Comparing Quality of Fitting of Different Filtering Face Pieces in a Healthcare Worker: A preliminary observational study

Chew Heng Hai[1], Koh Kim Hua[2], Gan Quan Fu[3], Kshtrashal Singh[4] Yu Chye Wah*[5]

[1,4,5] *School of Physiotherapy, Faculty of Allied Health Professions, AIMST University, 08100 Bedong, Kedah, Malaysia.*

[2]*School of Nursing, Faculty of Allied Health Professions, AIMST University, 08100 Bedong, Kedah, Malaysia.*

[3]*Pre-Clinical Sciences Department, Faculty of Medicine and Health Sciences, UTAR Sg Long Campus, Selangor, Malaysia.*

[1]*chewhenghai@gmail.com,* [2]*kkimhua7@gmail.com,* [3]*ganqf@utar.edu.my,* [4]*kshtrashal@aimst.edu.my* [5]*chyewah@aimst.edu.my*

*Corresponding author: Yu Chye Wah- chyewah@aimst.edu.my
School of Physiotherapy, Faculty of Allied Health Professions, AIMST University, 08100 Bedong, Kedah, Malaysia. Tel: +604-4298000 ext 6104

Abstract

A quantitative fit test was performed in a healthy adult who wore four different types of mask to assess the quality of fitting for respiratory protection. The results of portacount tests based on OSHA modified Quantitative Fit Test (QNFT) protocol showed surgical mask, double surgical mask, and N95 mask did not meet the good fit factor of minimum criteria. Surprisingly, stick-on mask Lekad emerged as an excellent filtering face piece with fit factor exceeding 200 and served to be a promising respiratory protection face piece in the future. However, more research is required to examine its properties in term of filtration efficiency, environment contamination protection, aerosol penetration, comfort and other quality characteristics in comparison to the existing filtering face pieces available in the market.

Keywords: COVID-19; filtrating face pieces; fit factor; fit test; N95; portacount

Introduction

One of the main reasons for vaccination in mass community is to create herd immunity in response to COVID-19 infection. Nevertheless, those who have been vaccinated could still stand a risk of infection, this pose serious doubt on whether vaccine alone is sufficient to fight the virus infection during the pandemic.

While the world is still yet to contain the first variant of COVID-19, many nations across the globe are challenged with more emergent variants which seem to be less effective with the available vaccine. Looking at the rapid rate of mutation to the current omicron variant, everyone is wondering of possibility that the world may face a variant of airborne disease which offers no protection from any vaccine to control such as HIV infection.

Considering the unique feature of mutation in corona virus, use of face mask as barrier method seems to be more reliable solution, additionally it serves as supplementary role to mitigate the spread, and enhance the opportunity to succed with vaccination plan.

In the battle against COVID-19 infection particularly at community level, maintaining strict standard operating procedure (SOP) with physical distancing, frequent hand washing or use of hand sanitizer, face mask plays a significant role to reduce the spread of COVID-19 (1). Even though face mask wore by many people is loosely fitted, but it does reduce

contamination of environment by infected patients. But at individual level, infection could be transmitted through leakage between facial region and mask. Thus, it becomes a main reason why even with mask wearing, general public are repeatedly advice to avoid 3Cs (confined space, congested area and close communication between people). On the other hand, healthcare providers are spending a lot of their time in work setting during the pandemic within 3Cs with high risk patients infected with the deadly corona virus.

Despite the use of N95 mask as the gold standard filtering face piece, coupled with practice of appropriate personal protective equipment (PPE), healthcare workers remain as the most susceptible group to contract COVID-19 infection (2). N95 mask could be a better protective tool if the quality of fitting is to be taken into consideration, as previous studies argued that good fit factor of filtering piece can enhance quality of protection from diseases transmission and environment contamination (3). The fit test can be conducted based on quantitative fit-test protocol. The standard test measures the number of ambient particles inside and outside the respirator mask. The ratio between both is called fit-factor. The fit-test is successful for a respirator mask when the fit-factor is equal or superior to 100 (4). In a study assessing the filter performance and facial fit of a sample of surgical masks in a dental setting, Quantitative fit factors for surgical masks with low particle penetration recorded a range from 2.5 to 9.6. None of these surgical masks exhibited adequate filter performance and facial fit characteristics to be considered respiratory protection devices (5). A comparative study between P100 and N95 filtering face pieces found P100 retained their fit better than N95 in hot, humid environments. However, at low to moderate work rates, physiologic impact for P100 was similar to N95 as exhalation valves appeared to offer no benefit. Both face pieces used in hot, humid environments did not add to body heat burden (6). Till present, there are no clear evidence to delineate the fit factors between various types of mask particularly surgical mask, N95 and other kind of masks. Hence this study attempts to identify these discrepancies and comparing the fit performance between them. With this in mind, the purpose of this preliminary laboratory study is to determine the fit factors of four different types of filtering face pieces worn by one healthy adult.

Methods

This is a preliminary observational study conducted in OSHA (Occupational Safety and Health Administration) certified laboratory located in Kuala Lumpur, Malaysia. The study has identified one healthy adult who has good knowledge on masking and showing interest on properties and performance of different types of masks. The subject was a 33 years old physiotherapy lecturer currently employed at private institute of higher learning. He was provided with four (4) different types of filtering face pieces (FFP) to undergo the fit test. The filtering pieces consist of (i) Normal surgical mask, (ii) Double mask: cloth mask on top normal surgical mask, (iii) N95 mask, (iv) New innovative stick-on mask, LEKAD.

All the FFPs were obtained without considering the fitting quality for the subject. The 4 types of FFP were posted to him and appointment for the fit test were made with the OSHA certified lab run by a authorized company One Gasmaster Sdn Bhd located in Kuala Lumpur. This company is associated with US company TSI, USA. The company has business dealing with NIOSH (National Institute of Occupational Safety and Health) and Ministry of Health Malaysia.

Fit tests were done based on OSHA's modified CNC (Condesation Nuclei Counter) Quantitative Fit Test (QNFT) protocol - 29CFR1910134 which is the world recognized standard and latest protocol accepted by OSHA. The protocol used Portacount respirator fit test which is currently the gold standard fit test for N95 mask.

The Respirator Fit testing was operated by a qualified technical expert who was trained in TSI, USA. He has vast experience in handling fit test with different users from various background from Oil & Gas, defence, first responders, health official and educational sector personnel.

The Portacount tests were done in sequential manner, first with surgical mask, then double mask, follows by N95 and lastly stick-on mask Lekad. For the double mask, cloth mask was used on top of normal surgical mask. N95 respirator mask was prescribed without prior fitting information of the subject. The subject has never undergone any fitting test before. The subjcet had volunteered and participated in the study. Informed consent was obtained and the

he was briefed on the study purpose and other possible risks and benefits of the study. The study was registered with AIMST university Human Ethic Committee (AUHEC No.0213/2021).

Results

Portacount respiratory fit tests were conducted on 4th June 2021 in licensed OSHA laboratory located in Kuala Lumpur. The subject was instructed to perform four (4) types of exercises which consist of bending over, talking, head side to side and head up and down. A total of 48 measurement results were obtained in the fit tests comprising 16 measurements from duration of fit tests in seconds, while 16 measurements were recorded on fit factor, and lastly 16 interpretations results were determined on the pass or fail status of portacount respiratory fit tests of different types of masks (Table 1). The mean duration of fit tests performed for each exercise is 25 seconds while the mean fit factor scored at 54.31.

Table 1: Characteristics of measurements from quantitative fit tests

	Mean (SD)	Frequency	Percentage (%)
Duration of fit test (sec)	35 (8.94)		
30		12	75
50		4	25
Fit factor	54.31 (86.87)		
4.00		2	12.5
5.00		3	18.8
6.00		4	25.0
7.00		2	12.5
8.00		1	6.3
200.00		4	25.0
Status			
Pass		4	25
Fail		12	75

Note: SD: Standard deviation

The results from portacount fit tests revealed that normal surgical mask and double surgical mask did not meet the criteria of good fit results (overall fit factor of 5 and 5.75 respectively). Surprisingly N95 mask supposed to be the gold standard mask also did not fare well in the fit test as it has only fit factor of 6.5. While the stick-on mask Lekad has very extremely high fit factor of 200+ in comparison with other three types of mask. The Kruskal-Wallis test was conducted and the results on fit factor showed significantly differences between stick-on mask Lekad and normal surgical mask, double surgical mask and N95 mask (H(3)=10.533, p<0.05) (Table 2).

Table 2: Results of portacount fit tests

Types of mask	Exercise				Overall fit factor	Overall status	P[a]
	Bending over	Talking	Head side to side	Head up and down			
	Duration/fit factor						
Normal surgical mask	50/5	30/6	30/5	30/4	5	F	
	Status						
	F	F	F	F			0.012
Double mask	50/6	30/6	30/6	30/5	5.75	F	
	Status						
	F	F	F	F			

					FF	Status
N95 mask	50/6	30/7	30/6	30/7	6.5	F
	Status					
	F	F	F	F		
Stick-on mask Lekad	50/200*	30/200*	30/200+	30/200+	200+	P
	Status					
	P	P	P	P		

Note: F: Fail status; P: Pass status; FF (Fit factor); Pass level: 100; a: Kruskal-Wallis test

To further demonstrate how significant the fit factor of stick-on mask Lekad in comparison to surgical mask, double mask and N95 mask. The figure below (Figure 1) show the fit factor achieved from portacount for stick-on mask Lekad is 30 times higher than N95 mask, whereas when comparing with normal surgical mask and double mask the improvement achieved by stick-on mask Lekad was even better with 40 times and 35 times higher respectively.
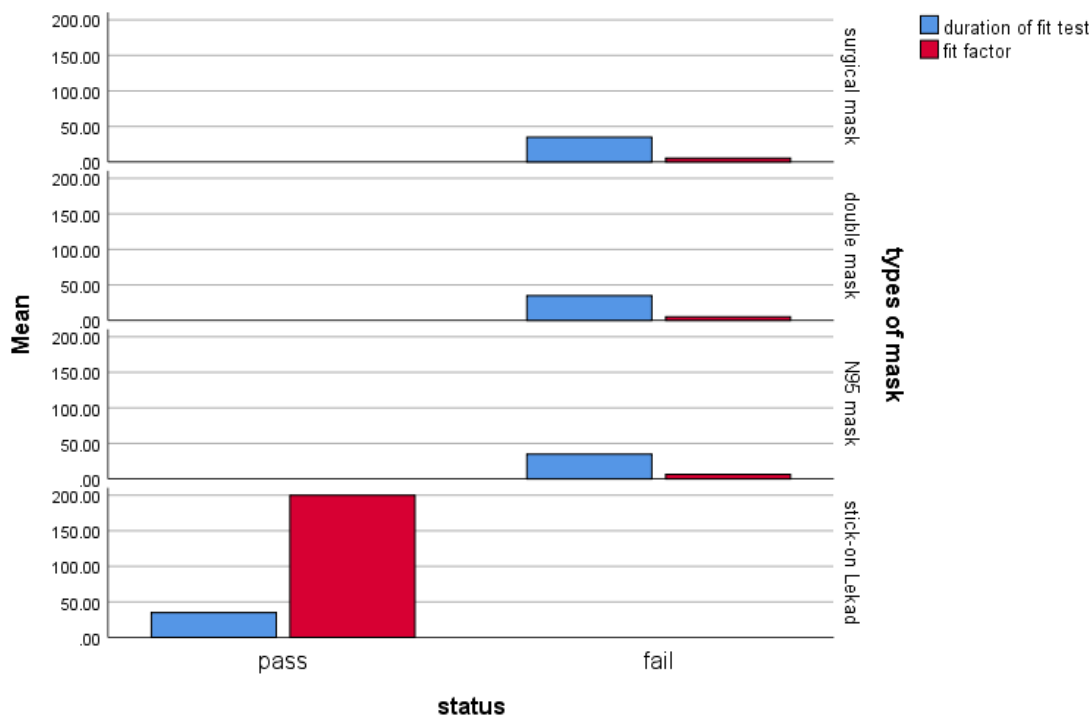

Figure 1: Distribution of fit test duration and fit factors by types of mask and status

Discussion

In prevention of health hazard among workers in industry, the hierarchy of the approach follow inverted triangle principle, in which PPE is a last in priority (7). In the protection against airborne hazards in industry, PPE, filtering face piece (FFP) are used to supplement other more effective strategies like elimination, substitution, engineering control and administrative control. Even though filtering face piece is last in hierarchy of prevention of airborne hazard in industry, N95 is classified as class 2 medical device which is regulated by FDA (Food Drug Authority) and National Institute of Occupational Safety and Health (NIOSH) are used. Besides that, the user needs to undergo fit test to be certified that they meet minimal standard of fitting to ensure sufficient quality of protection from industrial airborne hazards.

In medical field, healthcare providers are typically protected from airborne hazard with surgical mask. As we all know original purpose of surgical mask is to protect environment, typical example is to protect patient wound from droplets from surgeon. Mask is only

regulated by FDA as class 1 medical device, thus, it is subjected to least regulatory requirements compared to the rest of medical devices (8). There are some improvements now after thousands of healthcare providers lost their life in the COVID-19 pandemic. Now healthcare providers are encouraged to use N95 mask but fit testing is not commonly practiced in general medical field (9).

Industry airborne hazards pose health issue to the workers but the airborne hazard in medical field not only risking the life of the healthcare workers but also their family and society. During the enforcement of movement control order (MCO), most of the industries are closed but the healthcare providers are stretched beyond limit with relatively substandard PPE compared to that used by their industrial counterparts.

Even though the study is only on one subject but it gives a meaningful implication. The study may not provide strong conclusive findings but it gives rise to a number of concerns.

With a fit factor of 5, surgical mask indeed should be only be use to protect the environment not to protect the user especially in healthcare setting where the hazard is deadly airborne diseases. During COVID-19 pandemic where there is great shortage of N95 masks, the most important role of the surgical mask for healthcare provider is probably its placebo effect which give the healthcare providers some sense of security.

Event-though there are limited scientific evidences but there is clear scientific logic that double masking would increase protection to the wearer (10). The second layer if wear properly would reduce leakage, from the observation there is logical possibility it gives some benefits. It implies a more objective study needed to evaluate its potential benefit from the double masking.

N95 mask, being the gold standard filtering face piece recommended for healthcare workers. There are plenty of scientific papers highlight its superior compared to normal surgical mask. In short it should be stated that it is more logically rather than scientifically better than normal surgical mask. In a laboratory study on fitting filtering efficiency of various filtering face pieces, N95 has only 9% leakage compared to normal surgical mask which has 35% leakage (11). However, in a separate study it showed N95 mask showed no significant advantage to

protect nurses from influenza compared to those who used normal surgical mask (12).

This study focused on a single healthcare provider implies that N95 may not give any significant positive difference if it is not fitted properly. As what has been stated above, the N95 respirator was purchased online before the subject was determined for the study. In this study the average fit factor is only 6.5, about 1.5 unit and 0.75 unit better than that of normal surgical mask and double masking respectively. We understood the limitation of this study, being conducted on one single healthy subject might not be generalizable in other settings. However, this study has served an eye opening for alternative mask which provide a finding because general public including healthcare worker generally feel more secured with N95 respirator compared to normal surgical mask without sufficient attention to fitting. In occupational medicine, for optimal benefit, there are strict regulations requiring certain industry workers who need N95 as respiratory protective equipment to undergo fit testing with certification from authorized personnel at regular interval. In medical field, to serve our society, healthcare worker is facing invisible, colorless, odorless and deadly airborne pathogen, risking their life and their family safety as well. Sadly, for the noble professional which is sacrificing so much for our society, there is yet to have sufficient awareness about the importance of fitting of N95 respirator for optimal effect. There is still a lot to catch up comparing to other industry.

Stick-on mask Lekad which made from medical grade mask fabric with surgical grade adhesive along the borders on its inner surface. It has the enhanced quality of the adhesive. In this study stick-on mask Lekad recorded fit factor of more than 200, which is a maximum reading Portacount recorded for N95 respirator testing. In other words, stick-on mask Lekad by the appearance and material it is more of a surgical mask but functionally it is probably the best filtering face piece respirator. It also implied, in filtering face pieces, the available technology already able to give sufficient filtration efficiency, as the ultimate fitted filtration efficiency is greatly influenced by quality of fitting (13). Users especially healthcare workers should understand and aware the importance of fitted filtration efficiency, not only the filtration efficiency of the fabric.

Fitting with long and well accepted surgical adhesive indeed a very practical option deserve due attention to provide a better protection for healthcare providers with a simple stick-on mask with safety concern reflected by its excellent fit factor.

The fact that the medical world failed to develop a vaccine for HIV but we are able to manage HIV pandemic successfully with only barrier method called condom. The situation would be greatly different if condom has 35% leakage. This should create awareness of the importance of using barrier method like mask during COVID-19 pandemic to optimize the preventive measures in the war against corona virus beside vaccination program.

Conclusion

There are rooms for improvement on respiratory protection in medical field comparing to industrial area. The awareness of systematic objective fitting measurement is relatively low in medical fraternity and it deserves due attention urgently. Each and everyone especially healthcare workers should understand the importance of donning mask in regards to its actual functional quality of a filtering face pieces and its fit factors rather than filtration efficiency of the fabric face mask alone. A very practical user-friendly innovative stick-on mask Lekad warrants due attention for uses in medical field. A larger and more systematic studies need to be conducted to translate the facts discussed above into scientific language and be acceptable for implementation in evidenced based medicine.

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