J Korean Med Sci. 2021 Jul 19;36(28):e209
https://doi.org/10.3346/jkms.2021.36.e209
eISSN 1598-6357·pISSN 1011-8934

JKMS

Original Article
Medicine General & Policy

Respiratory Protection Effect of Ear-loop-type KF94 Masks according to the Wearing Method in COVID-19 Pandemic: a Randomized, Open-label Study

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Received: May 4, 2021
Accepted: Jul 6, 2021

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ABSTRACT

Background: Ear-loop-type Korean Filter 94 masks (KF94 masks, equivalent to the N95 and FFP2) are broadly used in health care settings in Korea for the coronavirus disease 2019 pandemic.
Methods: A prospective randomized open-label study was designed to identify differences in the fitting performance between mask wearing methods in three different types of KF94 mask with ear loops between January to March 2021. General-fitting involved wearing an ear-loop-type KF94 mask, and tight-fitting involved wearing a mask aided by a clip connecting the ear loops. Each of the 30 participants wore three types of masks according to a randomly assigned order in both methods and performed a total of six quantitative fit tests (QNFTs) according to the occupational safety and health administration protocol.
Results: All fit factors (FFs) measured by the QNFT were significantly higher for tight-fitting method with the clip in all KF94 masks ($P < 0.001$). However, the total FFs were very low, with a median (interquartile range) of 6 (3–23) and 29 (9–116) for general-fitting and tight-fitting, respectively. When wearing tightly, the horizontal 3-fold type mask with adjustable ear-loop length had the highest FF, with a median of 125, and the QNFT pass rate (FF ≥ 100) increased significantly from 4 (13%) to 18 (60%).
Conclusion: Even with sufficient filter efficiency, ear-loop-type-KF94 masks do not provide adequate protection. However, in relatively low-risk environments, wearing a face-seal adjustable KF94 mask and tight wearing with a clip can improve respiratory protection for healthcare workers.

Trial Registration: ClinicalTrials.gov Identifier: NCT04794556

Keywords: Respiratory Protective Devices; Quantitative Fit Test; COVID-19; N95 Filtering Facepiece Respirators; Infection Control; KF94 Mask

INTRODUCTION

Infection prevention and control measures are important for the safety of patients, healthcare workers (HCWs), and the community worldwide during the coronavirus disease 2019 (COVID-19) pandemic. The World Health Organization (WHO) currently recommends

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Trial Registration
ClinicalTrials.gov Identifier: NCT04794556

Disclosure
The authors have no potential conflicts of interest to disclose.

Author Contributions
Conceptualization: Yoon H. Methodology: Yoon H. Formal analysis: Yoon H. Data curation: Yang HJ, Yoon H. Writing - original draft: Yang HJ, Yoon H. Writing - review & editing: Jo IJ, Yoon H, Kang SY, Lee G, Park JE, Kim T, Lee SU, Hwang SY, Cha WC, Shin TG. Supervision: Yoon H.

droplet and contact precautions for HCWs caring for patients with COVID-19 and airborne precautions for settings where aerosol generating procedures or support treatment are performed.[1] For airborne precautions, it is recommended to wear a particulate respirator with at least National Institute for Occupational Safety and Health (NIOSH) certified N95 respirators (N95), European Union (EU) standard filtering facepiece 2 (FFP2), or an equivalent level of protection.[1]

Filtering facepiece respirators (FFRs) are labeled according to national regulations for filtering efficiency. Given the global shortage of N95 during the COVID-19 pandemic, the Korean filter 94 (KF94) mask was recommended for respiratory protection in Korea for situations involving any contact with suspected or confirmed COVID-19 patients under the guidelines of the Korea Center for Disease Control and Prevention (KCDC).[2] Korean standards follow European standards (EN149:2001), and are classified as KF80, KF94, and KF99, similar to the European standards FFP1, FFP2, and FFP3, according to their filtering efficiency (80%, 94%, and 99%, respectively) (**Supplementary Table 1**).[3,4]

However, in addition to the filtration efficiency, such FFRs can provide adequate protection only when the face seal fits tightly throughout the actual work process.[5,6] Therefore, the National Institute of Occupational Safety and Health (NIOSH) recommends conformance tests for wearers every year.[7] Also, fit tests should be used to identify respirators that suit best each individual and include training on how to best fit the masks prior to use.[8] However, since KF94 masks are generally used among HCWs without undergoing fit tests, the adequacy of respiratory protection is uncertain.

The KF94 masks use ear loops instead of an elastic head-band as in N95s. In our pilot tests, most of KF94 masks failed to fit properly when undergoing the occupational safety and health administration (OSHA) fit test protocol. The general fitting applied through ear loops may be weaker than a head-band, and this can be a severe concern that hinders mask fitting. Some people who wear ear-loop masks apply a mask clip that connects the ear loops behind the head to reduce pain around the ears. The use of this clip may also increase tension on the entire mask through additional tension on the ear loops; thus, it was reasoned that using a clip may improve the face seal of ear-loop-type masks.

Currently, there are no NIOSH-approved FFRs with ear-loop designs.[9] Furthermore, no study has assessed the adequacy of respiratory protection of ear-loop-type FFRs using a randomized design. Therefore, we aimed to evaluate the fitting performance of ear-loop-type KF94 masks by the quantitative fit test (QNFT) according to the OSHA protocol. In addition, by quantitatively comparing the "tight-fitting" method using a clip and the "general-fitting" method, we tried to evaluate whether the tight-wearing method improves the fitting performance of KF94 masks.

METHODS

Study design and settings

A prospective randomized open-label study was designed to identify differences in the fitting performance between mask wearing methods in three different types of KF94 FFRs with ear loops. This study was performed at a tertiary academic hospital between January to March 2021. The experiments were conducted in an isolated room in the hospital, where the temperature and humidity were controlled at approximately 23°C and 30%, respectively.

Participants

We recruited 30 healthy HCWs aged 18–65 years old with experience in wearing FFRs working in the hospital. Participants who performed OSHA FFR fit tests at least once within a year were included. Individuals with expected difficulties in wearing masks or undergoing OSHA fit tests because of factors such as a facial anomaly, lung disease, or lower back disorder, were excluded. The sample size was calculated based on a pilot study of 10 participants, which examined the FF of general-fitting. The mean FF was 20.3, and the log-transformed FFs were assessed due to skewed data, which was 1.98 (standard deviation: 1.34). We assumed that the FF for tight-fitting would increase by 50%, with an α value of .05, and a β error of .10 (power = 90%) for two-sided hypothesis testing. The estimated sample size calculation revealed a required sample of 24 participants. Therefore, 30 participants were enrolled to account for a 20% dropout rate.

Measurements

Preparation

Participants were randomly assigned to groups A, B, and C using a block randomization method to reduce learning effects. There were five blocks, with six masks each (1 = A group, 2 = B group, 3 = C group), and a three-arm, parallel design was performed using SAS (SAS Institute, Cary, NC, USA). After briefing participants of the study procedures, mask fitting and user-seal-check were performed. For user-seal-check, positive and negative pressure checks were performed by the wearer to determine if the respirator was being properly worn.[10] Participants were asked to inform the investigator if they felt that the mask was slipping off during QNFT. Participants completed a questionnaire to collect data on their demographic characteristics.

KF94 FFRs with ear loops

To generalize the fitting performance of KF94 masks, three types of KF94 masks with different shapes were selected for this study. These masks are commonly used in hospital settings in Korea and have been certified by the Korea Food & Drug Administration (KFDA) as the Korean standard FFRs (**Supplementary Table 1**). For each mask, the size generally recommended by the manufacturer for adults was selected. The first mask was a horizontal 3-fold type mask (Welkeeps, Seoul, Korea). The second was a horizontal 3-fold type mask with an adjustable ear-loop length for the face seal (Yuhan-Kimberly, Seoul, Korea). The third was a vertical 2-fold type mask (Yuhan-Kimberly, Seoul, Korea). Furthermore, we used a mask clip that could fix both ear loops behind the head, and the degree of fitting was adjusted in three steps (**Fig. 1**).

QNFT

For the QNFT, we used a TSI model 8026 particle generator and PortaCount 8048 accelerator fit tester (TSI Inc., Shoreview, MN, USA). While wearing the respirator, participants completed

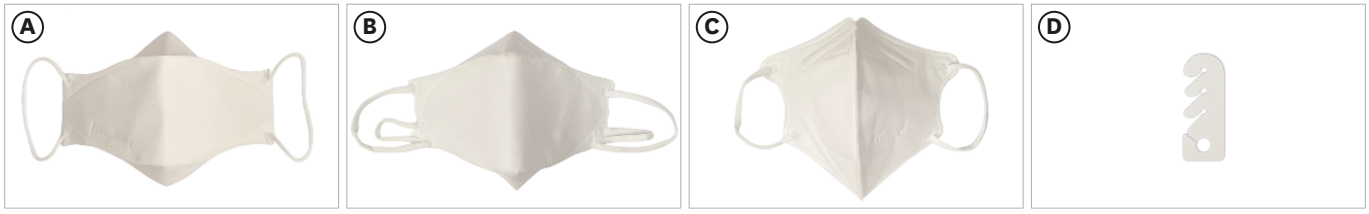

Fig. 1. KF94 mask types and clip.
(**A**) horizontal 3-fold mask, (**B**) horizontal 3-fold mask with adjustable ear loops length, (**C**) vertical 2-fold mask, (**D**) clip.

https://doi.org/10.3346/jkms.2021.36.e209

four test exercises according to the OSHA Quantitative Fit Testing Protocol (Modified Ambient Aerosol CNC Quantitative Fit Testing Protocol for Filtering Facepiece Respirators) and the total score was calculated.[11] A fit factor (FF) of over 200 was scored as 200 by the tester, and a FF above 100 was defined as having adequate protection and passing the QNFT.

Intervention

In this study, we used two types of wearing methods with three types of KF94 masks. The general-fitting method involved wearing a mask with ear loops, and the tight-fitting method involved wearing a clip that connected ear loops on the occiput after wearing a mask according to the general method (**Fig. 1**). Participants wore masks according to their assigned groups. Each participant wore three types of masks in both general and tight fitting methods. After general-fitting QNFT measurement, masks were not changed during tight-fitting QNFT measurement. They performed a total of six QNFTs, in the following order: After wearing each mask, a user-seal-check was performed by the participants, and the mean FF was recorded for 10 s. Then, an additional mask fitting adjustment was performed while the participants checked the real-time FFs via a monitor. After reaching the maximum fitting factor for 2 min, the FF value was measured when the ± 10 range of the peak value was held for 10 s, and the QNFT protocol was initiated (**Fig. 2**).

Outcomes

The primary outcomes included the total FFs of the QNFTs according to the wearing method of the three types of KF94 masks. The secondary outcomes included the FFs after user-seal-check

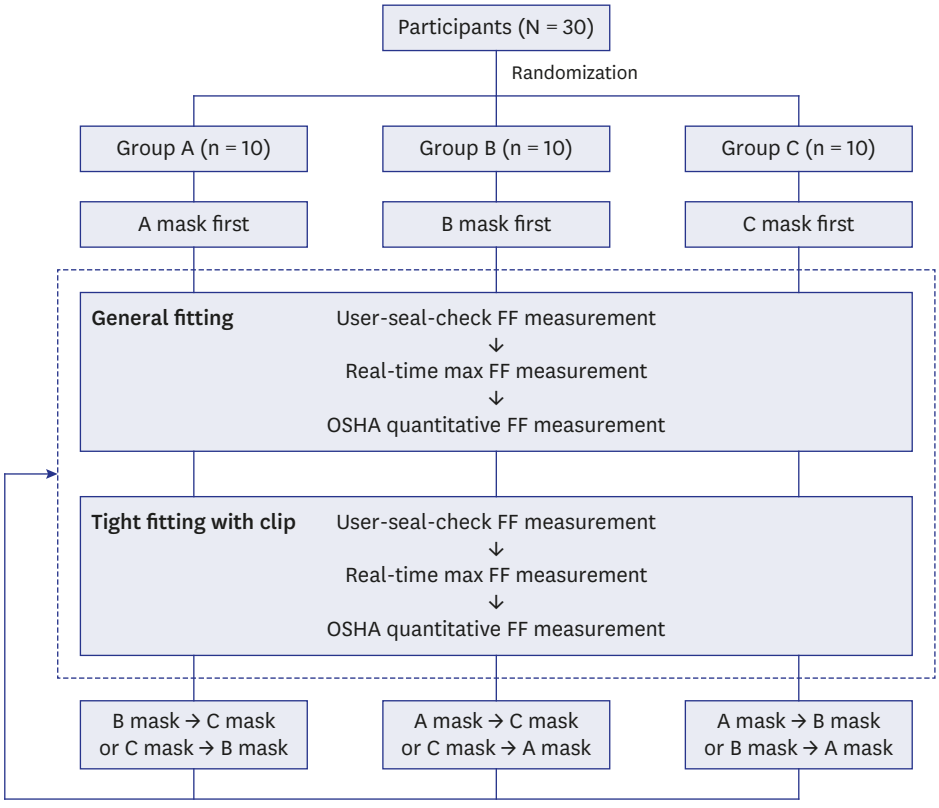

Fig. 2. Study flow.
A: horizontal 3-fold mask, B: horizontal 3-fold mask with adjustable ear-loops length, C: vertical 2-fold mask.
FF = fit factor, OSHA = occupational safety and health administration.

https://doi.org/10.3346/jkms.2021.36.e209

and real-time adjustment. In addition, we evaluated the passing rate of the QNFT according to the wearing method. We also compared the FFs of the three types of KF94 masks. Furthermore, we recorded the event of mask loosening during the fit test for each mask.

Statistical analyses

Standard descriptive statistics were used to present all the data. Continuous variables were presented as median (interquartile range [IQR]). Categorical data are presented as numbers with percentages. Since the data were skewed, the log-transformed FFs were assessed before statistical analysis and used for all subsequent analyses. Repeated-measures analysis of variance or generalized estimating equations were used to compare the FFs or passing rate of the QNFTs for the three mask types according to the wearing method. Paired t-tests or Wilcoxon signed-rank tests were used to compare the FFs according to the wearing method for each mask type. McNemar's test was used to compare the passing rate of the QNFT according to the wearing method. Bonferroni's correction was performed for all results of each subgroup analysis. SAS ver. 9.4 software (SAS Institute) was used to perform all statistical analyses.

Ethic statement

The study was conducted according to the guidelines of the Declaration of Helsinki and written informed consent was obtained from each participant. This study was approved by the Institutional Review Board (IRB) of Samsung Medical Center (IRB-ID 2020-10-154-002; 15 December 2020) and registered with Clinicaltrials.gov on 08/03/2021 (NCT04794556) (study protocol in **Supplementary Data 1**).

RESULTS

All 30 participants completed the study. Of these, 15 (50%) were women; the median age was 30 years (IQR, 28–33). Most participants were doctors (77%, n = 23), with an average clinical experience of 4 (2–7) years. Most participants (74%) had a normal body mass index (**Table 1**).

The total FF of the QNFT according to the wearing method was significantly higher for the tight-fitting method with a clip for all masks ($P < 0.001$). However, the total FFs of KF94 masks were very low, with a median of 6 (IQR, 3–23) and 29 (9–116) for general and tight fitting, respectively. FFs after user-seal-check and real-time adjustment increased significantly when KF94 masks were worn tightly for every mask type ($P < 0.001$). Regarding

Table 1. Demographics

Variables	n = 30
Sex, female (%)	15 (50)
Age, yr (median, IQRs)	30 (28–33)
Occupation, (%)	
Doctor	23 (77)
Nurse	1 (3)
Emergency medical technician	6 (20)
Occupational experience, yr (median, IQRs)	4 (2–7)
Body mass index, BMI (%)	
Underweight (< 18.5)	4 (13)
Normal (18.5 ≤ BMI < 25)	22 (74)
Overweight (25 ≤ BMI < 30)	4 (13)

Data was presented as median with interquartile range (IQR) or number (%).
Body mass index was categorized according to the World Health Organization classification system.

https://doi.org/10.3346/jkms.2021.36.e209

Table 2. FF comparison by wearing methods

Kinds of mask	General fitting	Tight fitting	*P* value
A (n = 30)			
User-seal-check FF	4 [3, 9]	28 [8, 168]	< 0.001
Real-time max FF	7 [4, 14]	87 [19, 200]	< 0.001
Total FF	4 [3, 8]	27 [8, 83]	< 0.001
Passing rate, n (%)	1 (3)	4 (13)	0.250
B (n = 30)			
User-seal-check FF	53 [24, 118]	200 [85, 200]	< 0.001
Real-time max FF	102 [46, 200]	200 [200, 200]	< 0.001
Total FF	39 [21, 69]	125 [67, 189]	< 0.001
Passing rate, n (%)	4 (13)	18 (60)	< 0.001
C (n = 30)			
User-seal-check FF	3 [2, 4]	10 [5, 58]	< 0.001
Real-time max FF	4 [3, 8]	18 [8, 200]	< 0.001
Total FF	3 [2, 5]	9 [5, 23]	< 0.001
Passing rate, n (%)	1 (3)	3 (10)	0.472
Total[a] (n = 90)			
User-seal-check FF	5 [3, 32]	46 [8, 200]	< 0.001
Real-time max FF	12 [4, 72]	141 [19, 200]	< 0.001
Total FF	6 [3, 23]	29 [9, 116]	< 0.001
Passing rate, n (%)	6 (7)	25 (28)	< 0.001

Data are presented as median with interquartile range [IQR] or number (%). *P* value was adjusted *P* value by Bonferroni's correction.
A = horizontal 3-fold mask, B = horizontal 3-fold mask with adjustable ear-loops length, C = vertical 2-fold mask, FF = fit factor.
[a]It was an analysis including all types of masks, its types were adjusted.

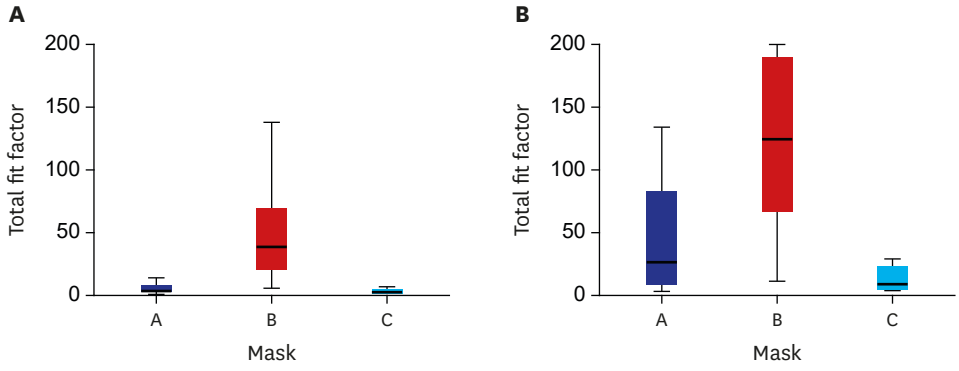

Fig. 3. Total fit factors of general fitting (**A**) and of tight fitting (**B**) for the 3 KF94 masks.
A: horizontal 3-fold mask, B: horizontal 3-fold mask with adjustable ear loops length, C: vertical 2-fold mask.

passing rates (FF ≥ 100), it was increased significantly from 4 (13%) to 18 (60%) after tight-fitting of only the horizontal 3-fold mask with adjustable ear-loop length (**Table 2**, **Fig. 3**).

When comparing the types of KF94 masks, the total FFs for general-fitting and tight-fitting of masks A, B, and C (median, IQR) were 4 (3–8), 39 (21–69), 3 (2–5), and 27 (8–83), 125 (67–189), and 9 (5–23), respectively. The type B mask with adjustable ear-loop length had a significantly higher FF, while the vertical 2-fold type C mask had a significantly lower FF in both wearing methods (**Table 3**).

There were two events of mask slipping during the test with the mask with an adjustable ear-loop in tight-fitting.

https://doi.org/10.3346/jkms.2021.36.e209

Table 3. FF comparison by mask type

Variables	KF94 mask			*P* value		
	A	B	C	A vs. B	A vs. C	B vs. C
General fitting						
User-seal-check FF	4 [3, 9]	53 [24, 118]	3 [2, 4]	< 0.001	0.003	0.001
Real-time max FF	7 [4, 14]	102 [46, 200]	4 [3, 8]	0.001	0.019	< 0.001
Total FF	4 [3, 8]	39 [21, 69]	3 [2, 5]	0.001	0.001	0.001
Passing rate, No. (%)	1 (3)	4 (13)	1 (3)	0.333	[a]	0.333
Tight fitting						
User-seal-check FF	28 [8, 168]	200 [85, 200]	10 [5, 58]	0.001	0.223	< 0.001
Real-time max FF	87 [19, 200]	200 [200, 200]	18 [8, 200]	0.003	0.302	< 0.001
Total FF	27 [8, 83]	125 [67, 189]	9 [5, 23]	0.001	0.014	0.001
Passing rate, No. (%)	4 (13)	18 (60)	3 (10)	0.001	> 0.999	0.001

Data are presented as median with interquartile ranges [IQRs] or number (%). *P* value was adjusted *P* value by Bonferroni's correction.
A = horizontal 3-fold mask, B = horizontal 3-fold mask with adjustable ear-loops length, C = vertical 2-fold mask, FF = fit factor.
[a]It was not analyzed at the same frequency.

DISCUSSION

KF94 masks are broadly used and recommended in Korea as universal masks for the COVID-19 pandemic. However, there have been no quantitative studies on the fitting performance considering inward leakage. In this study, the FFs of the tight-fitting method with a clip were significantly higher in all recorded variables for every mask type, including the user-seal-check FF, real-time monitored maximum FF, and total FF ($P < 0.001$). However, the tight-fitting median FF was 29, which was still lower than 100, the OSHA fit test passing criteria. That is, the ear-loop-type KF94 masks did not provide sufficient tension, so the face seal was not maintained with movement. Therefore, this study proved that KF94 masks with ear loops cannot provide adequate respiratory protection when dealing with highly contagious patients, such as those with COVID-19, in a healthcare setting.

However, these results are not specific to KF94 masks. In a study on the fitting performance of 10 types of N95, 54% of the participants were not adequately protected by any of the FFRs tested.[12] Additionally, a more recent study found that the fit test passing rates of four N95s were below 50%.[13] In a simulation study using a manikin, it was found that a poorly fitting N95 had a 30% lower infectious virus blocking rate than a tightly fitting respirator, and did not show any beneficial effect compared to unsealed surgical masks.[14] Therefore, the above mentioned studies showed that it is not easy to properly wear FFRs. On the other hand, one study demonstrated that the fitting performance was increased by approximately 50% after training in FFR wearing.[12] In our study, the FFs were significantly increased in all masks during self-mask adjustment after the user-seal-check. Furthermore, although the type B mask showed the highest FF in most of the participants, a small number of participants showed a better fit with other mask types. Therefore, it is important to choose a suitable FFR for each individual and learn how to wear the mask tightly in advance, preferably with a fitting test.

During the COVID-19 pandemic, studies have been conducted on how to improve the mask fit of various FFRs considering the global shortage of N95s. Han et al.[15] introduced a tight fitting net in their study, which consisted of a flexible plastic net connected to the strap, which covers the exterior surface area around the filtering media, and found that it significantly increased the fitting performance. For medical procedure masks, modifications that enhanced the fit between the mask and the wearer's face, that is, simply tying the ear loops and tucking the corners of the mask against the wearer's cheeks, visibly improved the mask fit

and increased the filtration efficiency from 38.5% to 60.3%.[16] Furthermore, sealed surgical masks using adhesive medical tape led to a marked reduction (60–98%) in inward leakage of aerosols in all participants.[6] However, complex modifications of the mask and the wearing method may not be used much because it is difficult to apply these interventions in the actual workplace. In this study, the FFs of all ear-loop-type KF94 masks increased significantly when wearing tightly with a simple modification using a clip. In particular, face seal adjustable KF94 mask had a significantly higher FF in both general and tight wearing methods, and its FF and QNFT pass rate increased significantly when using the clip. Therefore, our study showed that the fitting performance of an ear-loop-type mask can be properly maintained when the mask is more tightly fitted to the face, which occurs when more tension is applied through the ear loops by adjusting the ear-loop length or using a clip.

Even if the N95s become more accessible, KF94 masks are preferred in general healthcare settings in Korea. The important factors when choosing a mask type are not only safety but also the comfort of wearing the mask, especially if prolonged wearing is needed. In a study on long-term use of N95, blood CO_2 levels of nurses became significantly elevated and many subjective symptoms, such as perceived exertion, dyspnea, headache, and lightheadedness also increased over time compared to beginning-of-shift baseline measures.[17] Over time, touching or non-fitted wearing of FFRs due to discomfort can be a major factor that hinders adequate respiratory protection of HCWs. Considering that the clip used in this study were originally designed to improve wearing comfort by relieving pain behind the ears, especially in prolonged wearing, the results indicate not only a more comfortable but also a safe way to use ear-loop-type KF94 masks.

For one participant with a beard, the FFs of all masks were extremely low (below 10), and there was no significant change even with the clip. This proves once again the importance of adjusting the mask to the face, and it is better to remove the face-seal area hair when wearing FFRs, according to the CDC recommendation for facial hairstyles and FFRs.[18] Furthermore, when the fit test was performed after tight-fitting of the adjustable ear-loop mask, there were two cases when the ear loops connected to the clip slipped and the mask became loose. This may be a disadvantage of wearing a head-strap type mask. In N95 donning, downward slippage of the top strap off the crown of the head is a relatively frequent occurrence with general use, leads to a negative impact on the fit and, by extension, on the protection afforded to the wearer.[19,20] When the ear-loop-type KF94 mask is tightly connected with a clip, it is necessary to check in advance if there is any slipping after head movement and adjust the mask according to the hairstyle. Eliminating factors that interfere with the facial seal and proper wearing of respirators are paramount to minimize the risk of infection.

In this study, we demonstrated that an adequate face seal cannot be achieved with ear-loop-type KF94 masks. However, our results suggest that selected adjustable models of ear-loop-type FFRs modified using a clip can provide significantly improved respiratory protection over general ear-loop masks. Therefore, if the FFRs labeled according to their own national regulations are of the ear-loop type, a modified fitting, such as using clips or adjusting the ear-loop length, is indicated to increase the mask-face seal. In addition, to improve the respiratory protection of HCWs during the COVID-19 pandemic, it is important to choose a suitable FFR for each individual and teach them how to wear the mask tightly through a fit test in advance.

Our study had certain limitations. First, we used only three KF94 types with ear loops of different shapes; thus, these may not be representative of all KF94 masks or all ear-loop-type

https://doi.org/10.3346/jkms.2021.36.e209

masks, and there is a limit to generalize the results. Furthermore, although KF94 masks with filtration efficiency certified by the KFDA were used, comparison with N95 or EU FFP2 was not carried out. Thus, it is difficult to draw conclusions regarding the effectiveness of respiratory protection compared to that of these masks. Second, the total FF of QNFT was measured only once according to the wearing method for each mask per participant. Even if the participants wear the same mask, in the same way, the FF may change for each test, limiting the interpretation of the results due to the single-measure design. Third, QNFT was conducted according to the OSHA protocol consisting of some activities, which might differ from the actual clinical activities. Moreover, the QNFT conducted within 3 min cannot guarantee whether the protective effect will be maintained during prolonged use. Forth, after general-fitting QNFT measurement of each mask, masks were not changed during tight-fitting QNFT measurement, which may have affected the results. However, the FFs of the tight-fitting method were significantly higher in all measurements for every mask type, thus it does not seem to be a meaningful change. Fifth, in addition to the wearing method, we did not consider related factors, such as face size and presence of a beard, that interfere with mask fitting. Sixth, we did not assess the user experience of KF94 masks according to the wearing methods and mask types. Finally, we did not consider the expediency and infection risk associated with the donning and doffing of masks.

In conclusion, even with sufficient filter efficiency, KF94 masks with ear loops do not provide adequate protection. However, in relatively low-risk environments, wearing a face-seal adjustable KF94 mask and tight wearing with a clip can improve respiratory protection for HCWs.

SUPPLEMENTARY MATERIALS

Supplementary Data 1

Click here to view

Supplementary Table 1

Comparison of respirator approval standards for KF masks and EU FFP respirators

Click here to view

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