



Respiratory Protection Newsletter April 2021
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Un-reliable Respirator/Mask Research
Single versus Double Masking

Let's Think About This:
Un-reliable Respirator/Mask Research
Single versus Double Masking
It's time to STOP the nonsense.

Nearly every day I read about respirators or respiratory protection. At times, the amount of information can be overwhelming and confusing, especially when the studies are poorly designed.

Some of these articles are published in highly respected journals representing the fields of aerosols, fluid dynamics, toxicology, medicine, occupational medicine, infection control, industrial hygiene, etc.

Unfortunately, you can no longer judge the quality of the study by the reputation of the journal or the institution that conducted the study. Since the pandemic, it seems anyone who's purchased fit testing equipment is compelled to publish their results. They feel their data is unique, often because they're unfamiliar with the science of respiratory protection. There are so many poor studies, it's difficult to nearly impossible to trust what you read. Information about respirators and face masks is of interest to the public. Consequently, the news media picks it up and distributes the information to an even larger audience. In some cases, the flaws identified and corrected,

but few people are aware of the corrections. In other cases, the data and/or conclusions are so distorted, the article is retracted.

Some articles remain unchanged, for others to believe as reliable and accurate.

For example, an April 2021 "Research Letter" in JAMA Internal Medicine reported a mean increase in fitted filtration efficiency (FFE) when human volunteers switched from a single mask (55%) to a double mask (66%). They concluded: "double masking improves FFE". In other words, two masks are better than one??? This study was partially funded by the Centers of Disease Control (CDC) and was used to update CDC face covering guidelines.

Here's my perspective. In this article, the authors used the word "fitted" and the study was not designed to evaluate source control. So, let's look at this study from a respiratory protection perspective. The study included just three (3) subjects. Using three subjects is inadequate to compare fitting characteristics. Factors that determine the capability of a facepiece or mask to fit a population of wearers include, face shape, face size, race/ethnicity, gender, extent of training, donning technique, etc. Three (3) subjects is inadequate to address these factors. More of this will be mentioned below.

The authors also expressed their results as: “fitted filtration efficiency” (FFE). Since few people are familiar with this terminology, I recalculated their data to express results as fit factors, a term more commonly used with respiratory protection. The reported fitted filtering efficiency values of 55% and 66%, are equivalent to fit factors of 2 and 3, respectively. This means both conditions (single & double masking) had excessive inward leakage.

These values are far below the OSHA minimum fit factor of 100 for an N95 filtering facepiece respirator. In other words, there was no practical difference between the two tested conditions and they did not offer significant protection to the wearer. When something fits this badly in a laboratory, imagine how it would perform in the real world. Did the researchers evaluate consistency in donning a double mask? The answer is **No**. I’ve conducted lots of fit testing with single and double layers of surgical masks and other facepieces. Donning these consistently is a nightmare. Even the process of probing a double facepiece can influence positioning and fit.

The facial features of these three (3) subjects are not known. The authors reported head circumferences of 56.0, 58.5, and 55.9 cm. This would be useful information if I wanted to purchase a baseball hat for these subjects online, but doesn’t provide information about face size or shape. Study subjects should have facial measurements taken and compared to a representative population of potential wearers, such as the one specified in ASTM Standard Method F3407, which uses a NIOSH bivariate anthropometric panel representing approximately 98% of a U.S. population. At the very least, when the requirements of a representative bivariate panel are not met, the number of subjects within each cell, and cell number (which identifies face size measurements), should be reported.

Did this study evaluate the effect of increased breathing resistance of double masking and whether or not a general population of users would consistently wear double masks correctly? The answer is **No**.

The illusion of greater protection with double masking may cause a false sense of security with potential for wearers to increase time and proximity (decreased distancing) around an infected person. In addition, the increase in breathing resistance may cause repositioning or even removal of the mask resulting in additional face seal leakage. With so many different styles and materials of masks available, it's unpredictable which models would be used. When combined with unpredictable filtration and fitting characteristics, double masking becomes an unreliable recommendation and doesn't make sense at this point in time.

Another study compared the fitting characteristics of N95 and KN95 filtering facepieces, with just three (3) people. It appears some researchers believe three (3) subjects is the standard for comparing respirators and face masks. In the absence of having a representative panel of test subjects, the conclusions are not useable.

In many cases, it’s impossible to understand what type of respirator or model was even studied. Here’s an example from a different 2021 article, where the author said: “Multiple groups have now demonstrated that barrier face coverings and masks can help slow the spread of SARS-CoV-2.”

What is a “mask”? Do they mean a “surgical mask” or something else? Perhaps this will become clearer, as we read further.

“In this study, a model 8511 mask and a model 8210 mask (3M) were used.”

Apparently, they’re identifying 3M models 8511 and 8210 as “masks”, rather than N95 filtering facepiece respirators. In that case, I wonder what the previous sentence was referring to when they wrote “barrier face coverings and masks”?

There are thousands of different make and model respirators, surgical masks, and barrier face coverings. Results for one model, often don’t apply to another. Therefore, at a

minimum, it's important to know what make or model respirator or facepiece was tested.

Elsewhere I've read:

"This work demonstrates the qualitative fluid flow characteristics of a standard N95 respirator with and without an exhalation valve."

What is a "standard" N95 respirator?
Is this an N95 filtering facepiece respirator?
Is it an elastomeric half facepiece with N95 filters? Is it an elastomeric full facepiece with N95 filters? In this particular case the author eventually clarified the specific make and model respirators used. But, this is not always the case.

Another highly cited article from one of the most recognizable medical journals in the world compared the fitting characteristics of an FDA surgical mask, and various types of fabric face coverings to that of a single N95 filtering facepiece respirator. This article then ranked how well each category fits potential wearers. However, all of the testing was conducted on a single person. Consequently, the results only apply to the person tested and not anyone else.

Too many "researchers" with bad study designs are given free money from taxpayers. They use this money to buy instrumentation and may be clueless regarding how to use the instrument properly, design a study, and/or interpret results. The results are published and everyone believes its truthful because it comes from a well-known medical center or university. Once published, the researchers achieve greater notoriety, making it easier to get more money.

Pilot studies should have strong statements study limitations. Conclusions should be carefully written to ensure the results do not extend beyond the weaknesses and limitations of the study. Pilot studies do have an important role and can be used to support the need for additional research. However, results from pilot studies should be presented at scientific meetings where others can critique study design, results, limitations, and conclusions. They should rarely be published.

This nonsense must be stopped.

Bad studies don't contribute to our knowledge base, they confuse and distort it. The studies I selected for this column are not the worse I've seen. They just happen to be the ones still sitting on my desk.

Initially, the article on Graphine was my lead story, but I felt compelled to change the order. We often make fun of people getting information from the "internet". Now the same can be said of many published respirator and face mask studies.

Note: "Let's Think About This" is intended to provide readers information "outside the box" of traditional thinking. The content may at times be funny, light-hearted, spirited or identify unusual observations. It's tongue and cheek and does not necessarily represent the views of Dr. McKay.