"The use of the surgical mask: a documented review due to the COVID-19 pandemic"

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Medical face masks are medical devices and must comply with European standards in order to be safe for use. According to European standard EN 14683: 2019, medical masks are classified into three types: Type I, which has bacteria filtering effectiveness ≥ 95%, Type II, which has bacteria filtering effectiveness 98%, and Type II, which has bacteria filtering effectiveness ≥ 98% but is also resistant to liquids. Type I surgical mask is considered a consumable medical device and is also used by patients to reduce the risk of infection spreading, especially in epidemics or pandemics. Type II and IIR masks are mainly intended for use by healthcare professionals in operating rooms or other medical procedures with similar requirements.[1] They can be used from 3 to 8 hours according to the manufacturer's instructions [2].

The European standard clearly defines the materials for the construction, design, performance requirements (bacterial filtration efficiency, breathability, biocompatibility, etc.) as well as marking, labeling, and proper packaging. The information to be provided by the manufacturer is a) the number of the European Standard EN 14683: 2019 and b) the type of mask as defined by the same standard (I, II or IIR).

More complex respirator masks protect against airborne agents that cause infections, such as pollen, dust, bacteria, and viruses. In Europe, they are categorized as FFP1, FFP2, and FFP3 while in USA are categorized as N, P and R depending on the filtration rate and leakage. The N95 (or FFP2) respirators filter ≥95% of the airborne bacteria inhaled through it, including viruses. However, not everyone is able to wear a respirator mask due to respiratory or other medical problems that may be exacerbated during breathing, and are addressed exclusively to specialized or medical staff. [3] Before using a respirator, health professionals should be aware of how to apply it properly and have undergone a medical evaluation to make sure they are able to wear it safely. [4]

There are still many types of masks on the market that are intended for use by workers who need protection from dust, particles, chemicals, etc. but they are not medical devices and should not be considered as such. These masks have different standards and are in no way intended for use by medical staff, patients or the public.

![Figure 1: Non-medical masks used in different professions](W1)

It should be made clear that the surgical mask does not protect people who are not infected with viruses, thus the surgical mask does not protect from COVID-19 too. This is due to the structural features of the mask itself. The surgical mask usually consists of 3 layers of materials: 1) the external hydrophobic which is waterproof against spraying 2) the intermediate layer which acts as a filter against particles (dust, pollen, etc.) and bacteria and 3) the interior which is absorbent in order to absorb the moisture coming out of the mouth and the nasal passages. [5][6]

The high level of filtration efficiency is achieved with a very thin layer of filter layer made of fibers that form the main grid. The thickness of the fibers is from 1 to 10 μm. In addition to the selection of fibers, the filtering efficiency of surgical masks also depends on the method of its manufacture, the structure of
the fiber-forming grid, the shape of the cross-section of the fibers, the change in fiber diameter when the mask is applied, as well as the correct application of the mask on the face.

The materials that are suitable for the manufacture of medical masks are polymeric materials such as: Polypropylene, polystyrene, polycarbonate, polyethylene and polyester. These polymers are converted to non-woven sheet using a variety of techniques, with the aim of achieving uniform density, high degree of filtration, with the size of their pores ranging from 15 to 50 μm and with a lower final grid weight. [7],[8] The internal filter is usually made of polypropylene with a density of 20-25 gr / m² and is effective against particles larger than 1 μm.

The fact that COVID-19 is 0.12-0.16 μm in size, it is easy to understand that a simple surgical mask can in no way be an effective barrier against the virus as it is almost 10 times smaller than the pores of the mask.[9] Depending on the way that the different types of masks are constructed, each mask has its own properties. It is common that the performance of the mask is determined using in vitro tests of the material from which it is made.

An additional factor that has to be considered, is the ability of the mask to absorb the moisture from the exhaled air and thus maintain its performance for a longer period of time. The more advanced designs maintain their performance throughout even very time-consuming processes of a few hours, while the less advanced designs are intended for shorter procedures. [7]

Cloth face masks are not medical devices and should not be marketed as such.

The most common material used to make them is cotton or a synthetic fabric made from a combination of cotton and polymer and is usually considered as reusable. According to studies, these masks do not protect against viruses due to the size of their pores ranging from 80 to 500 μm, a size much larger than the size of the pores of surgical masks. The number of pores per surface is not constant and can be from 10 to 50. When used, the fabric dilates, causing the pores to deform and increase in size.

In addition, after each wash and dry cycle there is a gradual reduction in filtration efficiency. Studies on the use of handmade masks as an alternative to surgical masks have shown that the surgical mask is 3 times more effective in blocking the transmission of microorganisms than the handmade or cotton ones, and none of them is an effective barrier against viruses.[10],[11]

According to the World Health Organization (WHO), surgical masks should only be used by medical, nursing and other staff who come in direct contact with patients and therefore the risk of infection from COVID-19 is greater. [12] In addition, patients and people with symptoms such as fever and / or coughing should wear masks to protect others from airway mucosal droplets during exhalation and speech that may reach 1 meter, while for coughing and sneezing can reach up to 8 meters. [13] The biggest threat, however, is believed to be large droplets carrying the highest microbial load, but due to their weight
they fall quickly to the ground and do not reach a distance of more than 2 meters. [13, 14]

Healthy people who do not belong to the above categories and follow the personal protection measures, such as regular hand washing with alcohol-based hand rub if hands are not visibly dirty or soap and water when hands are visibly dirty, minimizing social interactions and adhering to distance measures from other people, they do not need to use masks. The use of a mask is recommended only in special cases of people working in places where social interaction or crowding (eg public transport) cannot be avoided, due to reports of the existence of asymptomatic patients or patients at the stage of virus incubation. [15]

However, if it is chosen a mask that is not certified and/or it is used in a wrong way, it may result to the opposite effect. For example if the front surface of the mask is touched by the hands, either during or after its use, microorganisms are transferred to the hands that are infected and therefore become themselves a source of infection. In the case of overusing the mask, there is a risk of moisture accumulating on its inner surface, which is a favorable environment for the survival and multiplication of germs.

For this reason, the World Health Organization (WHO) emphasizes that the used mask should be discarded properly and always in a closed bin, hands should always be washed thoroughly after disposal and should not come into contact with the eyes and the face.

The mask should be used sparingly and prudently. Mass use of a mask for any activity would create significant deficiencies in their availability to people who really need to wear it. Assuming that all residents of two major urban centers such as Athens and Thessaloniki with a total population of about 5 million needed a mask for each of their outer activities, even for a single outer activity per day, the number of masks needed would reach 5 million masks per day or 150 million per month.


https://www.thomasnet.com/articles/other/how-surgical-masks-are-made/

[6] JOSEPHA. PALOMO, FOX LAKE, IL (US); STEPHANIE C. CARROLL, WINTHROP HARBOR, IL (US); SARA (K. WEGENER, LIBERTYVILLE, IL (US); CHRISTOPHER M.AGUILAR,EL PASO, TX (US); JOE MILLER, EL PASO, TX (US), Surgical Mask, Aug. 18, 2016


[11] “Testing the Efficacy of Homemade Masks: Would They Protect in an Influenza Pandemic?” Anna Davies, BSc, Katy-Anne Thompson, BSc, Karthika Giri, BSc, George Kafatos, MSc, Jimmy Walker, PhD, and Allan Bennett, MSc, 22 May 2013


[W1] https://www.hse.gov.uk/pubs/priced/hsg53.pdf?fbclid=IwAR1FSB7ms3sYrQqka93phmnxmd9VPTe3EQW Ks-j8KiziRzQ5DylhhPWsk

[W2] https://medium.com/@cestclaire/masks-how-to-choose-wear-dispose-video-b22b4792b881