■Concise communications

# Performance evaluation of masks for medical use — including the comparison with commercially available masks for general use —

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## Summary

The performances of masks/respirator for medical use as well as for general use have become clear. Non-woven surgical masks were proved to be effective in the differential pressure (ΔP) values (air exchange pressure: AEP) and the bacterial filtration efficiency. Gauze masks, molded-out masks and paper masks were supposed to be insufficient in the filtration efficiency, and inferior in the effectiveness of infection prevention. For N95 respirators, in comparison with the bird's beak type, both the cup type that was low in the leakage rate when worn and the type of the folding trihedral structure showed good results.


## 1. Objectives

With the pandemic influenza imminent, the importance of the N95 mask (respirator) and a surgical mask (including a medical face mask) has been pointed out. For the commercially available masks, their performance indications are ambiguous, or some masks do not describe at all any scavenging efficacy of bacteria, while some others describe exaggerated claims on the labels. Even for the masks designed for medical use, the performance of N95 masks in Japan and in the U. S. has been indicated in accordance with the standard of filtration efficiency for particulates. However, there have been few verification tests performed on whether or not these masks have the biologically required performance level in the clinical settings.

For the surgical masks and several representative masks that have been generally used, we have examined the clinical usefulness has been examined[1-7).

## 2. Method

For the N95 respirator, the "leakage rate" from the peripheral area around the mask during wearing it is important, and we measured the leakage rate by using the ISL (Institute for the Science of Labor)-developed mask-fitting tester (MT-3, Shiba Model MT-9100) as the testing equipment.

ISL-developed mask fitting tester MT-3 is an equipment to measure the count of particulate concentration (the ratio of the number of particles for the dust inside and outside mask) of >0.5μm size particulate by a laser beam scattering method. The measurement was made at the suction air of 1 L/min for 30 seconds.

SHIBATA MODEL MT-9100 measures the leakage rate for one minute, simultaneous suction of the upstream and downstream particulate concentration by a digital dust sampler having a laser beam scattering method for particulates of approx. 0.08μm size. The suction flow rate

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is 2.1 L/min. These measurements evaluate the contact fitness between a mask and the face.

The subjects were 11 adults (A~K in Table 1), and 4 kinds of the masks were tested for each subject.

The types of the masks tested were folding types (Type-1870, folding trihedral structure), cup-types (Type-1860/1860s, MoldeX 1151/1152) and a bird's beak type (PFR 95) respectively.

For the surgical masks, Nelson Laboratories evaluated bacterial filtration efficiency (BFE), and differential pressure as a third-party institution. The tested samples were non-woven surgical masks (standard surgical masks, standard ear-loop face masks), gauze masks, punched-out masks and paper masks.

For BFE measurment, *Staphlococcus aureus* ATCC #6538 which population was, 2,200±500 CFU/test sample was used. The nebulizer used was a Chicago nebulizer, and the mean bacterial size was 2.7μm. For bacterial count detection, the measurement was conducted by Andersen sampler with the rate of 1CFM (cubic feet per minute) at every 2 minutes interval.

Moreover, for the filtration efficiency of a mask, it was measured by the so-called "chew test" of the modified Greene and Vesley (hereinafter called G&V method), in which a subject spoke the word "Chew" 120 times within 2 minutes with wearing a test mask on the face, and the bacterial filtration efficiency by size of particulate was able to be measured by sucking the leaked air from the mask under negative pressure using the Andersen sampler. This method is to compare the counts of the detected colonies for both the mask worn on the face and the mask not worn on the face. By using this G&V method, the mask filtration efficiency of the mask and fitness to the face are evaluated simultaneously.

The differential pressure (ΔP), which is also called the air exchanging pressure (AEP), is a yardstick for easiness of breathing during the activity at the time when a mask is worn. This pressure was measured as a water column pressure ($mmH_2O/cm^2$).

In case of the commercially available masks for general use, the measurement was carried out, at 85L/min, using the particulate scavenger equipment CERTITEST$^{TM}$ Model 18130 with NaCl particulates of 0.1μm size.

## 3. Results

The leakage rate test was conducted for 4 kinds of the N95 mask respirators.

Table 1 N95 respirator leakage rate

| % | ISL (Institute for the Science of Labor)-developed mask-fitting tester | | | | mask-fitting tester (MT-3, Shiba Model MT-9100) | | | |
|---|---|---|---|---|---|---|---|---|
| | Cup-type 1860 | Trihedral structure | Cup-type 1151 | Bird's beak type | Cup-type 1860 | Trihedral structure | Cup-type 1151 | Bird's beak type |
| A | 1.37 | 1.06 | 0.53 | 7.05 | 1.59 | 2.11 | 0.21 | 3.86 |
| B | 1.32 | 1.51 | 0.94 | 12.02 | 1.41 | 0.88 | 2.14 | 5.49 |
| C | 2.40 | 3.79 | 4.05 | 7.40 | 1.34 | 3.32 | 3.73 | 10.06 |
| D | 1.23 | 0.63 | 4.34 | 23.34 | 0.94 | 0.53 | 1.36 | 30.77 |
| E | 1.71 | 0.27 | 2.39 | 5.26 | 1.21 | 0.25 | 3.18 | 4.85 |
| F | 0.81 | 0.23 | 4.15 | 3.39 | 3.72 | 0.29 | 2.07 | 43.93 |
| G | 1.69 | 1.47 | 17.11 | 15.38 | 1.17 | 1.21 | 17.30 | 15.52 |
| H | 2.64 | 0.91 | 6.01 | 5.80 | 1.02 | 1.29 | 7.35 | 14.49 |
| I | 1.29 | 0.98 | 3.10 | 10.47 | 1.69 | 0.83 | 2.85 | 13.24 |
| J | 0.97 | 0.73 | 3.93 | 4.32 | 1.09 | 0.68 | 1.39 | 1.68 |
| K | 2.01 | 3.56 | 6.34 | 17.14 | 1.30 | 1.44 | 4.80 | 23.20 |
| mean | 1.59 | 1.38 | 4.81 | 10.14 | 1.50 | 1.17 | 4.22 | 15.19 |
| Max | 2.64 | 3.79 | 17.11 | 23.34 | 3.72 | 3.32 | 17.30 | 43.93 |
| Min | 0.81 | 0.23 | 0.53 | 3.39 | 0.94 | 0.25 | 0.21 | 1.68 |

Table 2 BFE・ΔP

| NO. | Tested samples | ΔP ($mmH_2O/cm^2$) | ΔP mean | BFE (%) | BFE mean |
|---|---|---|---|---|---|
| 1 | surgical masks | 1.7 | 1.7 | 80 | 74.3 |
| 2 | | 1.7 | | 72 | |
| 3 | | 1.7 | | 71 | |
| 4 | ear-loop face masks | 1.3 | 1.3 | 71 | 74.7 |
| 5 | | 1.3 | | 77 | |
| 6 | | 1.3 | | 76 | |
| 7 | gauze masks | 1.3 | 1.3 | 50 | 55.0 |
| 8 | | 1.5 | | 62 | |
| 9 | | 1.2 | | 53 | |
| 10 | punched-out masks | 0.6 | 0.6 | 50 | 49.0 |
| 11 | | 0.5 | | 42 | |
| 12 | | 0.6 | | 55 | |
| 13 | paper masks | 17.3 | 17.2 | 39 | 36.7 |
| 14 | | 16.6 | | 35 | |
| 15 | | 17.6 | | 36 | |

BFE : bacterial filtration efficiency, ΔP : differential pressure

Table 3 filtration efficiency of a mask modified Greene and Vesley "chew test"

| NO. | Tested samples | Mean particle size (μm) | MPS mean | BFE (%) | BFE mean |
|---|---|---|---|---|---|
| 1 | non-woven surgical masks A | 4.9 | 5.2 | 99.82 | 99.34 |
| 2 | | 4.9 | | 99.72 | |
| 3 | | 5.7 | | 98.49 | |
| 4 | non-woven surgical masks B | 4.9 | 5.2 | 99.91 | 99.59 |
| 5 | | 4.9 | | 99.71 | |
| 6 | | 5.7 | | 99.14 | |
| 7 | non-woven surgical masks C | 4.9 | 5.2 | 99.44 | 98.94 |
| 8 | | 4.9 | | >99.99 | |
| 9 | | 5.7 | | 97.39 | |
| 10 | non-woven surgical masks D | 4.9 | 5.4 | 99.67 | 99.25 |
| 11 | | 5.7 | | 98.54 | |
| 12 | | 5.7 | | 99.53 | |
| 13 | punched-out masks | 4.9 | 5.4 | 98.79 | 96.01 |
| 14 | | 5.7 | | 93.50 | |
| 15 | | 5.7 | | 95.75 | |
| 16 | paper masks | 4.9 | 5.4 | 99.43 | 97.76 |
| 17 | | 5.7 | | 97.68 | |
| 18 | | 5.7 | | 96.16 | |

In the experiment using SHIBATA MODEL MT-9100, the average leakage rate of the cup type 1860/1860S was 1.59%, that of the folding, trihedral structure type 1870 was1.38%, that of the Cup-type MoldeX 1511/1512 was 4.81%, and that of the bird's beak type PFR95 was 10.14%. In the measurement by the ISL-developed mask-fitting tester MT-3, the mean leakage rate of the cup-type 1860/1860s was 1.50%, that of the folding trihedral structure type 1870 was 1.17%, that of the cup-type MoldeX 1511/1512 was 4.22%, and that of the bird's beak type PFR95 was 15.19%. (Table 1)

The mean differential pressure (ΔP) of a surgical mask for the non-woven surgical mask (standard surgical mask) was 1.7 mm $H_2O/cm^2$, that of the non-woven surgical mask (standard ear-loop type face mask) was 1.3 mm $H_2O/cm^2$, that of the gauze mask was 1.3 mm $H_2O/cm^2$, that of the punched-out mask was 0.6 mm $H_2O/cm^2$, and that of the paper mask was 17.2 mm $H_2O/cm^2$.

On the other hand, the average filtration efficiency of BFE for the non-woven surgical mask (standard surgical mask) was 74.3%, that of the non-woven, surgical mask (standard, ear-loop type face mask) was 74.7%, that of the gauze mask was 55.0%, that of the punched-out mask was 49.0%, and that of the paper mask was 36.7%. (Table 2)

For BFE, in the so-called “chew test” measurement, the results for 4 kinds of the non-woven mask (manufactured by A~D companies) were from 98.94% to 99.59%, the rate of the punched-out mask was 96.01%, and that of the paper mask was 97.76%. (Table 3)

## 4. Discussion

A mask/respirator is indispensable for the prevention of air-borne infection and droplet infection. A mask is defined to be used for a patient with such an infections disease not to diffuse the particulates containing the organisms that may diffuse at the time of coughing or sneezing, by wearing a mask/ respirator, while, for discrimination from a mask, a respirator may be defined as a device to be worn by a healthy person or an easily infective patient in order to filtrate the air-borne infected organisms or droplet-infected organisms so as to breathe a clean air.

A N95 mask/respirator is defined to have a capability to filtrate over 95% of the NaCl particulates of 0.05~0.095μm size. Basically it is a respirator intended for prevention of dusts. The size of a common bacterium is 2~3 micron (μm) long, for instance, in case of tubercle bacillus with the diameter of more or less 0.8 micron. Therefore, if N95 mask/respirator is used, it will be basically able to filtrate all kinds of bacteria. As the filtration capability increases, the respiratory resistance will increase, and the ΔP value (air exchange pressure: AEP) will increase.

There are many masks commercially available in the market, but the indications on the labels seem to have the following exaggerated expressions. For instance, (1) particulate filtration efficiency (PFE) 91%, BFE 99%, (2) Virus droplet: 99% cutdown, Pollen: 99.9% cutdown, (3) 0.1 micron size particulates: 99% cutdown, Bacterial elimination rate: MRSA 94.2%, *Pseudomonas aeruginosa* 99.5%, *Klebsiella pneumoniae* 96.5%, *Salmonella* 98.1%, tubercle bacillus 99.7%, (4) Influenza virus: 99% eliminable, Pollen 99.9% eliminable, (5) 0.0001 mm-size particulates: 99.9% filterable, (6) 5 micron-size particulates: 99% eliminable, (7) Virus/pollen: 99.9% eliminable, (8) Penetration of pollen, dust and microorganism is prevented — such claims on the labels are described.

In the test of the leakage rate for N95 masks/respirators, it is obvious that a large degree of differences exist, depending on the shape. The type of the least leakage rate was N95 mask of a folding, trihedral structure (least rate: 0.23%, mean: 1.17%), while the type of the highest leakage rate was a mask of a bird’s beak shape (maximum: 43.93%, mean: 15.19%). The sites where the leakage was especially highly observed were around the nose and the spot covering the lower jaw. In the case that a mask/respirator is worn, it is important to conduct a fitness test as well as a fit check test.

Among the values of ΔP (differential pressure or air exchanging pressure: AEP) of surgical masks and gauze masks, molded-out masks and paper masks, the paper masks showed the maximum value of 17.2 $mmH_2O/cm^2$, but all the other masks showed the values of less than 2 $mmH_2O/cm^2$. As a surgical mask is expected to have the ΔP value of below 5.0 mm $H_2O/cm^2$, the good test results were obtained for the surgical masks. The bacterial filtration efficiency was measured by using *S. aureus* with the mean size of 2.7μm. Under this condition, even for the surgical masks, the filtration efficiency was 71~80%, for the gauze masks 50~62%, and for the molded-out masks 42~55%. In case of paper masks, the filtration efficiency was 35~39%. Therefore, it may be thought that a perfect filtration of *S. aureus* is impossible.

Also for the indexes, what levels of the filtration efficiency and the leakage rate are required to prevent infections, including virus infections, it will be necessary to conduct a further study in future.

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## ■Reference


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