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REVIEW ARTICLE

Surgical Face Masks: Manufacturing Methods and Classification

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Abstract

A surgical face mask is also known as a procedure mask and purposely to be worn by health care professionals during operation procedures. It helps to catch the bacteria shed in liquid droplets and aerosols from the wearer's mouth and nose. Normal activities such as sneezing, coughing, breathing and speaking may release oral, dermal and nasopharyngeal bacteria that may cause post-operative infections. Microorganisms have varying characteristics that can influence their potential ability to penetrate the facemask material including shape, size and their surface characteristics. Some studies reported that variety of pathogens are encountered in the hospital environment, a relatively limited number of hospital infections including *Escherichia coli*, *Pseudomonas aeruginosa*, *Enterococcus faecalis, Candida albicans* and *Staphylococcus aureus.* Some studies reported that the rod shaped bacteria penetrate less than spherically shaped bacteria of similar size. This review focuses on surgical face masks and their classification based on the performance like filtration efficiency, pressure difference, splash resistance etc. Further, the quality evaluation of surgical face masks and standards for manufacturing surgical face masks has also been reviewed.

Keywords: Surgical face mask, operation procedures, hospital infections, pathogens, filtration efficiency.

Introduction

Healthcare workers involved in treating and caring for individuals injured or sick as well as the patient can be exposed to biological aerosols capable of transmitting diseases. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health (Chellamani and Thiruppathi, 2009). Surgical face masks are used to cover the mouth and nose by doctors and other healthcare workers. It reduces the risk of contaminations from secretion of the mouth and nose in operation room or clinics. It is purposely to be worn by health care professionals during surgery and at same time to catch the bacteria shed in liquid droplets and aerosols from the wearer's mouth and nose (Hayavadana and Vanitha, 2009). Surgical face masks were originally developed to contain and filter droplets containing microorganisms that are liberation from the mouth and nasopharynx of healthcare workers during surgery, thereby providing protection for the patient. However, there are several ways in which surgical face masks contaminate the surgical wound. For example, due to poor tying of surgical face masks and incorrectly worn surgical face masks causes leaking of air from the side of the surgical face mask (Hofmeyr *et al.,* 2008). In 1897, Mikulicz, a German physician, published the first study which supports the need for wearing a surgical face masks. In 1906, Hamilton found that the transmission of Infectious diseases and the importance of droplets of sputum in the dissemination of tuberculosis infection.

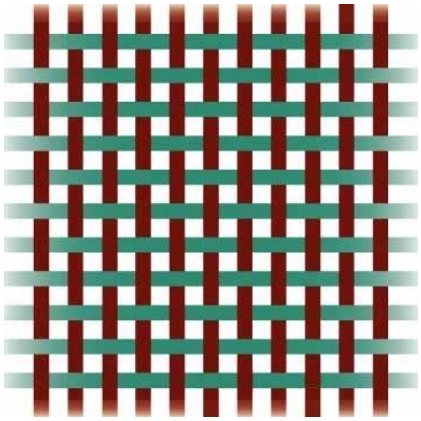
Hamilton also found that mouth is a source of streptococcal bacteria which causes the communicable diseases and recommended that physicians should wear a specially constructed mouth guard. In 1918, weaver published the results of his study on the surgical face masks which play a main role to spread of diphtheria, meningitis, pneumonia and so on. He introduced the practice to cover the nose and mouth when caring the patients (Hamilton, 1915).

Doust and lyon (1918) observed the role of surgical face masks is to prevent the respiratory tract based infections. They also found that the surgical face masks with two layers provide the better protection to the wearer as compared to the single layer face masks. They also found that speaking with a surgical face masks in an ordinary conversation for 5 min release relatively few bacteria from the mouth to a distance of only 1 to 2 ft. In case of without surgical face masks, for 5 min, the liberation of bacteria from the mouth is quite high. And the liberated bacteria are found even to as distance more than 3 ft (Belkin, 2009). Surgical face masks not only provide a barrier for airborne organisms, it also protects the wearer against splashing of blood and other body fluids (Woodhead *et al.,* 2002).

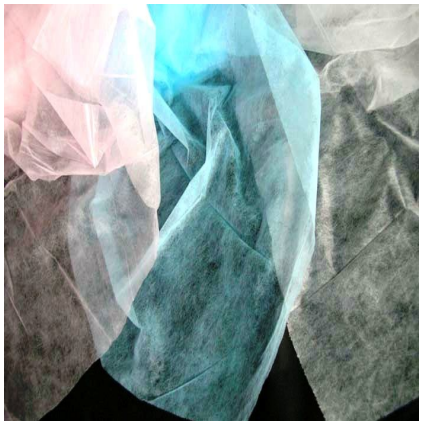
Manufacturing methods

The surgical face mask is produced using fabric forming technology as shown in Fig. 1. They are a. Woven, b. Non-woven and c. Knitted.

Fig. 1. Different fabric forming technology.



a. Plain weave (Anon, 2010).



b. Non-woven (diytrade, 2013).

c. Knitted (stellas, 2013).

Even though, there are three fabrics forming technology, nowadays, most of the surgical face masks are made up of non-woven with a view of disposing after use. Non-woven fabric forming technology is cheaper than other fabric forming technology like woven or knitted. Most of the surgical face mask manufacturers produce the surgical face mask using SMS (Spunbond Meltblown Spunbond) technology.

The typical material used to manufacture surgical face masks are polypropylene with 20 gsm made using spunbond technology and 25 gsm polypropylene non-woven sheet made using meltblown technology. The surgical face masks are made in different sizes like 17.5 X 9.5 cm for adult, 14.5 X 9.5 cm for child use and 12 X 7 cm for infants. They are available in different color like white, blue, green, yellow and pink (Hayavadana and vanitha, 2009). Over the past decade, there has been a tremendous increase in the demand for polymeric nanofibres which are used in various applications including tissue engineering, protective clothing, filtration and sensors (Nayak *et al.,* 2012). The nanofibers have a very large surface area to volume ratio, which makes them suitable to manufacture filtration products and particularly for medical textile products such as surgical facemasks, wound dressings, drug delivery systems etc. (Jayaraman *et al.,* 2004).

Fibres used to manufacture surgical face masks

More effective surgical face masks which provides 85% or even 99% protection is required to prevent the spread of transmission diseases. The high degree of filtration efficiency is attained with a very fine filter layer of textile fibres covered on both sides with conventional non-woven bonded fabrics. The thickness of fibre is from <1 to 10 µm. Polypropylene, polystryrene, polycarbonate, polyethylene, polyester etc. are suitable for manufacturing surgical face masks. Apart from fibre selection, the filtration efficiency of surgical face masks depends on the method of manufacture, the structure of web, the cross-sectional shape of the fibre and its change (McCarthy, 2011). The suitable polymers are converted as a non-woven sheet using spunbond technology or electrostatically produced web from solvents. The methods of electrostatically produced web have uniform web density giving a high degree of filtration efficiency and less web weight (Luneneschloss and Albrecht, 1985).

Benefits of non-woven based surgical face masks

Non-woven based surgical face masks are disposable. It is generally made up of three or four layers, often with two filters that filter the material, 1 µ in size. Hence, it traps bacteria of that size or larger. Face masks of this type can provide protection against bacteria for a minimum of 4 h (Lipp and Edwards, 2002). Advantages of non-woven fabrics over woven fabric in filtration are higher air permeability, higher bacterial filtration efficiency, no yarn slippage and low manufacturing cost (Kothari, 2008). The non-woven technology guarantees better barrier properties than cotton, polyester or even more advanced woven products. Besides, disposable non-wovens (surgical face masks, gowns, drape etc.) are sterilized, packaged, opened, used and then disposed. Hence, there is a less risk of contamination after using of disposable non-wovens than reusable products either woven or knitted.

Table 1**.** Comparison between disposable and reusable textiles used in healthcare applications.

Properties	Disposable non-woven	Reusable	
		Traditional textiles	Micro-porous textiles
Mechanical resistance	•	••	•••
Linting (reduction of particle emission)	•••	•	••
Resistance to bacterial penetration	•••	•	••
Resistance to liquid penetration	•••	•	••
Flexibility	•••	•	••
Drapeability	••	•••	•••
Comfort	••	•••	•••

• Minimum to •••Best adopted.

Table 2. Classification of medical face masks based on its barrier properties.

Quality evaluation characteristics	Surgical face masks		
	Low barrier	Moderate barrier	High barrier
Bacterial filtration efficiency (%)	≥95	≥98	≥98
Differential pressure (mm H_2O/cm^2)	<4.0	<5.0	<5.0
Sub-micron particulate filtration efficiency (%)	Not required	≥98	≥98
Resistance to penetration by synthetic blood (minimum pressure in mm Hg for pass result)	80	120	160
Flame spread	Class 1	Class 1	Class 1

In case of reusable non-woven, that should be decontaminated, washed, sterilized for every reuse. Table 1 shows that the superiority of disposable non-woven over other reusable products in terms of barrier properties (Najjar *et al.,* 2009). Disposable surgical face masks are often perceived to have protective advantages over reusable surgical face masks; they must be immediately discarded as bio-hazardous materials. In contrast, reusable surgical face masks can be sterilized and laundered for reuse, with a lifetime more than 50 cycles. However, reusable surgical face masks may be prescribed as less protective and more time-consuming for production as well as washing and sterilization for reuse. The repeated laundering of reusable surgical face masks may consume more energy and generate more waste water to the environment (McCarthy, 2011).

Classification of surgical face masks

As per international standard ASTM F 2100–07, surgical face masks are generally classified in to 3 types. They are i) Low barrier, ii) Moderate barrier and iii) High barrier. The basic characteristics to distinguish the surgical face masks based on its barrier properties are listed in Table 2 (ASTM F 2100, 2007).

Quality evaluation: European standards and ASTM standards provides the standardize quality evaluation procedure for surgical face masks to prevent transmission diseases from health care professionals to patients and in certain situations vice-versa. Also provide the critical requirements before marketing the surgical face masks (EN 14683, 2005). There are five test methods used to evaluate the performance of the surgical face masks.

Bacterial filtration efficiency in vitro (BFE): This test method is designed for measuring bacterial filtration efficiency of surgical face masks using *Staphylococcus aureus* as the challenge organism. *Staphylococcus aureus* is based on its clinical relevance as a leading cause of nosocomial infections. A bacterial challenge aerosol is passed through the test specimen either face side or inner side at a flow rate of 28.3 L/min, allowing evaluation of filtration efficiencies related to both patient generated aerosols and wearer generated aerosols. The mean particle size of the bacterial aerosol used in this test is maintained at 3.0±0.3 µm as per relevant ASTM specifications. A higher bacterial filtration efficiency percentage indicates the better protection level for the patient and healthcare professionals against transmission diseases from the source of patient as well as healthcare professionals. Classifications of surgical face masks as per BFE in European standard EN 14683 is as follows:

- BFE ≥ 95% indicates the Type-I surgical face masks
- BFE ≥ 98% indicates the Type-II surgical face masks.

Breathing resistance (ΔP): Breathing resistance is used to determine the resistance of airflow through the facemask. The surgical face mask is subjected to controlled flow of air. The difference in airflow pressure of inlet and outlet of the sample is measured. The difference in pressure is divided by the surface area (in cm^2) of the sample. A lower in breathing resistance indicates a better comfort level to the end user (patient and healthcare professionals). It means that breathing is easier through the surgical face mask by wearer. During breathing, the surgical face mask will maintain its shape in a better way.

Classifications of surgical face masks based on breathing resistance are as follows:

- For Type-I and II surgical face masks, the breathing resistance would be (non-splash resistant surgical face masks) ≤3.0 mm H_2O/cm^2.
- For Type-IR and IIR surgical face masks, the breathing resistance would be (splash resistant surgical face masks) ≤ 5.0 mm H_2O/cm^2.

The increase in comfort of surgical face masks needs to have a low breathing resistance value per cm^2. For that, the available surface area of the facemask is increased and thereby the total area available for ventilation is increased.

Splash resistance (ASTM F1862-07): Splash resistance is used to determine the penetration resistance of surgical face masks under high velocity stream of potentially contaminated fixed volume of fluid (splash of fluid) over a relatively short period of time. A specimen is supported on an apparatus that allows viewing the back side of the specimen from behind. A fixed volume of synthetic blood (stimulant fluid have equivalent liquid characteristics like surface tension of actual blood and other body fluids), is aimed at the specimen and dispersed at a known velocity. It simulates the impact of blood or other body fluid onto the specimen. Any evidence of synthetic blood penetration on the back side of the medical face mask constitutes failure. Specimen medical face masks are evaluated at a total of three different velocities corresponding to human blood pressures of 10.6, 16.0, and 21.3 kPa (80, 120 and 160 mm Hg). Test results are reported at each velocity and the medical face mask is rated at the highest corresponding blood pressure. A higher splash resistance means that the surgical face mask will protect the user in a better way against splashes of potentially contaminated fluid during a surgical procedure. Classifications of surgical face masks based on splash resistance in European standard EN 14683 are as follows:

- For Type-I and Type-II surgical face masks, this test is not applicable.
- For Type-IR and Type-IIR surgical face masks, the specimen should be tested under the constant velocity of 120 mm Hg.

Flammability (16 CFR 1610): There are many potential ignition sources in the operating room, including surgical lasers, electrosurgical units, endoscopic fiber optics and high-energy electro-medical devices. The materials used in operation theatre will burn if high intensity heat energy is applied to them, especially in the presence of elevated oxygen levels. Hence, the flammability test for surgical face masks is essential. The standards given below are used to determine the flammability by class for medical device like surgical face masks (Guidance for Industry and FDA staff, 2004).

- Consumer Product Safety Commission (CPSC) 16 CFR 1610: Standard for flammability of clothing textiles.
- National Fire Production Agency (NFPA) Standard 702-1980: Standard for classification of flammability of wearing apparel.
- Underwriters Laboratory (UL) 2154: Fire test for surgical fabric.

The flame spread characteristics are classified in terms of class 1 to class 4 for the above tests. For NFPA, class 1 indicates relatively slow burning where as CPSC standards, class 1 indicates that minimum of 3.5 sec or more required to ignite and spreading of flame on the specimen against the standard flame. In case of UL standards, test to measure the quantity of atmospheric oxygen required to propagate the flame while ignition is caused by an electro surgery unit or laser unit. Higher levels of oxygen required for flame propagation indicate that the materials are more flame resistant. FDA recommends that class 1 and class 2 flammability materials are to be used to manufacture the surgical face masks.

Conclusion

Disposable surgical face masks are worn by both patient and healthcare professionals to reduce the frequency of post-operative surgical wound infections. These infections result to increase the medical expenses. Hence, the quality of the surgical face masks is essential and the same is determined by standard testing procedure provide by internal standards like ASTM and European standards. Reusable surgical face masks can be sterilized and laundered for reuse, with a lifetime more than 50 cycles. However, reusable surgical face masks have less filtration and protection efficiency as compared to disposable one. As number of washing cycle is increased the protection efficiency is decreased for reusable one. Also the repeated laundering of reusable surgical face masks may consume more energy and generate more waste water to the environment

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