up to 66.16%), while the cup mask had the lowest. Proper wearing styles significantly reduced TOL by 1.3 to 3 times compared to improper methods, highlighting the importance of correct mask usage. The nose clip area was identified as a major leakage point, especially when masks were worn improperly (e.g., pulled down to the nose clip). The study also found that masks with better fit (e.g., cup mask) had lower TOL across all sampling points (nose clip, front, and side).

Breathing frequency and tidal volume impacted TOL differently across mask types. SM and FFP3NR-valve showed increased TOL with higher respiratory rates and volumes, while KN95-foldable and cup masks were less affected. The KN95-willow exhibited significant TOL increases only at higher breathing frequencies (30 breaths/min) and tidal volumes (2L per breath). These findings suggest that SM, FFP3NR-valve, and KN95-willow may be less suitable for activities requiring high respiratory effort.

Future mask designs should focus on improving fit and reducing leakage at critical points like the nose clip. Proper wearing styles and fit tests are essential for optimal protection.

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