보건학석사 학위논문

Performance of Filtration Efficiency, Pressure Drop and Total Inward Leakage in Anti-Yellow Sand Masks, Quarantine Masks, Medical Masks, General Masks, and Handkerchiefs

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ABSTRACT

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Objective In these days, anti-yellow sand mask, quarantine mask, medical mask during foot-and-mouth disease outbreaks and even handkerchief are used with a belief that it can protect wearer, vary widely in style, and can be found in a broad range of markets, hospital and health care settings. Still little data has been published about the effectiveness of these masks while wearer is rapidly increasing in hospitals year around or during an episodic period for general citizens. The purposes of this study were to evaluate the filtration efficiency and pressure drop of various types of masks mentioned above and to compare the test results using MFDS protocol and NIOSH protocol. In this study, we also evaluate the facial fit test of anti-yellow sand masks and quarantine masks using MFDS protocol.

Methods For filtration efficiency and pressure drop test, after consultation with several health care workers, we selected a total of fortyfour different models approved by the MFDS along with non-approved commercially available anti-yellow sand mask, quarantine mask, medical mask, general mask, and handkerchief. The two TSI 8130 Automatic Filter Testers, which were designed in compliance with MFDS protocol and NIOSH protocol, were used for NaCl Initial and loading tests. 6 samples of each model, 3 for MFDS protocol and 3 for NIOSH protocol, were tested. For TIL test, we selected a total of five masks; three anti-yellow sand mask and two quarantine mask. Tested masks were shown greatest filtration ability at filtration efficiency and pressure drop test. TIL test had been established in compliance with the MFDS regulations and guidelines for anti-yellow sand mask and quarantine mask criteria.

Results Wide variation of filtration efficiency and pressure drop values were observed by mask types. The lowest average filtration efficiency was measured in the quarantine mask. This was followed in order by the anti-yellow sand mask, the medical mask, the general mask, and the handkerchief. No significant difference in filtration efficiency was noted between the MFDS protocol and the NIOSH protocol. However, the pressure drop values was significantly different between mask types in both the MFDS protocol and NIOSH protocols. In case of TIL test, TIL values of anti-yellow sand mask and quarantine mask were significantly higher than filtration efficiency values. All anti-yellow sand mask and one of the quarantine mask shown low TIL values than MFDS criterion. But the other quarantine mask exceeded MFDS criterion.

Conclusion Quarantine mask shown the greatest itself filtration efficiency than other masks. However, when the test panel wear the masks to validate TIL values, because of one of the quarantine mask is not well fitted to facial skin and masks, anti-yellow sand masks shown the lowest TIL values than other masks. To reduce the risk for general citizens, MFDS need to do quality control system and need to reexamine the test protocol for anti-yellow sand masks, quarantine masks and other masks which is can used by general citizens in Korea.

Keywords: Mask, Filtration efficiency, Pressure drop, Total inward leakage,

MFDS, NIOSH.

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INTRODUCTION

Recently, many events have transpired related to hazardous air pollutants such as yellow-sand dust, foot-and-mouth disease, and avian influenza in Asia and other regions. Personal protective equipment (PPE) is often regarded to be a last resort measure after substitution, isolation, and ventilation in occupational hygiene areas. However, ordinary citizens use mask and even handkerchief as first-protection devices against the inhalation of external harmful substances such as influenza particles and dust. These masks and handkerchief are used with the belief that they protect the wearer. Many texts offer guidance but recommend only the use of a clean handkerchief when protection is required (Safar & Bircher, 1988, Blenkharn *et al.*, 1990). They vary widely in style, and can be found in a broad range of market, hospital, and health-care settings (Lai *et al.*, 2012). For example, seeing people wearing masks during influenza episodes, the yellow-sand dust season (i.e., spring in the East Asian region) and in hospitals (both patients and health-care workers) is not uncommon.

Yellow sand occurs in the loess area of northern China and is known to affect the air quality of China, Korea, Japan, and Taiwan (Chao *et al.*, 2012, Kang *et al.*, 2004, Zhang *et al.*, 2010). The number and degree of dust phenomenon events is increasing (Kim & Kim, 2003). Since the outbreaks of severe acute respiratory syndrome (SARS) in Asia that spread over approximately 30 countries, viruses have gained additional attention worldwide. Viruses in the air, such as SARS and foot-mouth disease, can cause inflammation of the lungs via inhaled droplets generated and spread from the nose or mouth (Lee *et al.*, 2008, Nassiri, 2003, Wang *et al.*, 2004).

Since respirators were developed, many studies on the degree of filtration efficiency, pressure drop, and face leakage of respirators for the workplace have been conducted, but few studies on masks for general citizens were conducted until recently.

Some studies tested a limited number of N95 respirator models and observed higher than 5% filtration efficiency. Six respirators (models N95, N99, R95, P100) were dipped in isopropanol for 15 s and allowed to dry. This isopropanol dip should reduce or eliminate any electrostatic charge on the fibers of each filter. So, filtration efficiency of six degraded respirators is over 5% (Martin Jr & Moyer, 2000). The performance of two model N95 respirators against nano-sized particles was evaluated at two inhalation flow rates, 30 and 85 L/min. At 30 and 85 L/min, the respirators showed less than 5% and above 5% filtration efficiency, respectively, of nanoparticles (Balazy *et al.*, 2006b). Two N99 and one N95 respirators exposed to a sodium chloride (NaCl) aerosol and three virus aerosols (enterobacteriophages MS2, T4, and *Bacillus subtilis* phage) were examined on manikins using three inhalation flow rates (30, 85, and 150 L/min). All respirators used in this study satisfied the criteria of N95 and N99 at both 30 and 85 L/min using the NaCl and virus, but neither respirator did so at 150 L/min. Filter filtration efficiency of the tested biological aerosols did not exceed that of the inert NaCl aerosol (Eninger *et al.*, 2008). Rengasamy *et al.* (2008) investigated the filtration performance of N95 and P100 respirators against six different monodisperse silver aerosol particles in the range of 4–30 nm diameter at 85 L/min. The data from this study confirmed that the N95 and P100 respirators provided filtration performances of greater than 95% and 99.97%, respectively.

In hospitals, the roles of masks for the protection of medical staff from the patient or the protection of patients from medical staff are controversial (Abramson, 1944, Diaz & Smaldone, 2010, Grinshpun *et al.*, 2009, Johnson *et al.*, 2009). Medical masks have been used to block blood and other droplets during patient handling and operations. However, their filtration efficiencies have not been validated for small aerosol droplets. Seeing people block their mouths and noses with handkerchiefs during dusty conditions is not uncommon (Jefferson *et al.*, 2009, Lai et al., 2012, Van der Sande *et al.*, 2008). Balazy *et al.* (2006a) conducted experiments using two types of N95 half-mask respirators and two types of surgical masks exposed to aerosolized MS2 virus. N95 half-mask respirators may not provide proper protection against viruses, which are considerably smaller than the accepted smallest particle filtration efficiency size (300 nm) used in the certification tests, and some N95 respirators may fall below 95%. The efficiency of the surgical masks is much lower than that of the N95 respirators.

One large prospective randomized control trial reported on general surgical patients. Half the group underwent operations during which the surgical team used masks, and in the other half, masks were not used. No significant difference was observed in the infection rate, and the bacteria that were subsequently cultured did not differ between the two groups. Indeed, a trend for more infections to occur was noted in the group wearing masks (Taylor & Reidy, 1998, Tunevall & Bessey, 1991). Another study suggested that surgical masks worn by potentially infectious individuals may effectively contain exhaled aerosols, offering protection to those around them (Fennelly, 1998, Johnson et al., 2009, Siegel *et al.*).

Another scale related to respirator is total inward leakage (TIL) testing. If there are any gap of facial skin and respiratory protection devices, regardless of goodness of filtration efficiency, the respirators are not appropriate to protect workers in workplace or citizen in general situation to their respiratory system (Lai et al., 2012). In the worst case, even though wearer are wearing respirators, they might be exposed to external harmful substances (Zhuang *et al.*, 2005, Rengasamy & Eimer, 2011, Rengasamy & Eimer, 2012). Therefore, respirator fit testing is desirable before entering hazardous working environments to ensure that the respirator worn satisfies a minimum fit, and that the user knows when the respirator fits properly (Colton *et al.*, 1991, Liu *et al.*, 1993, Zhuang et al., 2005, Reponen *et al.*, 2011, Viscusi *et al.*, 2011).

Whereas fit test only examine whether fitting is well or not, the advantage of TIL test is including all possible leakage. For example, filter filtration efficiency, facial leakage and exhalation leakage with/without speaking and motion (WR., 2000).

$$TIL=L_{fs}+L_{ape}+L_{ex}+L_{n}$$

Where L_{fs} leakage through the face seal, L_{ape}=leakage through the air-purifying element, L_{ex}=leakage through the exhalation valve, L_{n}=leakage through other pathways.

TIL of a test aerosol from all sources (e.g. face seal, filter and exhalation valve) is determined for a panel of people (e.g. 10 subjects) wearing the respirator with the filter to be used in the workplace. In many European countries, facial fit is evaluated during respirator certification using a TIL test instead of fit testing (EN136, 1998, EN140, 1998).

It is commonly assumed that size and position of face seal leaks constantly change during breathing, talking, and head/body movement (Myers *et al.*, 1996). Some studies tested respirators worn by human subjects. One study involving three half-masks and 10 FFRs tested on a panel of 10 human subjects concluded that the performance of elastomeric half-masks was better than that of FFRs (Han & Lee, 2005). Lawrence *et al.* (2006) conducted involving a panel of 25 subjects with varying face sizes reported superior performance of elastomeric N95 half-masks (15 models tested) over N95 FFRs (15 models tested) and surgical masks (6 models tested). But, these were obviously, limited to respirators for worker in some workplace such as hospital or using particular small particle laboratory (Derrick & Gomersall, 2005, Shaffer & Rengasamy, 2009, Lam *et al.*, 2011, Rengasamy & Eimer, 2011).

To verify the performance of the respirator used in the workplace, the European Union (EU) and National Institute for Occupational Safety and Health (NIOSH) protocols are typically used worldwide. In the European Union, the minimum efficiencies for filtering facepieces P1 (FFP1) and P1, and FFP2 and P2 products are 80% and 94%, respectively. For FFP3 respirators, the minimum filtration efficiency is 99%, while for P3 filters, the value is 99.95% (Howie, 2008). In Korea, since the EU standard was adopted, the efficiency requirements specified by the Korea Ministry of Labor (KMOL) for Second, First, and Special series are the same as the European requirements for FFP1/P1, FFP2/P2, and FFP3/P3, respectively (Cho *et al.*, 2011).

In the United States, the NIOSH tests and certifies 95, 99, and 100 series particulate filters and respirators, with minimum required filtration efficiencies of 95%, 99%, and 99.97%, respectively. Certification of respirators with test methods for measuring filtration efficiency in these standards vary with the type of aerosol and are designated by N (not resistant to oil), R (somewhat resistant to oil), and P (strongly resistant, oilproof) (Moyer & Bergman, 2000, NIOSH, 1996, Rengasamy *et al.*, 2011).

Unlike respirators for workers, which must be tested and certified by strict standards set by the NIOSH in the United States and the Korean Occupational Safety and Health Agency (KOSHA) in Korea, no strict regulations have been established for the filtration efficiency, pressure drop and TIL for medical (surgical/dental), quarantine, and general mask worldwide, and no data exist on the filtration efficiency of handkerchief.

The Ministry of Food and Drug Safety (MFDS) recently promoted testing criteria for mask filtration efficiencies. The maximum filtration efficiency value was 20% (KF 80) and 6% (KF 94) for anti-yellow sand mask and quarantine mask, respectively. The maximum pressure drop value was 6.5 mmH_2O (KF 80) and 7.2 mmH_2O (KF 94) for anti-yellow sand mask and quarantine mask, respectively. The maximum TIL value was 25% (KF 80) and 11% (KF 94) for anti-yellow sand mask and quarantine mask, respectively. Little data have been published on the effectiveness of these masks, but the number of wearers is rapidly increasing and many people are concerned about mask protection efficiency.

The first purpose of this study was to evaluate the filtration efficiency and pressure drop of various types of approved and non-approved mask using the MFDS (similar to EU test protocol) test protocol and the NIOSH test protocol and to compare the results. The second purpose of this study was to evaluate the TIL values of anti-yellow sand mask and quarantine mask using MFDS test protocol.

MATERIALS AND METHODS

1. Study Design

After visiting several pharmacy stores, searching e-markets on the Internet, and consulting with several health-care workers, we selected a total of fortyfour models, some of which are approved by the MFDS or NIOSH along with non-approved commercially available mask and handkerchief for this study.

For filtration efficiency and pressure drop test, nine adults and seven children's anti-yellow dust mask brands were chosen. In addition, nine quarantine masks, seven medical masks (four surgical, three dental), nine general masks, and three handkerchiefs were tested (Table 1).

Medical (surgical/dental) mask were tested in both airflow directions; an inward test (from the outer air to the mouth direction, mimicking inhalation) and an outward test (from the mouth to the outer air, mimicking exhalation). Handkerchief is not mask but is used in situations when people feel that dust is in the air. Therefore, we tested handkerchief in one to four layers separately.

Loading for filtration efficiency and pressure drop test was run until a mass of 200 mg of NaCl or paraffin oil aerosol on the respirator. In some cases, the test was stopped earlier due to a large pressure drop.

For TIL test, we selected a total of 5 kinds of half mask which had been proved to satisfy filtration efficiency and pressure drop criteria set by MFDS; three masks are anti-yellow sand mask, two masks are quarantine mask.

Before testing the filtration efficiency, pressure drop and TIL, the tested aerosols were examined to meet the size criteria of the NIOSH and the MFDS with a scanning mobility particle sizer (SMPS, TSI-3910; TSI Inc., Shoreview, MN, USA).

Table 1. General Information of mask type

No.	Type		Approved Class		Material of respirator	Shape
			MFDS	NIOSH		
1*	Anti-yellow sand	Adult	KF80	-	Nonwoven	Flat
2			KF80	-	Nonwoven	Flat
3			KF80	-	Nonwoven	Flat
4			KF80	-	Nonwoven	Flat
5			KF80	-	Cotton	Flat
6			KF80	-	Cotton	Flat
7			KF80	-	Cotton	Flat
8*			KF80	N95	Nonwoven	Flat
9*			KF80	N95	Nonwoven	Flat
10		Child	KF80	-	Nonwoven	Flat
11			KF80	-	Nonwoven	Flat
12			KF80	-	Nonwoven	Flat
13			KF80	-	Nonwoven	Flat
14			-	-	Cotton	Flat
15			-	-	Cotton	Flat
16			-	-	Nonwoven	Flat
17	Quarantine		KF94	-	Nonwoven	Flat
18			KF94	-	Nonwoven	Flat
19			KF94	-	Nonwoven	Cup
20			KF94	-	Nonwoven	Flat
21			-	N95	Nonwoven	Cup
22			KF80	N95	Nonwoven	Cup
23			-	N95	Nonwoven	Flat
24			-	N95	Nonwoven	Cup
25			-	N95	Nonwoven	Cup
26	Medical	Surgical	-	-	Cotton	Flat
27			-	-	Nonwoven	Flat
28			-	-	Nonwoven	Cup
29*			-	-	Nonwoven	Cup
30		Dental	-	-	Nonwoven	Flat

31*		-	-	Nonwoven	Flat
32		-	-	Nonwoven	Flat
33	General	-	-	Nonwoven	Flat
34		-	-	Nonwoven	Flat
35		-	-	Nonwoven	Flat
36		-	-	Nonwoven	Flat
37		-	-	Cotton	Flat
38		-	-	Cotton	Flat
39		-	-	Cotton	Flat
40		-	-	Cotton	Flat
41		-	-	Cotton	Flat
42	Handkerchief	-	-	Cotton	-
43		-	-	Gauze	-
44		-	-	Towel	-

*These masks tested for Total inward leakage test.

2. Filtration efficiency and Pressure drop Test

Two TSI 8130 Automatic Filter Testers (AFTs) were used for NaCl initial and loading tests, and for paraffin oil quarantine mask initial tests. Initial test was to estimate the value of filtration efficiency of the beginning of experiment at ~ 1 minute. Loading test was to estimate the change of respirators pressure drop value by accumulated test particles on respirators to 200 mg. These two instruments were designed in compliance with the MFDS protocol and NIOSH Regulation 42 CFR Part 84 protocol, respectively. The samples were attached to plates with hot-melt adhesive. When we were testing on the TSI 8130 automated filter tester (AFT), the plate was placed into the lower chuck of the tester. A spacer ring (20 cm diameter and 10 cm height) fitted with a gasket was placed on top of the sample holder, and a second plate was placed on top of the spacer ring. When the AFT chucks were closed, the pressure of the top chuck on the upper plate compressed the plates and spacer ring together to form an airtight seal. The TSI instrument is based on the measurement of the flux of scattered light. It uses two aerosol photometers to measure the particle filtration efficiency, with one placed before and one after the filter (NIOSH, 1996, TSI, 2006). The photometer output signals were approximately proportional to the aerosol mass and used to calculate filter filtration efficiency P as

$$P(\%) = \frac{C_{down}}{C_{up}} \times 100$$

where C_{down} is the aerosol concentration downstream of the respirator filter and C_{up} is the challenge aerosol concentration upstream of the respirator filter. Tests using NaCl and paraffin oil aerosols were conducted according to MFDS and NIOSH protocols for filter filtration efficiency, with two exceptions. The samples were not preconditioned at 38°C and 85% relative humidity (RH) for 24 h prior to testing. Preconditioning might have been appropriate if all the products were MFDS and NIOSH certified. However, given that some of the products were not specifically designed to meet the MFDS and NIOSH preconditioning requirement, it was omitted from our test protocol. This approach is supported by the observation of Moyer and Stevens (1989), who in discussing the effect of humidity on filtration efficiency, stated that "the effect of particle charge and size is significantly larger than the effect of RH." This abbreviated test procedure (e.g., no preconditioning) provides results similar to those from longer NIOSH certification tests (Rengasamy et al., 2011, Viscusi *et al.*, 2009). To conduct filter tests using the MFDS protocol, the adopted EU method was similar to the NIOSH protocol, with the exception that the challenging NaCl concentration was 1%, with a flow rate of 95 L/min for initial filtration efficiency, and a loading test and 30 L/min for the initial pressure drop test.

NaCl was selected because it is commonly used in many respirator certification standards. Additionally, for the quarantine mask, we also evaluated the filtration efficiency using paraffin oil with a flow rate of 95 L/min. This was to test the oily mists according to the MFDS protocol. They were used to simulate oily mists, not solid particles. For the NIOSH protocol, a 2% NaCl solution was prepared with distilled water as specified by the TSI to obtain an aerosol with a count median diameter (CMD) of 75 ± 20 nm and geometric standard deviation (GSD) of ≤1.86. The aerosol was neutralized to the Boltzmann equilibrium charge distribution by injecting positive and negative ions from electrically pulsed tungsten needles into a dilution airstream that was mixed with the aerosol. A constant flow rate of 85 L/min was applied to the respirator and masks.

Most respirator standards also contain test methods for measuring breathing resistance through the respirator. Inhalation and/or exhalation resistance are measured at a given airflow rate using a pressure gauge. These measurements may be made separately from or during the filtration efficiency testing. Filtration efficiency can be measured as low as 0.001% and with pressure drops up to 150 mm H_2O. In some cases, the test was stopped earlier due to the high pressure drop. The filtration efficiency and pressure drop were recorded at about 1-min intervals throughout the test. Six samples of each model were tested: three for the MFDS protocol and three for the NIOSH protocol.

3. Total inward leakage test

MFDS protocol for TIL test, regardless of facial sizes, require 10 members of test panels (MFDS, 2009). The person who participated in this test are 25-75% quartile in Korea by facial size. The test panels consisted of 10 male and 2 female volunteers. Males clearly shaved their chin to participate to this study. They were measured their face sizes four parts which are chin to top of lip, ear to ear, ear to end of nose and width of mouth. Measurements were used as determinants for facial sizes. All measurements carried out by one investigator were made in centimeters to one decimal point using a sliding caliper (No.104, Siber hegner, Switzerland) and spread caliper (No.106, Siber hegner, Switzerland) to reduce measurement biases.

The test was conducted at the 3M Korea Innovation Center in which the experimental instruments and systems for TIL testing had been established in compliance with the MFDS protocol and guidelines (similar to European Standard) for anti-yellow sand mask and quarantine masks criteria (MFDS, 2009). Most instruments used this study were made in the UK, atomizer (Sodium chloride aerosol generator Type 4100250/F, SFP Service, UK), photometer (Model QL30F/RFI, Electron Tubes Ltd., UK) and pulse sampling unit (Sodium Flame Photometer Type 1150, SFP Service, UK). The photometer output signals were approximately proportional to the aerosol concentration and used to calculate total inward leakage (TIL) as

$$\mathrm{TIL}(\%) = \frac{C_2}{C_1} \times \frac{T_1 + T_2}{T_2} \times 100$$

where TIL is total inward leakage, C_1 is concentration in test chamber (mg/m^3), C_2 estimated concentration in respirator of test panel (mg/m^3), T_1 is sum of exhalation time (min) and T_2 is sum of inhalation time (min).

The test procedure for TIL was performed in compliance with the MFDS test protocol by using the sodium chloride (NaCl) method. Before testing each test panel was asked 'Does the mask fit?' and if the answer of test panel was 'yes' the test was continued. If not, the test panel was told to adjust the masks, and this could be repeated several times. Also, before testing zero calibration of test aerosol did. Each panel was subjected to test for all 5 masks one by one. Five test exercise periods were carried out, each exercise period spending 2 min. Test panels did the test according to this sequence, walking with normal breathing, side to side head turn, up and down of head , talking and a walking with normal breathing. This test was performed on the treadmill and repeated three times, at the speed of 6 km/h.

4. Statistical Analysis

All data on filtration efficiency and pressure drop values were analyzed using arithmetic mean values. According to the European standard for respirators, the filtration efficiency and pressure drop values of tested respirators should be analyzed using the arithmetic mean value (EN136, 1998, EN140, 1998). Using a *t*-test, we analyzed the difference in filtration efficiency and pressure drops of approved and non-approved anti-yellow sand masks for children and quarantine masks, inward (from the outside air to the mouth direction) or outward (from the mouth to the outside air direction). ANOVA tests were used for differences in the type of mask, handkerchief fold, TIL values by types of mask, the initial filtration efficiency and TIL values of the test mask, difference in the TIL values by test panels and difference in the TIL values of each test exercises. To compare with the MFDS and NIOSH protocol and TIL values in anti-yellow sand and quarantine mask types, we used a paired *t*-test. All analyses used SAS for Windows 9.3 (SAS Institute Inc., Cary, NC, USA) at $\alpha = 0.05$.

RESULTS

1. Particle Size Distribution of NaCl and Paraffin Oil Aerosol

Fig. 1 shows the size distribution of the NaCl and paraffin oil aerosol particles measured by a SMPS. For filtration efficiency and pressure drop test, we used the same testing equipment that was found to satisfy the NIOSH NaCl aerosol specification, as published previously (Cho *et al*., 2011). The average CMD of the NaCl aerosol was 77.9 nm with the MFDS protocol, which matched the target CMD for the MFDS protocol closely. The average GSD was 1.95, which was well within the MFDS specifications. The CMD was 224.9 nm (GSD 2.15) for paraffin oil aerosols with the MFDS protocol.

For TIL test, the average count median diameter (CMD) and geometric standard deviation (GSD) of the NaCl aerosol were 98.3 nm and 2.19, respectively. MFDS protocol defines test aerosol concentration within 8 ± 6 mg/m^3, particle size range is 0.02-2um and average diameter is 0.6um.

The result of our study matches the average aerosol concentration, particle size range with MFDS criteria. But, average particle diameter is not compared directly with MFDS criteria. Because of MFDS guidelines for mask test of anti-yellow sand and quarantine masks stipulate ambiguous statement about average particle diameter. They not define average particle diameter is count median diameter (CMD) or mass median diameter (MMD) but only state average particle diameter.

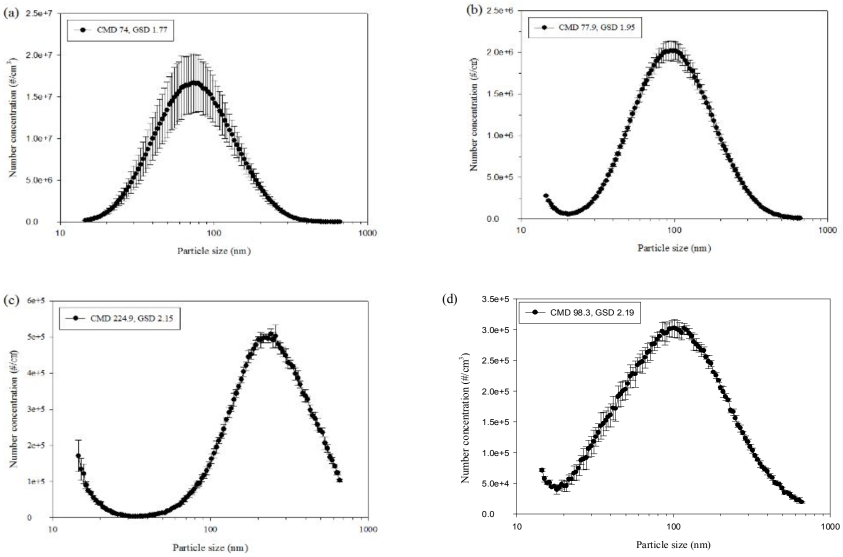


Figure 1. Size distribution of test aerosols measured by a scanning mobility particle sizer (SMPS). (a) Number concentration of NaCl aerosols tested by the NIOSH protocol. (b) Number concentration of NaCl aerosols tested by the MFDS protocol. (c) Number concentration of paraffin oil aerosols tested by the MFDS protocol. (d) Number concentration of NaCl aerosols tested by MFDS protocol. (a), (b) and (c) were for filtration efficiency and pressure drop test. (d) was for TIL test.

2. Filtration efficiency

The results of the initial filtration efficiency with NaCl aerosols are presented in Table 2. The data in the Table include the average reading for the three samples and the associated standard deviation in the format "x.xxx ± x.xxx" (Cho *et al.*, 2011). A wide variation of filtration efficiency values was observed with mask type. As seen in Table 2, the lowest average filtration efficiency was measured in the quarantine mask. This was followed in order by the adult anti-yellow sand mask, the children's anti-yellow sand mask, the medical mask, the general mask, and the handkerchief. No significant difference in filtration efficiency was noted between the MFDS (similar to EU) protocol and the NIOSH protocol (p = 0.1223). However, the filtration efficiency value was significantly different between mask types ($p < 0.0001$ in both the MFDS and NIOSH protocols). The initial filtration efficiency values of anti-yellow sand masks for adults were 15.1 ± 16.5% and 12.6 ± 14.5% with the MFDS and NIOSH protocols, respectively, satisfying the MFDS anti-yellow-sand mask criterion of 20% filtration efficiency (KF 80). The filtration efficiency value of the anti-yellow sand mask for children was 23.7 ± 19.5%, which was over the MFDS criteria of 20% for the anti-yellow sand mask. MFDS does not specify a criterion for children so we compared this with the KF 80 value. When we tested with the NIOSH protocol, the filtration efficiency value for the children's anti-yellow sand masks was 37.0 ± 25.5%, which was very different from the MFDS test result.

All quarantine masks showed low filtration efficiency among the tested mask types, with a value of 0.9 ± 0.8% using the MFDS protocol and 0.6 ± 0.5% using the NIOSH protocol, satisfying criteria of the MFDS (KF 94). The filtration efficiency values of medical (surgical/dental) masks were over 40% and those of general masks exceeded 60%. All of these masks seemed to have little protection function against test aerosols. Handkerchiefs showed more than 98% initial filtration efficiency regardless of the material (cotton or gauze), and more than 87% for a folded status (Table 3 shows each value for one, two, three, and four layers), which means that handkerchiefs had no protection function against tested aerosols.

Table 2. Initial filtration efficiency using MFDS (similar to EU) protocol and NIOSH protocol by mask types (FE:Filtration efficiency)

Mask classification	N	Initial FE (%)								P value‡
		MFDS				NIOSH				
		Mean	±	SD	P value*	Mean	±	SD	P value†	
Anti-yellow sand mask for adult	9	15.1	±	16.5		12.6	±	14.5		
Anti-yellow sand mask for children	7	23.7	±	19.5		37.0	±	25.5		
Quarantine mask[a]	9	0.9	±	0.8		0.6	±	0.5		
Quarantine mask[b]	9	2.1	±	0.3	<0.0001		-		<0.0001	0.1223
Medical mask	7	44.7	±	34.8		43.6	±	35.7		
General mask	9	62.4	±	23.5		63.1	±	26.2		
Handkerchief	3	97.6	±	2.1		97.0	±	3.2		

[a] MFDS test for quarantine masks using sodium chloride.

[b] MFDS test for quarantine masks using paraffin oil.

* Different of mask type using MFDS method (except quarantine masks test result using paraffin oil).

† Different of mask type using NIOSH method.

‡ Different of MFDS and NIOSH test methods (except quarantine masks test result using paraffin oil).

Table 3 shows the initial filtration efficiency classified by several characteristics of the tested masks. For children's anti-yellow sand masks, a significant difference in filtration efficiency was observed between certified (KF 80) and noncertified masks ($p < 0.0001$ with the MFDS protocol, $p = 0.003$ with the NIOSH protocol, respectively). The average filtration efficiency of certified and noncertified masks was 12.5 ± 10.1%, 38.6 ± 19.2% with the MFDS protocol and 23.7 ± 22.8%, 54.8 ± 17.0% with the NIOSH protocol, respectively. In Korea, the MFDS has a filtration efficiency criterion for anti-yellow sand masks and quarantine masks with maximum filtration efficiency of 20% (KF 80) and 6% (KF 94), respectively. Six of nine anti-yellow sand masks (67%) and four of seven children's anti-yellow sand masks (57%) satisfied the KF 80 criteria, and all quarantine masks satisfied the KF 94 criteria.

For quarantine masks using NaCl, certified masks with criteria of 6% filtration efficiency (KF 94) showed 0.6% and 0.4% filtration efficiency with the MFDS and NIOSH protocols, respectively. No significant difference was observed between test protocols ($p = 0.068$). Noncertified quarantine masks also met the KF 94 criteria, with a filtration efficiency of 1.1% using the MFDS protocol and 0.8% using the NIOSH protocol. These values were slightly higher than those for the certified quarantine masks. The values of the certified and noncertified quarantine masks using paraffin oil were 1.7% and 2.3%, respectively. Hence, the certified masks also showed better filter performance than noncertified masks using both NaCl and paraffin oil test aerosols.

In the case of medical masks, the filtration efficiency of dental masks was less than the filtration efficiency of surgical masks, but all of them showed over 20% filtration efficiency. The test results for inward and outward flow showed no significant difference (i.e., p = 0.993, 0.439 for the surgical and dental masks with the MFDS protocol, respectively, and p = 0.946, 0.731 for surgical and dental masks with the NIOSH protocol, respectively).

General masks, regardless of their material, showed little protection against the tested aerosols, even when they had a fancy brand name (i.e., Best Nano, Ultra Antibiotic, Anytime Guard, Hygiene). The average filtration efficiency values of nine tested general masks were 62.4% with the MFDS protocol and 63.1% with the NIOSH protocol, respectively (Table 2). Nonwoven material showed about 50% filtration efficiency while masks made of cotton displayed over 70% filtration efficiency (Table 3). Handkerchiefs demonstrated very little protection against the tested aerosols. Filtration efficiency was over 95% when tested with the MFDS protocol, decreasing to 87-91% when three and four layers were used. More handkerchief layers meant less filtration efficiency, but the filtration effect was small even when a well-folded handkerchief was used.

Table 3. Initial filtration efficiency classified by several characteristics of masks (FE : Filtration efficiency)

Mask classification		Variables	N	Initial FE (%)								
				MFDS				NIOSH				P value[‡]
				Mean	±	SD	P value[*]	Mean	±	SD	P value[†]	
Anti-yellow sand	Children	Certified (KF80)	4	12.5	±	10.1	0.0007	23.7	±	22.8	0.0029	0.0005
		Not Certified	3	38.6	±	19.2		54.8	±	17.0		
Quarantine[a]		Certified (KF94)	4	0.6	±	0.4	0.1117	0.4	±	0.3	0.0462	0.0679
		Not Certified§	5	1.1	±	0.9		0.8	±	0.6		
Quarantine[b]		Certified (KF94)	4	1.7	±	1.1	0.2928		-		-	-
		Not Certified§	5	2.3	±	1.8			-			
Medical	Surgical	Inward	2	58.8	±	36.2	0.9931	59.1	±	36.7	0.9459	0.6330
		Outward		59.0	±	35.8		57.7	±	33.7		
	Dental	Inward	3	31.9	±	12.6	0.4388	29.1	±	12.0	0.7305	0.0353
		Outward		27.7	±	10.1		31.2	±	14.3		
General	Nonwoven	-	4	52.7	±	10.4	0.0411	45.3	±	9.4	0.0004	0.8153
	Cotton	-	5	70.1	±	28.3		77.4	±	26.8		
Handkerchief	Cotton	One layer	1	98.0	±	0.3	<.0001	98.9	±	0.7	0.0013	0.0006
		Two layers		95.3	±	0.7		98.0	±	0.7		
		Three layers		91.2	±	1.0		96.9	±	0.4		
		Four layers		87.1	±	0.7		96.2	±	0.3		

Handkerchief	Gauze	One layer	1	99.6 ± 0.4	0.0069	99.3 ± 0.3	<.0001	0.0138
		Two layers		99.0 ± 1.0		98.6 ± 0.5		
		Three layers		98.2 ± 0.5		98.0 ± 0.4		
		Four layers		97.2 ± 0.3		96.4 ± 0.4		

[a] MFDS test for quarantine masks using sodium chloride.

[b] MFDS test for quarantine masks using paraffin oil.

[*] Different of mask type using MFDS method (except quarantine masks test result using paraffin oil).

[†] Different of mask type using NIOSH method.

[‡] Different of MFDS and NIOSH test methods (except quarantine masks test result using paraffin oil).

[§] No certified by MFDS but certified by NIOSH (N95 grade respirator)

Fig. 2 shows several examples of mask filtration efficiency patterns according to the mass loading of NaCl aerosol at the mask. The test masks were certified as KF 80 (maximum 20% filtration efficiency, product 9) or KF 94 (maximum 6% filtration efficiency, products 24, 25, and 27) class and were found to satisfy these criteria in this study. Filtration efficiency values were interpolated from the raw data at regular aerosol load intervals (10 mg, 20 mg, …) from each load test to permit averaging of the results for the three samples of each type. The error bars represent ± 1 SD.

As seen in Fig. 2, the shapes of the filtration efficiency curves are similar between the MFDS and NIOSH test protocols within the same products, although the patterns are somewhat different between the products. For example, products 25 and 27 showed a significant increase in filtration efficiency before decreasing, while products 9 and 24 displayed a decreasing pattern according to the NaCl aerosol loading. Nevertheless, they all remained well below the certification limit of 20% for anti-yellow sand mask filtration efficiency and 6% for quarantine mask filtration efficiency.

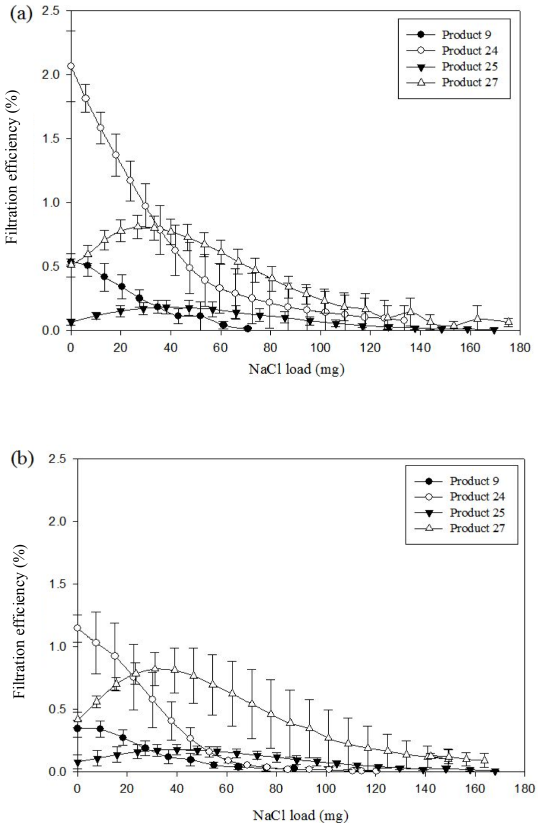


Figure 2. Filtration efficiency as a function of NaCl aerosol accumulation on the mask using (a) the MFDS protocol and (b) NIOSH protocol. Symbols represent mean values and vertical lines represent 1 SD of the results from the three tests conducted for each mask.

3. Pressure Drop

The results of the pressure drop are summarized in Table 4. The pressure drop showed little variation compared to the filtration efficiency in Table 2. The average pressure drops of all tested masks were 2.7 ± 1.4 (range 0.4–9.5) mmH_2O with the MFDS protocol and 10.6 ± 5.9 (range 0.6–26.3) mmH_2O with the US NIOSH protocol (data not shown). When tested using the MFDS protocol, the highest pressure drop was measured in the anti-yellow sand mask for adults (3.3 ± 2.2 mmH_2O), followed by the quarantine mask, the children's anti-yellow sand mask, the medical (surgical/dental) mask, the general mask, and the handkerchief. The pressure drops of all tested masks were below the criterion of 7.2 mmH_2O (KF 94 class) and 6.2 mmH_2O (KF 80 class). When using the NIOSH protocol, we found that the pressure drop for anti-yellow sand masks was the highest (13.7 ± 5.2 mmH_2O) and all masks except the handkerchief were over the KF 80 and 94 pressure limits. As expected, the pressure drop of the handkerchief was lowest (1.9 mmH_2O), while its filtration efficiency was over 97%.

Table 4. Initial pressure drop using MFDS (similar to EU) protocol and NIOSH protocol by mask types (PD : Pressure drop)

Level of class	N	Initial PD (mmH_2O) MFDS				NIOSH				P value‡
		Mean	±	SD	P value*	Mean	±	SD	P value†	
Anti-yellow sand mask for adult	9	3.3	±	2.2	0.0143	13.7	±	5.3	<0.0001	<0.0001
Anti-yellow sand mask for children	7	2.9	±	0.9		12.1	±	4.7		
Quarantine mask	9	3.0	±	1.3		12.5	±	6.9		
Medical mask	7	2.4	±	0.8		9.2	±	3.7		
General mask	9	2.2	±	0.8		8.2	±	4.5		
Handkerchief	3	1.9	±	1.9		1.9	±	1.6		

* P value between mask types using MFDS method.

† P value between mask types using NIOSH method.

‡ P value between MFDS and NIOSH test methods.

Table 5 shows the pressure drop classified by several characteristics of the tested masks. For children, we used anti-yellow sand masks. No significant difference was observed in the pressure drop between certified (KF 80) and noncertified masks ($p = 0.910$ with the MFDS protocol, $p = 0.653$ with the NIOSH protocol, respectively). However, a significant difference was detected in the pressure drop between test protocols ($p < 0.0001$). In the case of quarantine masks, significant differences were detected in the pressure drop between certified (KF94) and noncertified masks ($p = 0.0218$ with the MFDS protocol and $p = 0.0016$ with the NIOSH protocol, respectively) and between test protocols ($p < 0.0001$). No significant differences were observed in pressure drop when medical (surgical/dental) masks were tested inward (from the outside air to the mouth) or outward (from the mouth to the outside air), or for the composition of the general masks. The pressure drops of the handkerchiefs increased significantly with the number of layers ($p = 0.0001$), but all values were less than 4 mmH_2O.

Table 5. Initial pressure drop value classified by several characteristics of masks (PD: Pressure drop)

		Variables	N	Initial PD (mmH$_2$O) MFDS Mean ± SD	MFDS P value[*]	NIOSH Mean ± SD	NIOSH P value[†]	P value[‡]
Anti-yellow sand	Child	Certified (KF80)	4	2.9 ± 0.2	0.9102	11.7 ± 3.7	0.6534	<.0001
		Not Certified	3	2.9 ± 1.4		12.7 ± 5.9		
Quarantine		Certified (KF94)	4	3.7 ± 1.4	0.0218	17.5 ± 7.5	0.0016	<0.001
		Not Certified[§]	5	2.5 ± 1.0		8.5 ± 2.6		
Medical	Surgical	Inward	2	2.7 ± 0.1	0.2828	9.3 ± 1.1	0.0845	<.0001
		Outward		2.6 ± 0.1		13.3 ± 4.5		
	Dental	Inward	3	2.6 ± 0.2	0.7198	11.0 ± 2.2	0.8484	<.0001
		Outward		2.6 ± 0.2		10.8 ± 1.9		
General	Nonwoven	-	4	2.5 ± 1.0	0.1542	10.0 ± 5.1	0.0633	<.0001
	Cotton	-	5	2.0 ± 0.5		6.8 ± 3.5		
Handkerchief	Cotton	One layer	1	0.8 ± 0.1	<.0001	1.0 ± 0.0	<.0001	0.1935
		Two layers		1.4 ± 0.1		1.8 ± 0.1		
		Three layers		2.9 ± 0.1		2.7 ± 0.2		
		Four layers		3.4 ± 0.1		3.6 ± 0.3		
	Gauze	One layer	1	0.5 ± 0.1	<.0001	0.7 ± 0.1	<.0001	0.0164
		Two layers		1.7 ± 0.2		1.2 ± 0.0		

	Three layers	2.7 ± 0.2	2.0 ± 0.1
	Four layers	3.0 ± 0.1	2.8 ± 0.2

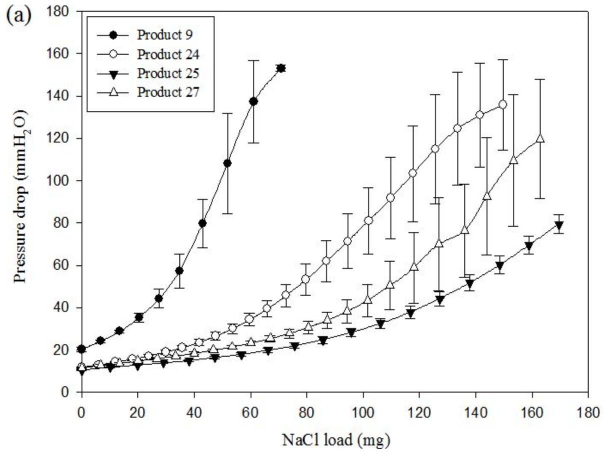
P value between mask types using MFDS method.

P value between mask types using NIOSH method.

P value between MFDS and NIOSH test methods.

No certified by MFDS but certified by NIOSH (N95 grade respirator).

Fig. 3 shows the mask pressure drop patterns for the masks, which were similar between the MFDS and NIOSH protocols. In all cases, the pressure drop increased over time due to particle loading on the filter, although a wide range was observed in the rates of increase.



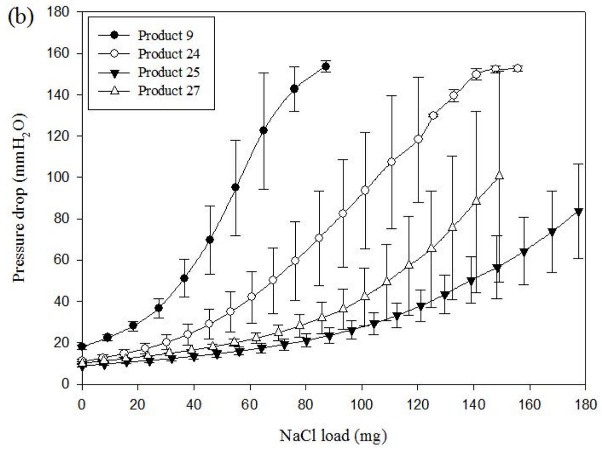


Figure 3. Pressure drop as a function of NaCl aerosol accumulation on the mask using (a) the MFDS and (b) NIOSH protocols. The symbols represent mean values and the vertical lines represent 1 SD for the results from the three tests conducted for each mask. The pressure drop test in (a) was done at 95 L/min according to the EU protocol, whereas the initial pressure drop test in Tables 4 and 5 was carried out at 30 L/min.

4. Total Inward Leakage

We evaluated the filtration efficiency in previous study(Jung *et al.*, 2013). Table 6 shows the comparison of initial filtration efficiency and TIL values by each mask. For anti-yellow sand masks, total inward leakage values were significantly higher in TIL test than in initial filtration efficiency ($p < 0.0001$).

The average initial filtration efficiency and TIL value of anti-yellow sand mask were 1.1 d ma2 and 2.9 ± 5.4%, respectively. For quarantine mask, total inward leakage values were also significantly higher in TIL test than in initial filtration efficiency ($p < 0.0001$). The average initial filtration efficiency and TIL value of quarantine mask were 0.9 ± 0.1 and 11.6 ± 17.2%, respectively.

For quarantine mask in Korea, the MFDS has an initial filtration efficiency criterion for anti-yellow sand masks for 20% (KF 80) and quarantine masks for 6% (KF 94). TIL criterion also exist for anti-yellow sand masks and quarantine masks with TIL of 25% (KF 80), 11% (KF 94), respectively. All anti-yellow sand masks showed low TIL values than MFDS criterion.

Quarantine mask 31 is satisfied with MFDS quarantine mask criterion of 11% TIL value (KF 94). But quarantine mask 29 exceeded 11% and shown double of TIL criteria. Mask 29 seemed to have little protection function with sealing the facial skin and mask.

Table 6. Comparison of arithmetic means of initial filtration efficiency and TIL values by mask type

Mask classification		Initial Filtration efficiency (%)			TIL values (%)			P value*	P value**
		Mean	±	SD	Mean	±	SD		
Anti-yellow sand	Mask 1	1.6	±	0.1	4.4	±	6.2	<0.0001	<0.0001
	Mask 8	1.2	±	0.3	0.7	±	1.0		
	Mask 9	0.6	±	0.2	3.6	±	6.4		
	Total	1.1	±	0.2	2.9	±	5.4		
Quarantine	Mask 29	1.1	±	0.1	22.4	±	19.0	<0.0001	
	Mask 31	0.8	±	0.1	1.8	±	5.7		
	Total	0.9	±	0.1	11.6	±	17.2		

*Difference of test results between initial filtration efficiency value and total inward leakage within each mask types

**Difference of test results between initial filtration efficiency value and total inward leakage of anti-yellow sand masks and quarantine masks

Table 7 shows minimum and maximum leakage values by mask types. There were huge differences between minimum and maximum leakage values. For example, there is a 350 times difference between minimum and maximum leakage values for the quarantine mask 31. The largest value out of minimum leakage such as 0.3% for the mask E and 0.2% for the mask 8 of mask may be the most important. Compared with MFDS criterion, these values are to be very small values. In contrary, maximum leakages are mostly very large values, far beyond MFDS criterion. Mostly masks shown upper maximum TIL values than criterion, except mask 8.

Table7. Maximum and minimum of arithmetic TIL values for mask types

Mask classification		TIL values (%)					
		KF 80			KF 94		
		Max.*	Min.**	Max./Min.	Max.*	Min.**	Max./Min.
Anti-yellow sand	Mask 1	28.3	0.2	141.5			
	Mask 8	9.0	0.2	45.0			
	Mask 9	45.8	0.2	229.0			
	Total	27.7	0.2	138.5			
Quarantine	Mask 29				76.1	0.3	253.7
	Mask 31				68.5	0.2	342.5
	Total				72.3	0.2	361.5

* Maximum value of TIL

** Minimum value of TIL

All anti-yellow sand masks and quarantine mask 31 satisfied the KF 80 and KF 94 criteria in all test panels. But seven out of eleven panels (64%) failed to meet the quarantine mask TIL criteria of 11 % in mask 29. TIL values of each test panel are summarized in Table 8 and it shows a wide variation of TIL value by test panels. For example, mask 29 shown the highest TIL values among test masks. In case of test panel 10, TIL was 47.9%while it was 3.8% in test panel 5 which shows 16 times differences. Comparing leakage values between the test masks were shown significant different TIL values in all test masks ($p < 0.0001$).

Table 8. Mean TIL value among test panels for each masks

Test panel (No.)	TIL values (%)				
	Anti-yellow sand mask			Quarantine mask	
	Mask 1	Mask 8	Mask 9	Mask 29	Mask 31
1	1.6	1.8	13.0	39.3	8.0
2	2.1	0.5	4.7	14.8	0.6
3	0.6	0.4	0.4	3.8	0.4
4	1.8	0.4	0.6	32.9	1.0
5	0.4	0.3	0.4	3.2	0.4
6	7.3	0.3	4.0	36.5	2.9
7	7.4	0.7	0.4	27.4	0.4
8	5.9	0.5	2.3	10.4	0.4
9	1.4	0.4	0.5	-*	0.6
10	6.0	1.8	2.2	47.9	3.1
11	3.6	0.5	0.5	10.1	1.6
12	14.6	0.4	13.7	19.8	1.6
P value**	<0.0001	<0.0001	<0.0001	<0.0001	0.0093

*Data was lost due to the fault of researcher of this study.

**Difference of TIL values of test panels within test masks.

Table 9 shows the comparison of each exercise of TIL test. In case of anti-yellow sand masks, there are no significant differences in TIL values among test exercise and have lower TIL values than MFDS criterion. Quarantine masks also shown no significant differences in TIL values among test exercise. But quarantine masks are not satisfied of MFDS criterion of 11% (KF 94). Especially, when tested by mask 29, during moving head up and down test exercising, a lot of leakage (26.5 ± 20.7%) was occurred.

Table 9. TIL values of each test exercise

Mask classification		TIL values (%)														
		Normal breathing			Turning head side to side			Moving head up and down			Talking			Normal breathing		
		Mean	±	SD	Mean	±	SD	Mean	±	SD	Mean	±	SD	Mean	±	SD
Anti-yellow sand	Mask 1	3.2	±	4.9	3.9	±	6.5	4.4	±	6.3	4.2	±	5.0	6.2	±	7.5
	Mask 8	0.4	±	0.1	0.4	±	0.2	1.0	±	1.7	0.9	±	0.6	0.8	±	1.1
	Mask 9	2.5	±	4.1	4.1	±	6.2	3.6	±	5.3	2.8	±	5.3	4.7	±	9.7
Quarantine	Mask 29	19.4	±	17.1	23.8	±	20.5	26.5	±	20.7	19.1	±	16.7	23.1	±	19.8
	Mask 31	0.9	±	0.9	1.5	±	3.1	1.8	±	3.3	1.5	±	3.5	3.2	±	11.5

DISCUSSION

The first aim of this study were to evaluate the filtration efficiency and pressure drop of various types of masks used by ordinary citizens or health-care workers, and to compare the test results using the MFDS and NIOSH protocols. We found that filtration efficiency was not significantly different between the MFDS and NIOSH protocols ($p = 0.1223$), but the pressure drop using the MFDS protocol was significantly lower than that using the NIOSH protocol ($p < 0.0001$). The difference in pressure drop values for the MFDS and NIOSH protocols can be explained by the difference in flow rates between the two protocols. The MFDS protocol uses a flow rate of 30 L/min instead of the 95 L/min of the EU protocol. This is because a low ordinary citizen's breathing rate was assumed for the MFDS but a heavy worker's breathing rate was assumed in the EU protocol. Hence, a low flow rate of 30 L/min during the initial pressure drop test could have caused a significant low pressure drop. The 1% NaCl aerosol solution in the MFDS (EU protocol) compared to the 2% NaCl solution of the NIOSH protocol could have affected the low pressure drop, but it appeared low because the initial pressure drop was measured during the first 1 min.

This study evaluated various types of masks and handkerchief used by ordinary citizens, including children and health-care workers. The filtration efficiency of quarantine masks was the greatest, while that of handkerchiefs and general masks was the lowest. Of the 44 products studied, including three handkerchiefs, seven (16%) products (6 quarantine masks and 1 anti-yellow sand mask) using the MFDS protocol and 10 (22%) products (7 quarantine masks and 3 anti-yellow sand masks) using the NIOSH protocol were within 1% filtration efficiency (i.e., FFP 3 under the EU criterion or N99 under the NIOSH criterion) (Fig. 4). All these were certified with at least one of the KF 80 or 94 classes in Korea or the N95 class in the United States. Sixteen (36%) products using the MFDS protocol met the KF 94 criterion, 21 (47%) products met the KF 80 criterion, and 17 (39%) met the N95 criterion. Our results suggest that general masks and handkerchiefs provide little protection against airborne aerosols.

Three of four certified and one of three noncertified children's masks satisfied the KF 80 criterion, with average filtration efficiency of 9.9 ± 7.9%. The average filtration efficiency of failed children's masks was 42.1 ± 16.3%. Another study showed that when children wore the masks for adults, they were significantly less-protected from exposure than the adults. This might have been related to the inferior fit of the masks on their smaller faces (Van der Sande et al., 2008). The children's masks used in this study seemed to be simply adult masks that were reduced in size. As far as we know, no specific criteria for filtration efficiency and pressure drop exist for children's masks, even though their breathing volume, pattern, and rate are different from those of adults (Jammes *et al.*, 1979, Jung, 2008, Leigh *et al.*, 2006, Tobin *et al.*, 1983, Tabachnik *et al.*, 1981, Zeman, 1998). Therefore, just reducing the mask size might not be a suitable strategy.

In this study, the filtration efficiency efficiency of medical masks ranged from 10% to 90%, except for one product (certified as a N95 class), which showed 1.82% filtration efficiency. Other studies also reported that filtration efficiency ranged from 10% to 47% in dental masks and 53% to 96% in surgical masks (Oberg & Brosseau, 2008). In this study, the filtration efficiency range of the dental mask was 16.8–47.9% with the MFDS protocol and 17.2–45.0% with the NIOSH protocol. For surgical masks, it was 1.56–98.0% with the MFDS protocol and 1.11–98.7% with the NIOSH protocol (data not shown).

In view of the possibility of airborne transmission, current guidelines issued by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) state that health-care workers should wear N95 masks or higher-level protection during all epidemic situations (Derrick & Gomersall, 2005). However, no strict regulation exists for the filtration efficiency and pressure drop for surgical or dental masks worldwide. Filtration efficiency results using medical masks in this study exceeded the maximum MFDS criteria for anti-yellow sand masks of 80% (KF 80). In extreme cases for medical masks, the maximum filtration efficiency was almost 98%.

Our results show that the main determinant of the magnitude of protection was the type of mask. The expected superior protection conferred by a professional FFP2 mask compared to a surgical or homemade mask was maintained (Van der Sande et al., 2008). Leakage tests were performed on readily available materials such as cotton handkerchiefs or towels to measure the extent of filtration efficiency. Leakage fractions were determined by comparing the filtration efficiency of the same aerosol for the materials held to the face versus being fully taped to the face. At a breathing rate of 37 L/min, mean leakages for the materials ranged from 0.0% to 63%, depending on the material. Mean filtration efficiencies exclusive of leakage ranged from 0.6% to 39%. Use of nylon hosiery material ("panty hose") to hold the handkerchief material or the disposable face mask to the face was found to be very effective in preventing leakage(Cooper *et al.*, 1983b). Such a combination could be expected to reduce leakage around the handkerchief to about 10% or less in practice, and around the mask to less than 1.0%, which suggests that the adaptation and use of such an approach for industrial hygiene would be effective (Cooper et al., 1983b). The fabrics provided a statistically non-significant reduction in methyl iodide. In practice, any leaks around the seal to the face would lessen the protection offered by such materials (Cooper *et al.*, 1983a). One study using modified heavyweight T-shirts similar to the 2-ply battle-dress uniform T-shirts showed that a hand-fashioned mask can provide a good fit and a measurable level of protection from a challenge aerosol (Dato *et al.*, 2006). This T-shirt mask had three ear bands (tie type), but the ear bands of the general masks in the study had only two bands (fixation with elastic cord type) and no effects of electrostatic force were added. Therefore, when wearing a general mask, the possibility of filtration efficiency increases compared to respirators certified by government organizations.

We measured the initial filtration efficiency for 1 min and compared it with filtration efficiency criteria. However, as shown in Fig. 2, a slight increase in filtration efficiency could occur before a decline for a certain mask (i.e., products 25 and 27 in Fig. 2). In our previous study (Cho et al., 2011, Cho & Yoon, 2012), we found that the initial filtration efficiency could be used to compare with the filtration efficiency criteria. The initial filtration efficiency levels have the advantage of avoiding any loading effects for better comparison with other testing methods (Viscusi *et al.*, 2009). The initial filtration efficiency measured for 1 min has been used in many studies in place of the entire NIOSH 42 CFR Part 84 test protocol (Cho et al., 2011, Lisowski *et al.*, 2001, Stevens & Moyer, 1989, Rengasamy *et al.*, 2009, Viscusi et al., 2009).

As seen in Fig. 2 and Fig. 3, considering the basis of respirable dust criteria 3 mg/m^3 for eight hours per one day, if wearer want to protect them using a mask, they can wear a masks to only eight hours. However, if wearer use more than eight hours per one day, pressure drop is increased and filtration efficiency is decreased. Degraded mask not shown enough their protection ability.

Unlike for worker's respirators, no national or international standards seem to exist for filtration efficiency and/or pressure drop in masks for ordinary citizens. In Korea, only the KF 80 (20% filtration efficiency, which adopted the EU FFP1 criteria) for anti-yellow sand masks and KF 94 (6% filtration efficiency, which adopted the EU FFP2 criteria) for quarantine masks have been promoted recently. One could argue that both criteria (20% in KF 80, 6% in KF 94) are suitable to protect people against the corresponding aerosols because yellow-sand dust contains hazardous metals and microorganisms, while quarantine masks are used during epidemic events.

The second aim of this study was to evaluate the TIL values of anti-yellow sand masks and quarantine masks used by general citizens or health-care workers using Ministry of Food and Drug Safety (MFDS) (similar to EU test protocol) test protocol.

We found that initial filtration efficiency values and TIL values were significantly different ($p < 0.0001$). And TIL values were significantly different within the anti-yellow sand masks and quarantine masks, respectively ($p < 0.0001$). In case of quarantine mask 29, TIL values more than twice of the MFDS TIL criterion, there was a serious problem of wearing masks. Filtration efficiency of this mask shown 1.08 ± 0.10%, less than 6% of the MFDS initial filtration efficiency criterion (KF 94). A nose clip of mask 29 that secures for helping masks to face closely was made rigid material and not fit well to nose and face. It impede that the mask cover the area of near the nose and had occurred a lot of leakages due to retaining nose clips on the face which made it difficult to close to the face. In case of anti-yellow sand masks, mask 8 shown minimum TIL values of 0.67 ± 0.96% and mask 1 shown maximum leakage of 4.40 ± 6.15%. But all the anti-yellow sand masks are satisfied of MFDS TIL criterion. These results could be interpreted that the mask are well wrapped nose, chin and both face to face are adhere closely to face and masks. Test panels showed a minimum value has the jaw to philtrum length is smaller than the other panels, and showed maximum value panel has ear to nose length was bigger than the other test panels. It seems the values that jaw to philtrum and ear to nose are effect the value of the facial leakage rate (data are not shown).

The comparison of maximum and minimum TIL values were shown 350 times in mask 31. Because worst fitted mask 31, anti-yellow sand masks had low TIL values than quarantine masks.

The results of test panels are compared by mask type. Difference in TIL values by test panel, all masks has significant difference in test panel ($p < 0.0001$). The mask used in the experiment was not selling by the size distribution. Though before the experiment, supervisor of this test teach how to wear a mask and how to do test exercise to test panel, the result shown when the general citizen wear these mask, masks cannot properly represent the protection efficiency. This results suggest that the child or the person who has abnormality value of facial size, smaller or bigger than facial size of general citizen or has a lot of breathing volume. These persons are danger to exposure external harmful substances when they wear the mask to protect their health. A variety of test panels who has variety of facial size are participate to certified-mask performance and development variety size of masks are needed.

Despite of high filtration efficiency, quarantine masks are shown much TIL values more than anti-yellow sand mask. If filter has high filtration efficiency, pressure drop is growing due to thickness of filter (Cho et al., 2011). Because of this, when wearer use high filtration efficiency mask, wearer will have more breathing burden (Yassi *et al.*, 2004, Roberge, 2008). As seen in table 9, when test panel did last normal breathing exercise, overall test result are higher than other test exercise. Total inward leakage test done on the threadmill of the 6km/h. It seems cause more breathing burden and more leakage. In the same vein, in case of anti-yellow sand mask, the highest leakage value in last stage normal breathing test exercise. This results came out are due to relatively well adhere than not well designed quarantine mask, and there is no space between the face and mask. Then breathing is caused by vigorous exercise, due to the lack and rough breathing.

If a mask is fitted well, the wearer's face filtration efficiency through filter media will be very small. These results indicate that while filtration efficiency through filter media may be insignificant, leakages would be mostly attributed to face seal leaks (Han & Lee, 2005). High efficiency and low pressure drop performance of the mask is important to make a good mask. However, when wearing mask and did not fit well, hazardous external substances without filter of mask and this should not coming into the gaps. Therefore, when making facial mask, consider design to the facial fit is to be very important also. Therefore, in order to decrease TIL values, developing well-fitting mask or respirator is much more a priority than developing a high efficiency filter in Korea.

As the result of tested masks filtration efficiency, pressure drop and TIL values in this study, quarantine mask shown the greatest itself filtration efficiency than other masks. However, when the test panel wear the masks, because of one of the quarantine mask is not well fitted to facial skin and masks, anti-yellow sand masks shown the lowest TIL values than other masks.

Although quarantine masks have great filtration efficiency, in terms of the price, anti-yellow sand masks are cheaper and easy to buying than quarantine masks. Thus, general citizens more use anti-yellow sand masks than quarantine masks.

Given that all conclusions, MFDS need to do quality control system and need to reexamine the test protocol for anti-yellow sand masks, quarantine masks and other masks which is can used by general citizens in Korea.

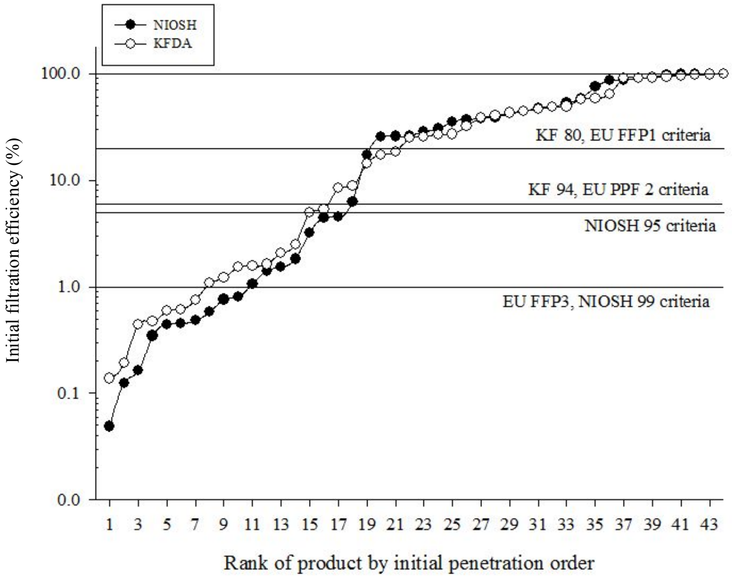


Fig. 4. Initial filtration efficiency of 41 tested masks and three handkerchiefs ranked by filtration efficiency order.

CONCLUSION

For filtration efficiency and pressure drop test, we tested all 44 different brands of mask, including anti-yellow sand masks for adults and children, quarantine masks, medical masks, general masks, and handkerchiefs using the MFDS (similar to the EU protocol) and the NIOSH protocols. All tested quarantine masks satisfied the maximum filtration efficiency criterion of 6% (KF 94). Six of nine anti-yellow sand masks (67%) and four of seven anti-yellow sand masks for children (57%) satisfied the KF 80 criteria. The filtration efficiency values of most medical masks were over 20%. Medical masks show no significant differences in filtration efficiency and pressure drop between inward tests (which mimic inhalation) and outward tests (which mimic exhalation). General masks and handkerchiefs have no protection function in terms of the aerosol filtration efficiency. No significant difference in filtration efficiency was noted between the MFDS and NIOSH protocols ($p = 0.1223$), but the pressure drop using the MFDS protocol was significantly lower than that using the NIOSH protocol ($p < 0.0001$). Studying and discussing criteria for masks is necessary to reduce the risk for general citizens and to make the role of medical masks clear. The government needs to prepare exact guidelines for mask use by citizens to avoid the inhalation of external harmful substances.

For TIL test, we evaluated five different brands of anti-yellow sand mask and quarantine mask using MFDS (similar to EU protocol) TIL test protocol. Most tested anti-yellow sand masks and quarantine masks satisfied the maximum TIL criterion of 25% (KF 80), 11% (KF 94), respectively, except quarantine mask E. All tested anti-yellow sand masks and quarantine masks satisfied the TIL criterion of 25% (KF 80), 11% (KF 94), respectively, except quarantine mask E. One quarantine masks in this study, has maximum TIL values are higher 350 times than minimum TIL values. A wide variation TIL values are shown in test panels. By wearing a mask for the general citizen, including health care workers to reduce the risk that the enactment of appropriate standards need to review, and the government need to establish for the exact reason for wearing a mask and method of how to exactly wear the mask guidelines.

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국문초록

I. 서론

일반적으로 개인보호구는 작업장에서 근로자를 보호하기 위한 마지막 수단으로 사용되고 있지만, 일반시민들은 외부 유해물질을 차단하기 위한 최초의 수단으로 마스크를 사용한다. 이러한 보호장비들은 착용자를 보호할 수 있다는 명목 하에 다양한 형태로 많은 곳에서 판매되고 있다. 산업안전보건공단, 미국 NIOSH (National Institute for Occupational Safety and Health in US) 에서 실험을 거쳐 인증을 받은 후 사용되는 작업장 내 호흡보호구와는 달리 의료용 마스크, 방역마스크 등 일반인들이 많이 사용하는 마스크의 필터효율과 압력강하에 대한 기준이 국가마다 다르며, 기준이 있는 국가일 경우에도 엄격하게 규제되지 않고 있다.

본 연구에서는 시중에 판매되는 여러 가지 마스크들의 필터 효율과 압력강하를 평가하고, 시중에 판매되고 있는 일부 마스크의 효율을 검사하는데 사용되는 한국식품의약품안전처 방법과 NIOSH 방법으로 실험한 결과 값들을 비교해보고자 한다. 또 안면부

누설률을 확인하기 위해 황사마스크와 방역마스크를 실제로 착용하여 얻은 결과값을 평가하고자 한다.

II. 연구방법

본 연구를 위해 시중에 판매되는 44개 마스크 (황사 9종, 어린이황사 7종, 의료용 7종, 방역마스크 9종, 보건 9종, 손수건 3종)를 선정하였다.

한국식품의약품안전처 (1% NaCl, 95 LPM)와 NIOSH (2% NaCl, 85 LPM)의 규정에 맞게 각각 제작된 두 대의 TSI Model 8130 automated filter tester로 염화나트륨 입자를 이용하여 초기 투과율과 압력강하를 측정하고 로딩 테스트를 통해 시간에 따른 마스크의 성능 변화를 확인하였다. 안면부 누설률검사를 위해 황사마스크 3종과 방역마스크 2종을 대상으로 한국식품의약품안전처의 가이드라인을 따라 시험자가 직접 마스크를 착용하여 6km/h의 속도로 작동되는 런닝머신 위에서 숨쉬기, 고개를 좌우로 젓기, 고개를 아래위로 젓기, 말하기 등의 규격 운동을 실시하여 실험 하였다.

III. 연구결과 및 고찰

마스크 별로 결과 값에 많은 차이를 보였다. 투과율의 경우 한국식품의약품안전처방법과 NIOSH 실험 방법간에 유의한 차이가 없었다. 방역마스크만 최대 투과 기준인 6 %(KF94)를 만족했으며 실험 마스크들 중 가장 좋은 효율을 나타냈다. 어른용과 어린이용 황사마스크, 의료용 마스크에서 기준(20 %, KF80)보다 높은 투과율을 보였고 보건마스크와 손수건은 보호 효과가 전혀 없는 것으로 나타났다. 안면부 누설률의 경우 황사마스크와 방역마스크 모두 초기 투과율보다 높은 누설률 값을 나타냈다. 실험에 사용된 황사마스크와 방역마스크 중 하나가 한국식품의약품안전처의 기준을 만족했으나 나머지 방역마스크는 기준을 넘는 값을 나타내었다.

IV. 결론

실험 결과 방역마스크가 다른 실험 마스크에 비해 마스크 필터 자체의 효율이 가장 좋았다. 그러나 실제로 실험자가 마스크를 착용했을 때의 안면부 누설률은 방역마스크 중 일부가 얼굴과 마스크가 잘 밀착되지 않는 특징을 가지고 있었기 때문에,

황사마스크가 방역마스크보다 더 낮은 값을 나타냈다. 한국식품의약품안전처에서는 의료종사자를 비롯한 일반 시민에 대한 위험을 줄이기 위해서, 황사마스크, 방역마스크와 기타 일반 시민들이 쉽게 사용할 수 있는 마스크들에 대한 품질관리를 실시할 필요가 있으며 현재 마스크의 성능을 검정하는 실험 방법이 적절한지에 대해 재 검토할 필요가 있다.

주요어: 마스크, 필터 효율, 압력 강하, 안면부 누설률,
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