



The surgical mask
has its first performance standard—
A century after it was introduced

by Nathan L. Belkin, PhD

From the day of its conception more than a century ago, there hasn't been a standardized test method for demonstrating the filtering efficiency of the surgical mask.

Today, however, there are two test methods that manufacturers are required to use in order to be granted marketing approval by the Food and Drug Administration.¹

The first test measures the mask's particulate filtration efficiency using a non-neutralized aerosol of 0.1 μ m latex spheres, at a challenge velocity between 0.5 and 25 cm/s (approximately 8 to 380 L/min for a 9-cm radius mask).²

The second test measures the mask's bacterial filtration efficiency using a non-neutralized 3 + 0.3- μ m *Staphylococcus aureus* and a flow rate of 28.3 L/min.³

The FDA does not require a minimum level of filter performance for either of the test methods.⁴

To the surgical community, the significance of the scientific tests developed by the industry-driven group, the Association Society for Testing Materials (ASTM), was the granting of manufacturer approval to market the product. However, the results of these testing methods do not appear to be relevant to the work conducted by previous clinical investigators.

Early testing for effectiveness

Mikulicz, a German physician, published the first study supporting the need for a mask, in 1897.⁵ Its use was predicated by the work of Flügge, another German clinician, who demonstrated the presence of bacteria in droplets from the nose and mouth.⁶

It was Hamilton's study in 1906 that focused on the transmission of communicable diseases and the importance of droplets of sputum in the dissemination of tuberculosis infection.⁷ Having found that the mouth was a fruitful source of streptococcal infection, he recommended that physicians wear a specially constructed mouth-guard. Notably, tests of these mouth-guards indicated that they almost completely held back the sputum droplets.

Several years later, in 1918, Weaver published the results of his study on the mask's role in preventing the spread of diphtheria, meningitis, pneumonia, and so on. He introduced the practice of covering both the nose and mouth when caring for patients.⁸ Masks proved to be such successful barriers when treating patients that they were

recommended for use in households containing diseases that could be spread by nasopharyngeal discharge.

That same year, Doust and Lyon examined the role of face masks in preventing infections of the respiratory tract.⁹ They defined the mask's twofold purpose: to protect the wearer from the infectious material from the patient's respiratory passages, and to protect the patient from such material that the wearer himself may carry in his or her nose and mouth. At that point, the authors assessed the filtering efficiency of some common types of masks that were said to prevent the dissemination of infectious material from the mouth during speaking or coughing.

As the first study of its kind, the findings proved to be quite revealing. For example, they found that speaking without a mask in an ordinary conversational tone for five minutes projected relatively few bacteria from the mouth, to a distance of only 1 to 2 feet. Speaking in the same manner, but for 30 minutes, produced similar results. On the other hand, speaking without a mask in a loud tone for five minutes generated considerably more bacteria, with one organism projecting more than 3 feet.

As was to be expected, coughing periodically, without the use of a mask, for five minutes generated the greatest number of colonies, some of which projected as far as 10 feet. In the process, they also observed that the effectiveness of masks consisting of as few as two layers of coarse gauze, compared with those consisting of as many as 10 layers of coarse gauze, was not dramatically different.

It is to be noted that the results from the use of masks made of five layers (rather than two) of a medium-quality of gauze did prove to be more effective in all circumstances.

A year later, in 1919, Weaver investigated droplet infection in terms of the distance traveled by mouth compared with droplets that had been driven out in forced respiratory efforts.¹⁰ His tests indicated that the distance to which the droplets were carried in the air depended principally on the force with which they were driven, and that small droplets could travel some distance, especially when carried by currents of air. He also reported that gauze could remove bacteria from the air when carried in a moist spray; the efficiency of the gauze was in direct proportion to the density of the weave and the number of layers used.

Based on these findings, Weaver's research group adopted the use of a mask made of three layers of absorbent gauze with a total thread count of 84 threads per square inch (44 x 40). They found the absorbent material preferable, because particles of mucus seemed to adhere to it more quickly and firmly.

Failure of an in vivo test

An outbreak of influenza in 1919 brought about a challenging situation, warranting compulsory use of the mask in order to keep the epidemic in check. Considering the fact that influenza is a droplet-borne infection, it appeared that wearing masks was a preventive measure based on sound reasoning, and that favorable results could be expected from their use. But that was not the case.

The failure of the masks to prevent the spread of the disease was disappointing. Although the masks had been worn cheerfully and universally, the state's health care officials reached two conclusions: that a mask's filtering capability varied by the number of layers and thickness of the mesh of the gauze; and when a sufficient degree of gauze was used to create a useful filtering influence, breathing was difficult, and leakage took place around the edges of the mask.¹¹

New developments

These results were not a complete loss, however tragic the circumstances, as these early masks were the forerunners to the era of new materials. The first change in mask design was disclosed in Walker's study in 1930.¹² In establishing the minimum standards for a mask to be germ-proof, he determined that it should be constructed so as not to permit organisms to pass through the mask when the wearer, with both nose and mouth covered, talked for one hour, with the area in front of the mouth moistened during the last 15 minutes. In addition to placing a 6-inch square of rubber (taken from a discarded surgical glove) in the front area of the mask, he also introduced a small piece of aluminum in the upper part of the mask that could be bent to fit the nose.

The need for a surgical mask

Although Walker's article was the first to mention a "surgical" mask, previous attention had been primarily directed to its use in conjunction with

respiratory infections. At the time, the general belief was that there was no room for improvement in the operating room, as these techniques had been handed down for several decades. In other words, there was no need to improve the excellent results that were already being achieved in healing wounds.

Nevertheless, the use of masks during surgery did become widespread after 1926 with the publication of Meleny's first study, in which he reported having experienced a reduction in the incidence of surgical site infections (SSI).¹³ However, in his subsequent study, published nine years later, he reported that the rate of infection with the use of masks was closer to 15 percent than the 2 percent to 5 percent range that had been originally anticipated.¹⁴

The fact of the matter is that since the days of the Meleny studies, much has been written about the mask's impact on surgical site infections.^{15,16} To date, the use of a mask is still not evidence-based, since its effectiveness for preventing infections has yet to be conclusively demonstrated. One of the many variables to be considered is the filtering efficiency of the mask during in vivo conditions. Others variables include:

- 15 to 20 air changes per hour in high-efficiency particulate air (HEPA)-filtered circulatory systems
- The length of time it can be worn while maintaining filtering efficiency
- A discomfort for the wearer that could be accompanied by the leakage of exhaled air around its edges


It should be noted that one manufacturer has already announced the availability of a new surgical mask that incorporates proprietary filtration media that meets the requirement of a totally different standard. Although the new mask is recommended for wearing in longer procedures where comfortable, breathable masks are important, the manufacturers qualify its performance by saying that their testing protocol does not reflect expected levels of filtration in actual in-use conditions.

Conclusion

During the early period of the development of the surgical mask, Castaneda eloquently and astutely summarized its status:

The ideal mask has yet to be developed. None, so far, has succeeded in combining comfort with bacteriologic security. Even upon the development of such a device, whether it is in the form of a more perfect mask or some bactericidal medium, other aspects of surgical technique and the care of the wound will continue to be of paramount importance in the prevention of post-operative sepsis.¹⁷

Thus, to this day, questions remain unanswered. What effect, if any, will the new standard for the mask's filtering efficiency have on a reduction in the incidence of SSIs? On the other hand, should mask use continue to be predicated on its theoretical effectiveness? In the meantime, alleged improvements will increase the cost of masks at a time when continuous pressures are being put on reducing, let alone containing, costs. This, then, raises the question as to whether the performance standard is just another example of an industry generating the need for a more expensive product rather than the surgical community generating a genuine need.

Although this article will not have any impact on present practices, its purpose is to enlighten the reader on the new performance standard that does nothing other than provide the manufacturer with a point of reference for the filtering efficiency of his product. 

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Dr. Belkin retired in 1991 after 40 years in research and development of surgical textiles. He lives in Largo, FL.

