Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Major Article

Comparison of filtration efficiency and respiratory resistance of COVID-19 protective masks by multi-national standards

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Keywords:
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Standard comparison

Background: Face masks from worldwide satisfy different standards during the COVID-19 pandemic, which led to the public misunderstanding of the concepts.

Methods: We systematically evaluated the quality of face masks provided by different companies according to multi-national standards, including EN 149-2001+A1: 2009, GB 2626-2019 and NIOSH 42 CFR Part 84-2019, focusing particularly on the particulate filtration efficiency (PFE) and respiratory resistance performance.

Results: Three types of masks (planar, folding and cup type masks) were measured based on different standard protocols. The results indicated that the PFE of the mask decreased in sequence of folding mask ≈ cup type mask > planar mask. The respiratory resistance of the masks ranked as follows: cup type mask > folding mask> planar mask. Overall, when PFE was used as the quality indicator, all the masks have a higher chance of meeting criteria of the EN149-2001+A1:2009, followed by the stricter standard set by the GB2626-2019 and NIOSH 42 CFR Part84-2019. Conversely, the respiratory resistance of the masks fulfilled the highest requirement of the EN149-2001+A1:2009 standard, while it is easier to satisfied the standard of GB 2626-2019 and NIOSH 42 CFR Part 84-2019.

Conclusions: We believe that our study provides effective guidance for customers worldwide to choose proper face masks under different epidemic situations.

In March 2020, the World Health Organization (WHO) declared the novel coronavirus pandemic (COVID-19) that had spread rapidly around the world and caused thousands of deaths.[1] As of 18 September 2021, more than 227 million cases and 4.67 million deaths have been confirmed, making it one of the deadliest pandemics in history.[2] Besides the huge strains on the global health systems, we will also likely witness the global economic repercussions and possible retaliation caused by this pandemic.[3] Therefore, essential preventive measures include social distancing, wearing face masks in public, hand washing and so on have been highly recommended by the WHO to self-protect from possible infection.[4] Due to the main routes of COVID-19 spread caused by the droplet transmission, wearing a mask is one of the most important and popular preventive measures suggested by health institutes and relevant guidelines.[5]

Since then, wearing a face mask in daily life activities has become the norm for various population around the world. However, it has been reported that the ubiquitous use and unprecedented demand of face masks worldwide with several times has contributed to the shortage of this product.[6] Besides, the raw materials used for production of face masks is unfit because they do not meet relevant standards or legislation, thus increasing portions of ineffective masks entering the worldwide market.[7,8] For example, it has been reported that using homemade mask with different materials can also reduce the possible infections to a certain extent.[9,10] What's more, reuse of mask after disinfection and prolonged use time is also a common phenomenon in many countries where the epidemic is serious and the masks shortage is severe.[11-13] According to the previous report,

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Table 1
The filtration efficiency requirement in European EN 149+A1 standard for face masks

Classification	Filtration efficiency of aerosol		FE %
	FE of non-oily particles %	FE of oily particles %	
FFP1	≤20	≤20	≥80
FFP2	≤6	≤6	≥94
FFP3	≤1	≤1	≥99

the quality of 48.8% of selective brands of masks with a total amount of 160 on the markets is questionable or invalid.[14] Therefore, the quality of some face masks is controversial and necessary to be evaluated with the emergence and exponential spread of COVID-19. Up to now, there are several different national standards worldwide to provide the protocol testing the important factors that determined the quality of the face masks such as the particulate filtration efficiency (PFE), bacterial filtration efficiency (BFE), fluid resistance, breathability and so on.[15] For examples, EN166:2001 and EN 149:2001 + A1:2009 are the harmonized standards developed by a recognized European Standards Organization to evaluate the quality of the respiratory. As illustrated in Table 1, the masks can be divided into three levels (FFP1, FPP2 and FFP3) according to the filtration efficiency.[16] In China, there are many different standards used for various kinds of face masks. The GB2625-2019 standard is the new version that issued in December 31, 2019. The standard specifies the classification and marking, technical requirements, testing methods and identification of self-priming filter anti-particulate respirators (Table 2).[17] Similarly, respirators in the American market should be certified by the National Institute for Occuppedational Safety and Health (NIOSH).[18] NIOSH test protocol defines N-, R-, and P-series respirators with the filtration efficiency of 95%, 99%, and 99.97%, respectively, under 42 CFR Part 84. If the masks passed the standards, they can be certified as N95.[19] Overall, different kinds of masks have different scope of applications and standards (Table 3). However, the customers are misleading when choosing different kinds of face masks defined by various standards.

Herein, we systematically tested the particulate filtration efficiency and respiratory resistance of three types of masks (planar, folding and cup type) provided by different companies according to the above-mentioned standards protocol. Automated filter tester and breathing resistance tester were used to determine the filtration efficiency and exhalation resistance of face masks under specified conditions. The results suggested that the PFE of all the masks satisfied the criteria of EN 149-2001+A1: 2009, followed by the stricter standards set by GB 2626-2019. The NIOSH 42 CFR Part 84-2019 protocol had very strict requirement for the PFE of the masks. Conversely, the EN 149-2001+A1: 2009 standard is the strictest one for testing the respiratory resistance, while the respiratory resistance tested based on the GB 2626-2019 and NIOSH 42 CFR Part 84-2019 protocol has a higher chance to meet the criteria. This study will help consumers to comprehensively understand the basic concepts related to the performances of the masks and thus choosing proper face masks under different epidemic situations. What's more, it is convenient for domestic enterprises to grasp the differences between export regional standards and domestic standards, and provide some references for ensuring the quality and safety of mask products and smooth export.

Table 2
The filtration efficiency requirement in GB 2626-2019 standard for face masks

Classification	Filtration efficiency of aerosol	
	FE of non-oily particles %	FE of oil particles %
KN90	≥90.00	Not Applicable
KN95	≥95.00	
KN100	≥99.97	
KP90	Not Applicable	≥90.00
KP95		≥95.00
KP100		≥99.97

Table 3
The filtration efficiency requirement in NIOSH 42 CFR Part 84-2019 standard for face masks

Class	Filtration efficiency of aerosol	
	FE of NaCl aerosols, %	FE of Dioctyl phthalate, %
N95	≥95.00	Not Applicable
N99	≥99.00	
N100	≥99.97	
R95	Not Applicable	≥95.00
R99		≥99.00
R100		≥99.97
P95	Not Applicable	≥95.00
P99		≥99.00
P100		≥99.97

MATERIAL AND METHODS

Materials

Different types of face masks (Fig 1) were kindly supplied by different companies whose names are omitted to avoid any form of publicity.

Equipment

The PFE of marks was evaluated by an automated filter tester (TSI 8130A, TSI instruments Inc., America) equipped with aerosol at flow ranges from 1.0 μg/m^3 to 200 μg/m^3 (Fig 2a). The working principle of the automated filter tester Model 8130A is illustrated in Figure 2b. The operation of the model 8130A is simple, fast and highly automated. The flow of gas is adjusted from 15 to 110 L/min with stated accuracy 2.0% of full scale (FS). The range of pressure is from 0 to 150 mm H_2O (0 to 1470 Pa) with accuracy of ±2% of FS. The efficiency measurement of PFE ranges from 0.0001% to 99.9999%.

The instrument used to test inhalation resistance and exhalation resistance of masks under certain condition is the NW260 respirator resistance tester purchased from United States. As illustrated in Figure 2c, wear the tested masks on the matching head mold in an airtight way, adjust the ventilation, measure and record the maximum inhalation resistance; then test the exhalation resistance of the tested sample with the same ventilation. The measuring range of flowmeter is 0-200 L/min, and the accuracy is ± 3%. The range of the micro manometer is 0-1,000 Pa and the resolution is 1 Pa.

Procedure

The methodology used for determination of the PFE of face masks

There are several standards used worldwide to determine the PFE of masks, such as the GB 2626-2019, NIOSH, BS EN 14683:2019, AS/NZS 1716:2012, JIS T8151:2018 and so on.[20-22] In this work, we systematically measured the PFE of different kinds of masks using the EN 149:2001+A1:2009 (EN 149+A1), GB 2626-2019 and NIOSH 42 CFR Part 84-2019 standards, respectively.

PFE of the masks determined by the EN 149:2001+A1:2009 protocol

EN 149+A1 is the new version standard published by the European Personal Protective Equipment (PPE) Directive in 2009. All masks in European market shall be tested according to the

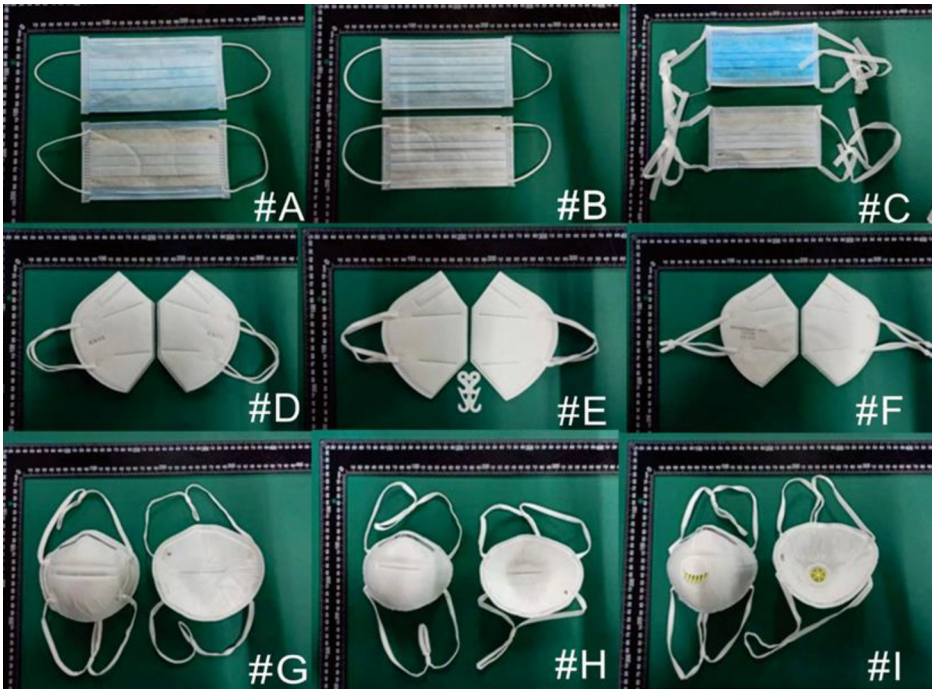

Fig 1. Photos of different types of face masks: #A-C represent the planar mask, #D-F represent the folding masks, #G-I represent the cup type masks. All the masks were ordered from different companies.

requirements of the EN 149+A1 and then re-approved according to the European PPE Directive. As shown in Table 1, the masks that comply with the European standard EN 149+A1 are suitable for both oily and non-oily particles, but they are also classified into three different levels according to different filtering efficiency. The classification system is divided into three FFP classes, where FFP stands for "Filtering Face Piece." FFP1, FFP2, and FFP3 represent the low, medium and high level of protection, respectively.

PFE of masks was measured using an approach based on the requirements of EN 149:2001+A1:2009 (EN 149+A1).[23] Firstly, we need to adjust the filtration efficiency detection system to the detection state, and set the related test parameters. Then connect the filter element to the detection device in an airtight manner with a suitable clamp. Typically, NaCl aerosol was first formed by an aerosol particle generator. Thereafter, the PFE is tested by measuring penetration of 0.06 μm NaCl aerosols at a flow rate of 95 L/min over a face mask. NaCl penetration measurements were conducted three times for each sample to ensure accuracy. Finally, a mean value of PFE was calculated prior to statistical analysis.

PFE of the masks determined by the GB 2626-2019 protocol

The Standardization Administration of China issued its mandatory national standard GB 2626-2019 Respiratory protection non-powered air-purifying particle respirator in December 31, 2019. This new standard became effective on July 1, 2020 and replaced the previous version of GB 2626-2006.[24] The standard applies to non-powered air-purifying respirator which can help provide respiratory protection against particles (Table 2). This mandatory national standard contains the technical requirements including the general requirement, appearance check, filter efficiency, respiratory resistance and so on. In terms of the PFE measurement, the NaCl aerosol with a mean diameter of 0.075 μm was first generated by an aerosol particle generator. The 2% NaCl aerosol was then loaded into the equipment to measure the PFE of the face masks with a flow rate of 85 L/min.

PFE of the masks determined by the NIOSH 42 CFR Part 84-2019 protocol

In 1995, the National Institute for Occupational Safety and Health (NIOSH) published a final rule changing certification requirements for particulate respirators.[19] NIOSH 42 CFR Part 84-2019 is one of the newly approved national standards that containing the requirement of particulate filtration efficiency test.[25] In a standard test, the NaCl salt aerosol with a mean diameter of 0.075 μm was first generated by an aerosol particle generator. The 2% NaCl aerosol was then loaded into the equipment to measure the PFE of the face masks with a flow rate of 85 L/min.

The methodology used for determination of the respiratory resistance of masks

Respiratory resistance data are also essential information to determine the quality of the masks. The respiratory resistance of the masks is tested by inhalation and exhalation.[26] The respiratory resistance of masks was evaluated according to the EN 149:2001+A1:2009 (EN 149+A1), GB 2626-2019 and NIOSH 42 CFR Part 84-2019 standards and the inhalation resistance ventilation was 95, 85, and 85 L/min, respectively. The exhalation resistance ventilation was 160, 85, and 85 L/min, respectively. Before experiment, the air tightness and working status of the detection device should be double-checked. Then adjust the ventilation to predetermined flow rate, and set the system resistance of the detection device to 0. Thereafter, take appropriate measures to wear the tested mask on the matching test head mold in an airtight manner to ensure that the mask is placed in the correct position. The fixing method should not affect the effective ventilation area of the filter element, and should not deform the mask. The maximum inhalation/exhalation resistance was then measured and recorded.

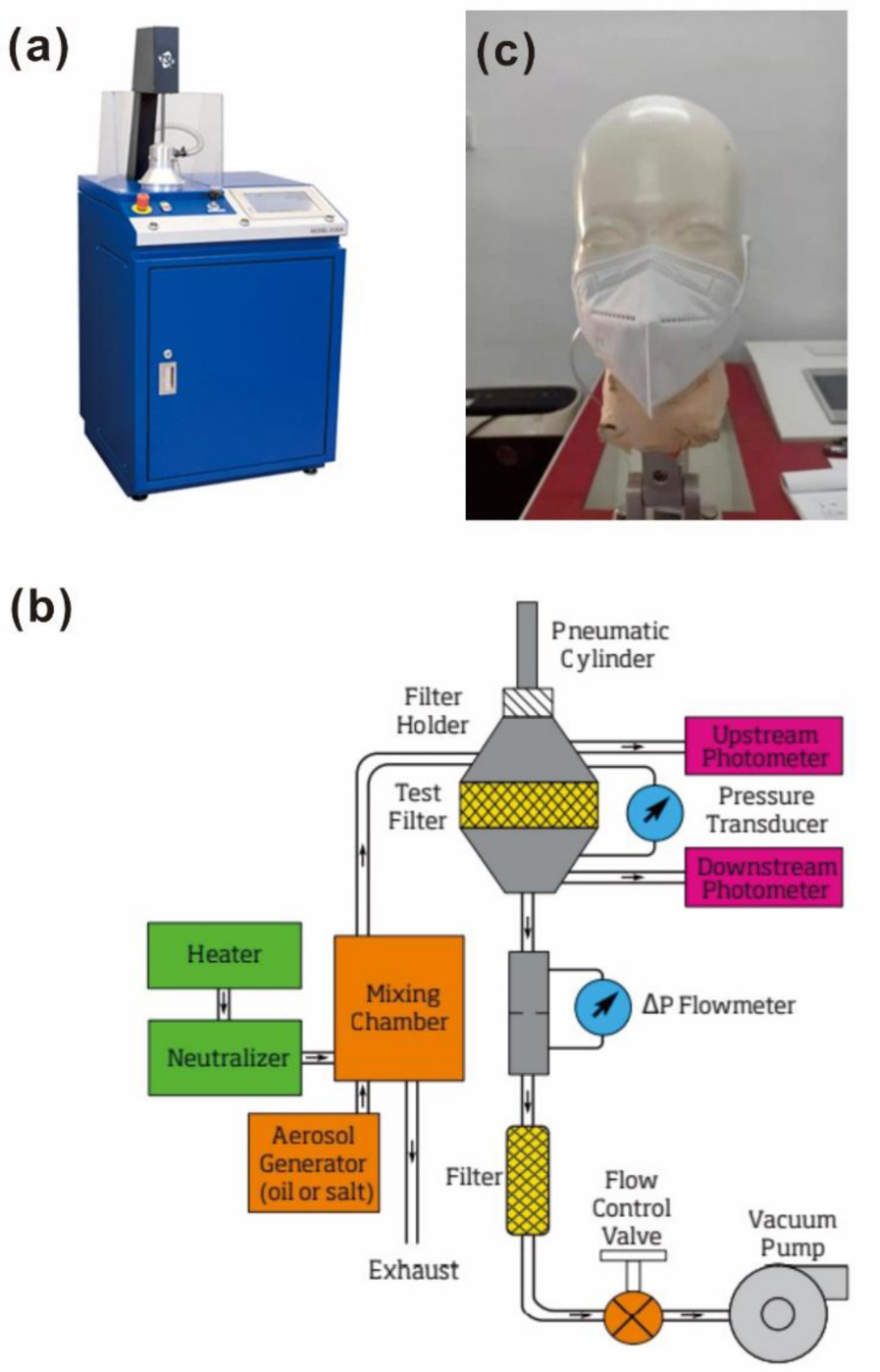

Fig 2. (a) Automated filter tester Model 8130A, (b) working principle of the automated filter tester, (c) breathing resistance tester used to determine the filtration efficiency and exhalation resistance of face masks under specified conditions.

RESULTS AND DISCUSSION

The PFE of the masks

The PFE of planar masks using different standards

The PFE of the planar masks was measured using three different kinds of protocols based on the EN 149-2001+ A1:2009, GB 2626-2019 and NIOSH 42 CFR Part 84-2019 standard, respectively. As illustrated in Figure 3a, the PFE of planar mask #A, #B, #C is 78.39%, 81.89%, and 88.02%, respectively, when measured using the EN 149-2001+ A1:2009 standard. Obviously, the PFE of the mask #B and #C meet the requirements of the FFP1. However, when the PFE were measured using the procedure of the GB 2626-2019 standard, the PFE of the flat mask #A, #B, #C increased from 68.26% to 90.71% (Fig 3b). The result indicated that only the mask #C meet the requirement of the KN90. The filtration efficiency of the masks #C increased to 90.91%, indicating that it was related to the particle size and the rate of the aerosol. In the GB 2626-2019 standard, the measure penetration is tested with 0.075 μm NaCl aerosols at a flow rate of 85 L/min, while the measure penetration is tested with 0.06 μm NaCl

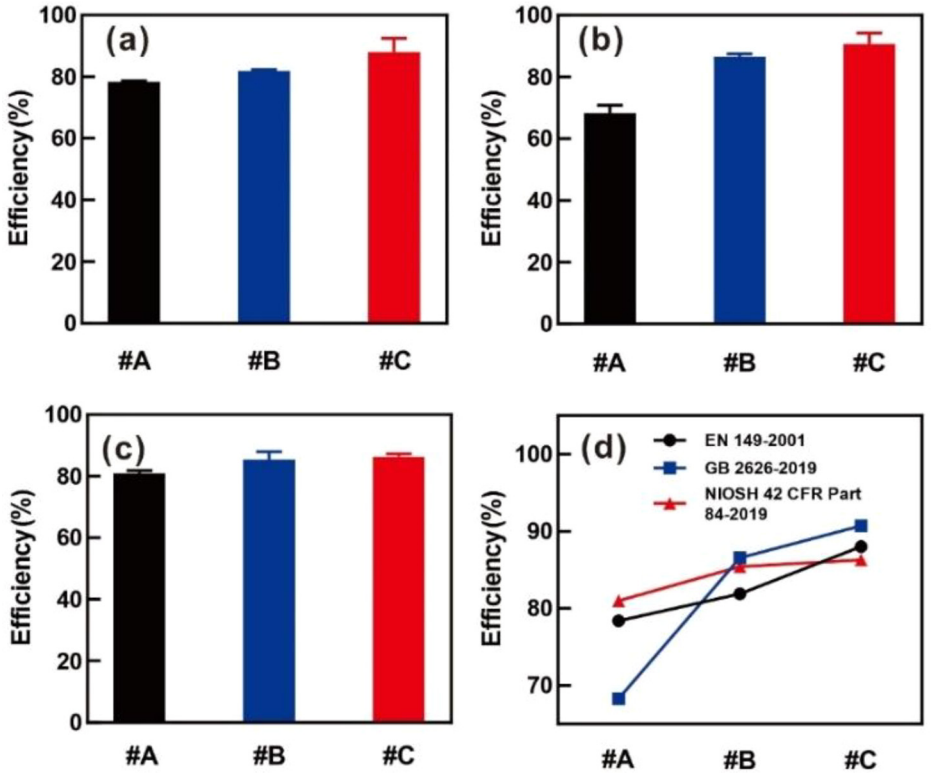

Fig 3. The PFE of planar masks tested by the protocol based on the (a) EN 149-2001+ A1:2009, (b) GB 2626-2019 and (c) NIOSH 42 CFR Part 84-2019, respectively, (d) the comparation of the PFE of planar masks measured using different standards.

aerosols at a flow rate of 95 L/min in the EN 149-2001+ A1:2009 standard.[27] We also use the NIOSH 42 CFR Part 84-2019 test protocol. As shown in Figure 3c, the PFE of the 3 brands of masks does not meet the standard of the minimum N95 level. Even though the sizes and flow rates of nanoparticles used in both the GB and NIOSH standards are the same, the NIOSH standard starts from 95% filtration efficiency and is divided into 3 grades: 95%, 99%, and 99.97%.[28] Based on the above analysis, we can make the conclusion that the PFE of the masks is different when tested using the procure of different standards (Fig 3d). Mask #A has the highest PFE using the NIOSH 42 CFR Part 84-2019 protocol, while mask #B and #C have the highest PFE using the GB 2626-2019 protocol. What's more, these planar marks only meet the minimum standards of the above-mentioned protocols, or even not meet the minimum standards. In conclusion, the PFE of the planar masks is #C>#B>#A under these standards. Therefore, it is necessary to take careful consideration of protection level when choosing a planar type mask in the COVID−19 period, because of planar mask has a lower protection level.[29]

The PFE of folding masks using different standards

The PFE of the folding masks were also tested based on the three standards including the EN 149-2001+ A1:2009, GB 2626-2019 and NIOSH 42 CFR Part 84-2019. As indicated in Figure 4a, the PFE of mask #D, #E, #F is 99.01%, 99.85%, and 99.77%, respectively, which all meet the requirements of the FFP3 on the EN 149-2001+ A1:2009. When caring for SARS-CoV-2 infected patients, the Das Robert Koch-Institut (RKI) recommends wearing particle-filtering half masks with a filter performance of at least 94 %, which corresponds to FFP class 2 according to EN 149:2001+A1:2009.[30] Therefore, mask #D, #E and #F can be worn to protect people against possible infections. Furthermore, the PFE of mask #D, #E, #F is 99.29%, 99.52%, and 99.63%, respectively, which all reach KN95 on the GB 2626-2019 (Fig 4b). NIOSH 42 CFR Part 84-2019 was also applied to test the PFE of the folding masks. According to Figure 4c, the PFE of mask #D, #E, #F is 99.26%, 99.78%, and 99.56%, respectively. It's obvious that all of folding masks meet the requirement of N99. Based on the above analysis, it's noteworthy that all kinds of folded masks possess high PFE when tested using these standards, indicating their excellent filtration effectiveness. Mask #D has the highest PFE based on the GB 2626-2019 protocol, while mask #E and #F have the highest PFE according to the EN 149-2001+ A1:2009 protocol (Fig 4d). In summary, the PFE of the folding masks decreased in sequence of #E>#F>#D, demonstrating the excellent filtration effectiveness of mask #E.

The PFE of cup type masks using different standards

In terms of the cup type masks, the PFE evaluated by different standards is also illustrated in Figure 5. When EN 149-2001+ A1:2009 was used to test the PFE of cup type masks, the PFE of mask #G is 98.12%, which only meet the requirement of FFP2. However, the PFE of mask #H and #I is 99.23% and 99.48%, respectively, which reach the highest level of FFP3 (Fig 5a). Additionally, the PFE of mask #G, #H, #I is higher than 95% when tested using the GB 2626-2019 protocol, which all meet the KN95 level (Fig 5b). Shown in Figure 5c, the PFE of mask #G, #H, #I is 97.86%, 99.79%, and 99.26%, respectively, as it is measured using the NIOSH 42 CFR Part 84-2019 protocol. It is obvious that the mask #G meet the requirement of N95 while mask #H and #I reach the level of N99. Overall, the PFE of the cup type masks differed slightly when measured using different standard protocols. As illustrated in Figure 5d, the PFE of the mask #H is the highest under the GB 2626-2019 and NIOSH 42 CFR Part 84-2019 standards, which provided the customers a theoretical guidance when choosing cup type masks provided by different companies.

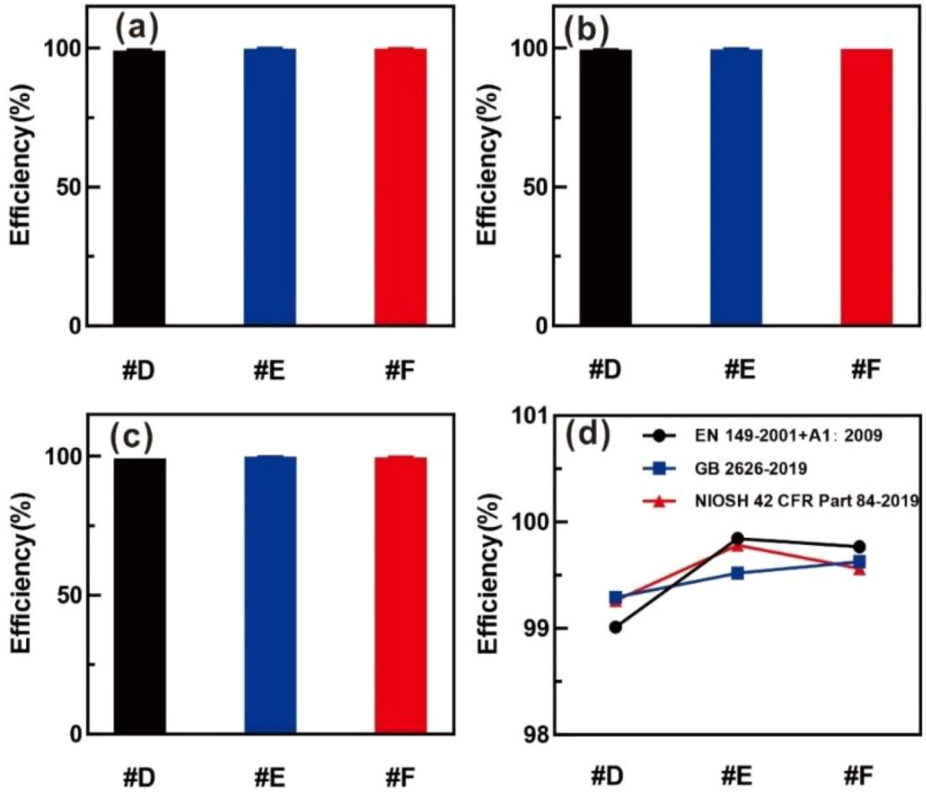

Fig 4. The PFE of folding masks tested by the protocol based on the (a) EN 149-2001+ A1:2009, (b) GB 2626-2019 and (c) NIOSH 42 CFR Part 84-2019, respectively, (d) the comparation of the PFE folding masks measured using different standards.

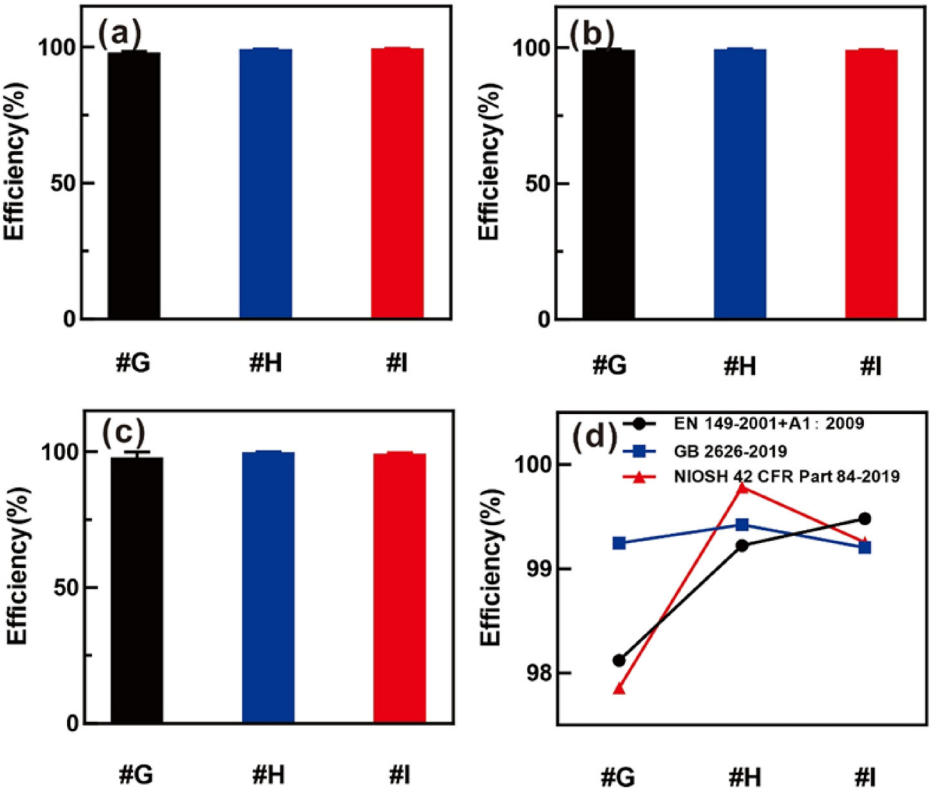

Fig 5. The PFE of the cup type masks tested by the protocol based on the (a) EN 149-2001+ A1:2009, (b) GB 2626-2019 and (c) NIOSH 42 CFR Part 84-2019, respectively, (d) the comparation of the PFE of cup type masks measured using different standards.

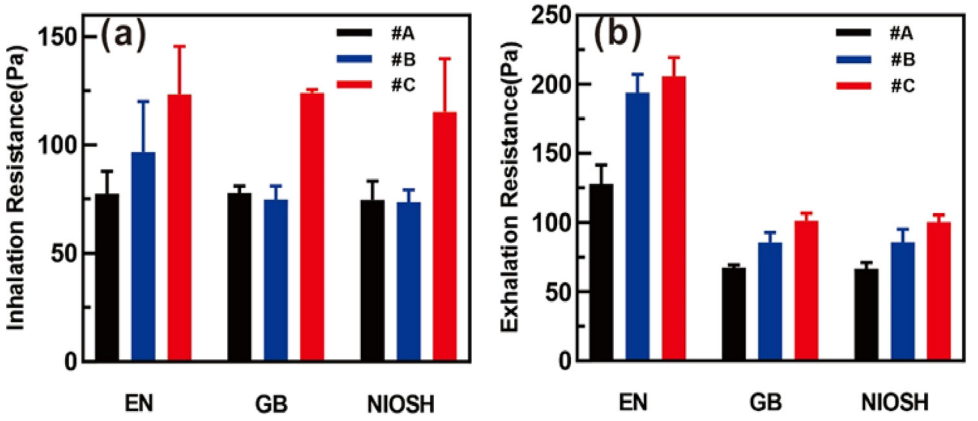

Fig 6. (a) The inhalation resistance and (b) exhalation resistance of planar masks #A, #B and #C tested by using the protocol based on the EN 149-2001+ A1:2009, GB 2626-2019, and NIOSH 42 CFR Part 84-2019, respectively.

The respiratory resistance of masks

The respiratory resistance of planar masks in difference standards. Respiratory resistance is generally measured by pressure difference or ventilation resistance, which is used to measure breathability and permeability. Generally, the higher the filtration effect, the greater the respiratory resistance.[31] The respiratory resistance of planar masks is measured by using the protocols recorded in the above-mentioned national standards. As shown in Figure 6a–b, the inhalation resistance and exhalation resistance reveal the same trends and all increased from #A to #C when the EN 149-2001 standard is used, demonstrating the higher quality of the mask #A. Besides, all the samples meet the requirement of the FFP1 class that defined in the EN 149-2001 standard (Table 1). As for the GB 2626-2019 protocol, the inhalation resistance of mask #C is higher than that of mask #A and #B. Besides, the exhalation resistance of the planar masks increased in sequence of #C>#B>#A, satisfying the criteria of the KN90 in the GB 2626-2019 standard. In terms of the respiratory resistance of planar masks evaluated by the NIOSH 42 CFR Part 84-2019 protocol, similar trends were observed to that of the GB 2626-2019. This result is caused by the same standard protocol that used for testing the respiratory resistance. Based on the above analysis, it can be concluded that the results were slightly different when measured by different standards. The expiratory resistance and inspiratory resistance of masks based on the EN 149-2001+ A1:2009 protocol is far greater than those measured by the NIOSH 42 CFR Part 84-2019 and GB 2626-2019 standards. The inhalation and expiratory flow rate is 95 L/min and 160 L/min, respectively.[32] Overall, brand #A does not meet the lowest level of the standards, while brand #B only meets the lowest level of FFP1 in EN 149-2001 standards. Brand #C meets the lowest level in other two standards except NIOSH 42 CFR Part 84-2019.

The respiratory resistance of folding masks in difference standards. The respiratory resistance of folding masks is also measured according to the three standards. As illustrated in Figure 7, the inhalation resistance of brand #D, #E, #F are 158.32 Pa, 155.82 Pa, and 118.78 Pa, respectively, when tested based on the EN 149-2001 protocol. Besides, the inhalation resistance of all samples is less than 3.0 mbar, which all achieve the FFP1 class (Table 1). In GB 2626-2019 standard, the inhalation resistance and exhalation resistance of brand #D is 139.33 Pa and 119.67 Pa, which are less than 170 Pa. The results indicated that the mask #D meet the requirement of KN90. Similarly, the inhalation resistance and exhalation resistance of brand #E and #F also fulfilled the requirement of the KN90 level. In terms of the NIOSH 42 CFR Part 84-2019 standards, the inhalation resistance of brands #D, #E and #F is 140.61 Pa (14.33 mm H_2O), 137.34 Pa (14 mm H_2O), and 106.27 Pa (10.83 mm H_2O), respectively, which are less than 35 mm H_2O (Fig 7a). The resistance differential is typically reported in the units of pascal (Pa) (1.0 Pa = 0.102 mm H_2O).[33] Furthermore, the exhalation resistance of all samples is less than 25 mm H_2O, demonstrating that brand #D, #E and #F are satisfied with all levels.

In summary, the respiratory resistance of the folding masks is in sequence of #D>#E>#F. In addition, all folding masks meet the minimum level of FFP1 in EN 149-2001, level KN95 in GB 2626-2019 and level N99 in NIOSH 42 CFR Part 84-2019.

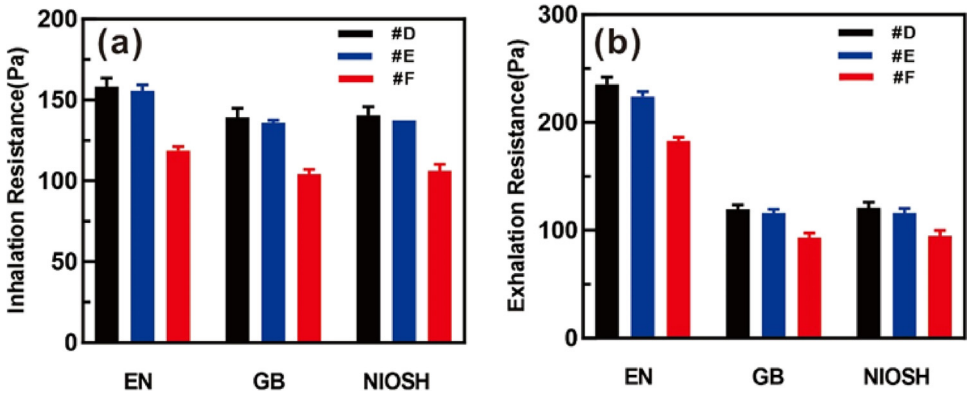

Fig 7. (a) The inhalation resistance and (b) exhalation resistance of folding masks #D, #E and #F tested by using the protocol based on the EN 149-2001+ A1:2009, GB 2626-2019, and NIOSH 42 CFR Part 84-2019, respectively.

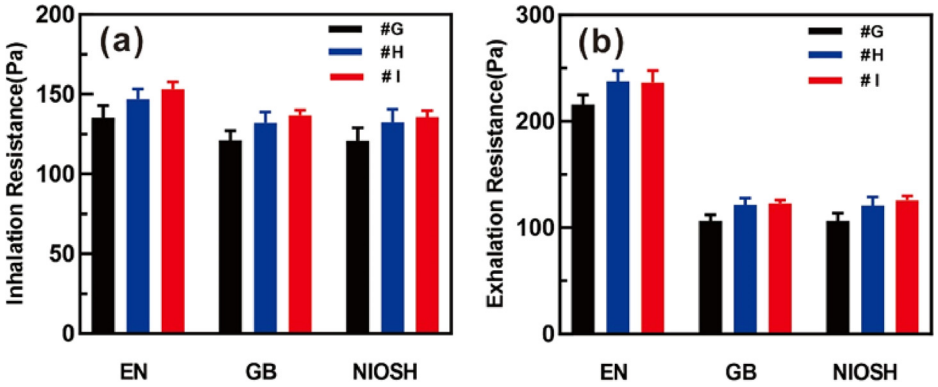

Fig 8. (a) The inhalation resistance and (b) exhalation resistance of cup type masks #G, #H and #I tested by using the protocol based on the EN 149-2001+ A1:2009, GB 2626-2019, and NIOSH 42 CFR Part 84-2019, respectively.

The respiratory resistance of cup type masks in difference standards. The respiratory resistance of cup type masks was measured based on the procedure of the three national standards. Under the requirement of the EN 149-2001, the inhalation resistance of masks increased from #G to #I (Fig 8a). As can be seen from Figure 8b, the exhalation resistance of mask #G, #H, #I is 215.88 Pa (2.16 mbar), 237.57 Pa (2.37 mbar), and 236.40 Pa (2.36 mbar), respectively, which is less than 3.0 mbar. The mask #G, #H and #I can be classified to FFP1 based on the results of the respiratory resistance. However, mask #G reaches level FFP2, and mask #H and #I reach level FFP3 based on the results of filtration efficiency. Overall, masks #G, #H and #I meet the requirements of level FFP1 in EN 149-2001. Shown in Figure 8, it is evident that the inhalation resistance and exhalation resistance of the mask #G is less than 170 Pa by using the GB 2626-2019 protocol. Therefore, it's reasonable to make the conclusion that all the masks reach the KN90 level. However, masks #G, #H and #I all reach the level of KN95 according to the results of the filtration efficiency. Overall, masks #G, #H and #I meet the requirements of KN90 level in GB 2626-2019.

According to the NIOSH 42 CFR Part 84-2019, the inhalation resistance and exhalation resistance increased from #G to #I. In terms of respiratory resistance, masks #G, #H and #I achieve all levels. According to the combination results of the filtration efficiency and respiratory resistance, mask #G meets level of N95, while mask #H and #I meet level of N99 in NIOSH 42 CFR Part 84-2019.

In summary, the respiratory resistance of three brands of cup type masks is in sequence of #G>#H>#I. What's more, all the cup type masks meet the lowest level of FFP1 in EN 149-2001, and reach the level KN90 in GB 2626-2019. Besides, mask #G meet the level of N95, mask #H and #I reach the level of N99 in NIOSH 42 CFR Part 84-2019.

CONCLUSION

In summary, multi-national standards protocols were used to test different kinds of mask products, so as to promote a comprehensive understanding of the test methods in terms of the filtration efficiency and respiratory resistance at home and abroad. The results indicated that no significant difference was noted between the PFE of the folding and cup type mask, but the PFE of the planar mask was significantly lower than the others. However, other studies on the effectiveness of the surgical masks and N95 masks have been revealed that there is no significant difference between the surgical masks and N95 masks. Besides, The NIOSH 42 CFR Part 84-2019 standard had most strict requirement for the PFE of the masks. Therefore, we recommended wearing the NIOSH-Approved respirators (N95, N99, N100, P95, etc.) if someone is caring for COVID-19 patient, at increased risk of severe illness, works a job with a high risk of exposure, traveling, or unable to keep physical distance. Otherwise, the cheaper planar mask is able to provide a certain level of protection. We believe that this study will help enterprises, testing institutions and the government to better control and supervise product quality and ensure that the general public can chose practical, user-friendly and practical protective mask products.

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