Evaluation of Physical Characteristics and Particulate Filtration Efficiency of Surgical Masks used in Iran's Hospitals

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ABSTRACT

Bioaerosols are the most significant risk for exposed people leads to infectious diseases. This study was aimed at evaluation of physical and microscopic characteristics and submicron particulate filtration efficiency of surgical masks used in hospitals throughout Iran. Five types of domestic (Zist Filter, ElhamTeb and Arman masks) and imported (Blosom, Face Masks) surgical masks were tested separately for physical characteristics and submicron particulate filtration efficiency based on Standards AS 4381-1996 and ISIRI 6138. Arman mask had the maximum levels in fluid resistance (112 cm of water), pressure drop (35±2.58 Pa) and particulate filtration efficiency (66.5475%±6.14951) and lowest averages of pore diameter (18.7micron).ElhamTeb had the least weight (59.51±2.46 g/m²) and fluid resistance (50.3 cm of water). Zist filter had the least thickness and pressure drop (11 ±1.82 Pa). Blosom had the least particulate filtration efficiency (27.8275 % ±4.44152) and highest averages of pore diameter (425 micron) and fiber diameter (20 micron).The particulate filtration efficiency in the domestic masks (56.130% ±10.07) was more than imported masks (31.906 % ±7.062). Domestic surgical masks have a better quality than imported masks but they cannot satisfy the required level of quality, yet.

KEYWORDS: Bio aerosol, Surgical mask, Particle filtration efficiency, Physical characteristics

INTRODUCTION

Bio aerosols include microorganisms (cultivable, non-cultivable or dead such as bacteria, fungi and viruses) and metabolic particles of living organisms (such as endotoxins and mycotoxins). These particles are very small and therefore can suspend in air for a long time. As a result, the risk of exposure to these particles is high. If the particles are pathogenic, they can easily cause different diseases for people exposed to them. The most important risk of these particles for people exposed to them is the outbreak of infectious diseases [1].

The hospitals and medical centers are among the important places in which there is a high level of bio aerosols and therefore the suspension of these particles in their environment could result in infections and diseases. The patients, health care personnel, operating room personnel and visitors are among those with the highest exposure to these pollutants.

The statistics show that 1 out of 10 patients who remain in hospital are infected by
this aerosol [2]. The reduction of postoperative infections is the duty of all those who are working in the operating room including surgeons, anesthesiologists, assistant surgeon and nurses. To reduce these risks people involved need to employ the infection control strategies. One of the best strategies to control postoperative infections is to use surgical masks [3].

The surgical masks have been employed for different purposes, e.g. their use by patients to prevent the spread of contaminated respiratory secretions to others; their use by health care personnel to avoid contamination with patients’ saliva and wound; their use by health care personnel to avoid contamination of wounds as well as keeping hands and fingers away from the mouth and nose pollution [4-5].

The pore size of masks has a great influence of filtration rate. There may be pores that particles pass through it, reducing the bacteria and particles filtration rate [4].

The infection may be spread at the time of talking and surgical masks could be used to reduce it [6]. In general, the infection spread could be decreased by surgical masks [7].

The particles' size is one of the factors affecting their penetration rate through surgical masks and the penetration rate of particles through surgical masks is different depending on their size [8].

The flow rate and the number of mask layers are among other factors affecting particulate filtration, while air resistance as another important factor as well [9].

Biological factors such as viruses also need to be regarded [10]. Those masks, which are similar in appearance, may have different efficiency. The best mask is the one that has the highest efficiency and lowest pressure drop. The pressure drop range of disposable masks is very diverse in the fixed flow rate and the large changes in pressure drop and masks’ efficiency demonstrate the very different quality of masks [11]. Since the masks are very diverse and every mask is produced for a specific application and due to rapid and uncontrolled increase in the production and import of surgical masks, health and commercial officials need to consider these issues and to be careful in choosing the masks suited for health promotion of health care personnel and to select them based on type, size and density of environmental pollutants.

The resistance of surgical masks to fluids and pollutant particles depend on several different variables; especially qualitative characteristics of surgical mask media such as thickness, type and fluid resistance of masks and their fitting with face as well as microscopic characteristics of surgical mask media. This project was aimed at evaluation of efficiency of domestic and imported surgical masks and different factors affecting it; based on Standards AS 4381-1996 and ISIRI 6138 for Surgical Face Masks.

MATERIALS AND METHODS
This analytical, cross sectional study was carried out Tehran University of Medical Sciences in collaboration with the Atomic Energy Organization of Iran and Textile Department of Amirkabir University of Technology. The study was conducted in six stages as follows:

   The information about domestic manufacturer of surgical masks was obtained with reference to Department of Medical Equipment, Ministry of Health which includes three domestic production companies (Arman Mask, ElhamTeb and Zist Filter).

2. Collection of information relating to manufacturers of imported surgical masks.
   The information about external manufacturers of surgical masks was obtained with reference to Department of Medical Equipment, Ministry of Health which mostly includes two external production companies (Blosom and Face Mask).

3. Determination of the main types of surgical masks used in the country.
   The main types of surgical masks used in hospitals throughout country including domestic and imported masks were specified through Ministry of Health as well as some information gathered from many hospitals.

4. Determination of the sample size.
   Given to information obtained from surgical masks used across the country, five types of masks including three domestic masks and two imported masks were selected.

5. Purchase order of determined masks.
After determining the types of surgical masks used in the country and the number needed to perform the tests, domestic surgical masks were obtained from their production companies and imported masks were obtained from external centers.

6. Perform the tests associated with surgical masks as follows:
   A: Determination of the physical characteristics of surgical mask media
   B: Evaluation of the efficiency of surgical mask
   C: Microscopic evaluation

   A: At first, the physical characteristics of masks were measured according to the Standards AS 4381-1996 and ISIRI 6138. The weight per unit area was measured by standard balance, model EORR80 manufactured by OHAUS Company. Initially, the balance was calibrated and adjusted. Then, around parts of every mask was cut, fabric's folds were smoothed and the length and width of each mask was measured in cm. The mask then was put on the balance and its weight was measured in grams. Using the ratio of proportionality, weight per unit area of every mask was determined in gr/m². In addition, thickness measurement was carried out by Thickness Gauge device, model 0/792 manufactured by SHIRLEY Company. Initially, masks thickness was read in millimeters. The measurements were done in different parts of the fabric surface of every mask and finally, average thickness of each mask was calculated.

   The air pressure drop in the flow rate of 28 L/min is measured out by a Micromanometer, model APM 50K manufactured by Air Flow Company.

   The level of fluid resistance was measured by a device measuring the resistance of fabrics to water penetration, model 1063 manufactured by SHIRLEY Company (6 cm diameter samples)

   B: Measurement of Particulate Filtration Efficiency

   Determination of submicron Particulate Filtration Efficiency was performed, using Filtration Efficiency test rig based on Standard AS 4381-1996 and ISIRI 6138 for Surgical Face Masks.

   To measuring the numerical concentration of particles on both sides of the mask substrate, a Condensation Particle Counter, model A3022 manufactured by TSI Company, was used.

   The efficiency of the filter bed was calculated using the numerical concentration of particles as well as formula (1).

   The efficiency of a mask (E) is the ratio of number of particles trapped in the mask (n₁-n₂) to input gas concentration (n₁).  
   \[ E = \frac{n_1 - n_2}{n_1} \]  \hspace{1cm} (1)

   Where:
   n₁ and n₂ are the numerical concentration of particles or gas volume concentration before and after penetrating through mask, respectively.

   Among the factors affecting the penetration ability of suspended particles through media filters are size, shape, type, density, special weight, and contact surface of particles. As noted previously, this study has used monodisperse particles with the size of 0.3 micron and flow rate of 28 L/min in all tests. The conditions were similar for all samples so that the error probability has been minimized.

   C: The microscopic evaluation (optical and Electron microscopic)

   The microscopic evaluation was carried out using optical microscope model NIKON manufactured by Japan with 400 magnification.

   Given the importance of fiber diameter, pore diameter and density of the fibers in the mask media, all three items were selected as the basis of observation and comparison in surgical masks.

   Data Analyses

   The data were analyzed by statistical software SPSS15 (Chicago, IL, USA) and ANOVA and Regression tests.

   RESULTS

   The physical tests and particulate filtration testing were performed on all five samples. Table 1 and 2 show the results of physical tests and particulate filtration efficiency testing, respectively.

   The comparison between weight per unit area of domestic and imported masks demonstrated that average weight of domestic masks (66.12 ± 5.83 g/m²) is less than that of imported masks (66.37 ± 1.75 g/m²). However, statistical test shows that, difference in weight between the two groups is not significant (P= 0.853). Zist Filter mask and ElhamTeb mask,
which both of them were among domestic masks, had the most (72.78 ± 2.22 g/m²) and the least (59.51 ± 2.46 g/m²) weight, respectively. Given to P<0.05, difference in weight is significant.

Moreover, the measured thickness of domestically produced masks (0.41-0.04 mm) was more than that of imported masks (0.38-0.01 mm). The difference in average thickness between two groups of domestic and imported masks is significant (P<0.05). Similarly, the thickness comparison between all the masks showed that Arman mask had the highest thickness among other masks, while the lowest thickness belonged to Zist Filter mask (P<0.001).

The comparison between levels of final air pressure drop shows that Arman mask has more air pressure drop than that of other masks (P<0.001) and the level of pressure drop in Zist filter is less than that of Arman mask and ElhamTeb, but it has not a significant difference with Blosom and Face mask.

The fluid resistance also has been checked. The average fluid resistance of domestic masks is slightly more than that of imported masks, but the difference between two groups is not significant due to P= 0.835.

The highest and lowest fluid resistance were observed in Arman mask (112 cm of water) and ElhamTeb mask (50.3 cm of water), respectively and the difference between two was significant.

The results showed that particulate filtration efficiency in the domestic masks (56.130%±10.07) was more than imported masks (31.906%±7.062) (P< 0.05).

There is a statistically significant difference between the means, implying that domestic surgical masks have a higher efficiency than imported masks. Among all the masks considered, Arman mask had the highest particulate filtration efficiency (P< 0.001). In addition, the average particulate filtration efficiency of Blosom mask is significantly different with (and less than) all other masks except Face mask.

The relationship between physical and microscopic characteristics of surgical masks and particulate filtration efficiency has been studied by regression test (Table3).

Given to regression analysis, the effect of physical and microscopic parameters on particulate filtration in the domestic surgical masks marked a significant relationship between pore diameter and particulate filtration efficiency given to P=0.022. Its equation is as follows:

\[ \text{Particulate filtration efficiency (domestic masks)} = -1.78 \text{ (pore diameter)} + 95.86 \]

In the case of imported masks, there is a significant relationship between air pressure drop and filtration efficiency given to P=0.009 that its equation is as follows:

\[ \text{Particulate filtration efficiency (imported masks)} = -1.41 \text{ (air pressure drop)} + 56.01 \]

In all surgical masks, a significant relationship between air pressure drop, pore diameter and fluid resistance has been found given to P-value that its total equation is as follows:

\[ \text{Particulate filtration efficiency (all surgical masks)} = [0.238 \text{ (fluid resistance)} - 0.63 \text{ (pore diameter)} +0.452 \text{ (air pressure drop)} +23.279] \]

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second after Arman mask. However, Zist filer mask has the highest quality factor among other masks in terms of air pressure drop.

The result of microscopic evaluation on studied masks has been given in Table 4.

The average density of fibers in all masks except Blosom is moderate, but Blosom mask has a low average density of fibers.

The highest fiber diameter (20 micron) and the highest pore diameter (425 micron) belong to Blosom (Figs. 1, 2).

DISCUSSION
This study demonstrated that of all physical and microscopic characteristics entered into the regression model, three characteristics of fluid resistance, air pressure drop and pore diameter were remained in the final regression equation. Given to $R^2$ value in this model, up to 68% of particulate filtration efficiency modifications could be predicted by three characteristics reminded in the model. In the case of domestic surgical masks, it could be stated based on $R^2$ value in Table 3 that 42% of particulate filtration efficiency modifications as dependent variable depends on independent variable remained in the model, i.e. pore diameter, and finally in the case of imported surgical masks, it could be also stated based on $R^2$ value in Table 3 that 70% of particulate filtration efficiency modifications as dependent variable depends on independent variable remained in the model, i.e. air pressure drop.

Evaluation of physical characteristics of masks showed that domestic masks have a higher thickness than imported masks due to difference in filter type as well as the type of filter's lower and higher layers. The thickness level of studied masks varies from 0.23 mm to 0.61 mm, but no significant difference between thicknesses of studied masks has been found [4].

The air pressure drop in the domestic surgical masks is higher than that of imported masks possibly due to higher density of fibers, lower pore diameter and higher thickness of domestic masks (Tables1,4).

The differences in filter structures and the diversity of filter manufacturers with various techniques and materials is the main reason for differences in air pressure drop of surgical masks. The level of resistance to blood flow varies from zero to 136 cm of water [4].

Although the resistance test in this study was performed by water, One of the reasons for difference between the results of current study and previous study could be difference in test method (testing by blood in the above study) as well as difference in mask media structure, density of fiber in filter and the type of fabric texture, because in previous study uses cellulose, polyester, and polypropylene fabrics, while all the masks used in current study are composed of polypropylene fabrics.

The Particulate filtration efficiency in different studies varied from 14 to 99% and fiberglass and plastic (fabric) masks had the highest and lowest particulate filtration efficiency, respectively that is due to the effect of type, size of the particles and structure mask's [4,12,14]. This reflects the effect of using appropriate materials for producing the masks media. Similarly, one of the most important reasons for low efficiency in this study could be usage of polypropylene media with a weak filtration.

Half-face and surgical masks tested using aerosols with the size of 0.3-10 micron and demonstrated that the filtration efficiency for those particles with the diameter of 5 micron and more is 95 percent. However, there was a more diversity for those particles with smaller diameter [13], which corresponds to high diversity in the efficiency of this study for those particles with the size of 0.3-10 micron.

Virus penetration through surgical masks was much more than that of N95 mask, suggesting that surgical masks are weak mechanical filters and those particles with the diameter of 300 nanometer have the most penetration through these masks [10]. In this study, measurements are performed based on 0.3 micron particles and the masks have not shown high efficiency compared to existing standards.

Zist filer mask and Blosom have the highest and lowest quality factor respectively. This is due to lower air pressure drop of Blosom than that of other masks. Although Arman mask has better particulate filtration efficiency than that of Zist filter, low air pressure drop in the Zist filter has cause the mask to have a better quality than Arman mask.

The results indicate that particulate filtration efficiency and air pressure drop could be equally effective on a mask quality and
these two characteristics have a close connection with the physical and microscopic characteristics of the mask media.

According to the results of microscopic evaluations, the highest fiber and pore diameter in Blosom mask could well explain why the particulate filtration efficiency of Blosom is low.

Since the filters are nonwoven fabrics and randomly putting of fiber layers on each other finally leads to the formation of filter, high fiber diameter could be effective on the formation of more pores in the filter surface. But, the another important factor in the microscopic view is the maximum diameter of pores observed in the filter surface, which is considered as one of the most important factors affecting the particulate filtration and air pressure drop. The average size of pores in the masks estimated between 16 and 51 micron and showed that the smaller masks’ pores, the filtration rate are higher [4].

The non-uniformity in the fabrics and filters' texture and the lack of appropriate quality produces many pores in the filter surface and other layers and these factors are crucial in determining the quality of surgical masks. The pore diameter is a crucial factor, because even a pore with a diameter greater than the other mask can cause more particles to penetrate through this mask [4].

The maximum pore diameters in the Arman mask justifying its high efficiency and high-pressure drop. The maximum pore diameter in the ElhamTeb mask which is more than that of Zist filter mask, suggesting that efficiency of Zist filter is higher than that of ElhamTeb mask.

CONCLUSION

Unfortunately, most of the masks used in the Iran's health centers do not follow existing standards. However, the domestically produced masks have a much better quality than those masks that are mostly entered into Iran from China. Therefore, requiring the domestic industries to comply with the standards and monitoring the imported masks are crucial because of their importance in the prevention of occupational infections.

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