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Case Report

Effect of the tight fitting net on fit performance in single-use filtering facepieces for Koreans

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Abstract: To get a better fit performance of filtering facepieces, a tight fitting net (TFN) was invented. This study was carried out to evaluate whether the TFN improves fit performance using a quantitative fit test (QNFT). The existing mask was of cup type with an aluminum clip on the nose bridge. The TFN mask was the same as the existing mask, but attached a TFN instead of aluminum clip. One hundred subjects (male 52, female 48) were selected to match fourfold in Korean 25-member facial size category for half-mask (KFCH). Fit factors (FFs) were measured using a QNFT by a Portacount®Pro+8038. Three QNFTs for each mask on the same subject was conducted and geometric mean FF (GMFF) was determined. The mean and median GMFFs of the TFN masks had higher than those of the existing mask (p=<0.001). The existing masks had tendency to have higher GMFFs with common facial size categories, while the TFN masks were regardless of facial size. The result indicates that putting even pressure on the entire parts of filter media would improve fit performance. In conclusion, to get a good fit when wearing filtering facepieces, a TFN would be an alternative to mask designing.

Key words: Tight fitting net (TFN), Fit performance, Single-use filtering facepiece, Fit test, Respiratory Protective Equipment (RPE)

Introduction

The differences of peoples' faces are significant among females, males, and representatives of different ethnic groups. Facial differences among different gender and ethnic groups imply that one kind of respiratory protective equipment (RPE) may be unlikely to fit all. If the RPE does not fit, it will not ensure that the wearer is protected. Therefore, an appropriate face-fit of the RPE is an essential factor to consider. Wearing a poorly fitting RPE may be more dangerous than not wearing a RPE at all, because the wearer may think s/he is protected, when, in reality, s/he is not[1]. Unlike several countries including USA, Canada, UK and so on[2–5], there is no mandatory fit test regulation in Korea, so the fit performance of a RPE seems to be more important to prevent the wearer from potential hazards.

To improve fit performance of a RPE, an elastomeric half-mask was designed to have a better fit for Koreans[6]. It is generally thought that improving fit performance of a single-use (or disposable) filtering facepiece (hereafter referred to as 'filtering facepiece') is more difficult than that of an elastomeric facepiece. The reason behind this is that, as compared to the latter, the former has limitations, such as shape and elasticity, to match face shape with the inner contact area. There are many design methods for filtering facepieces to increase fit performance, for example, cup-shaped, aluminum clip, or embossing form in the inner surface.

Besides suitable RPE designing, to get a better fit to RPE the way how to don it more properly and tightly is very

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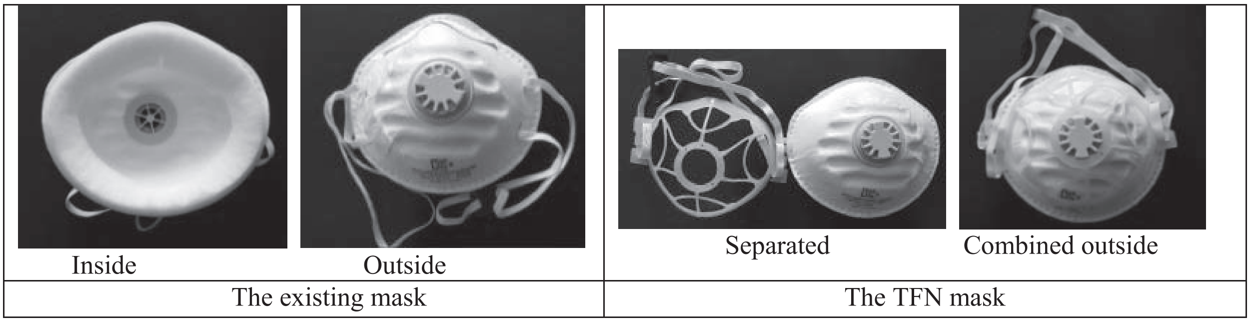

Fig. 1. Types of single-use filtering facepieces used in the present study.

important. However, compared with an elastomeric half-mask a filtering facpiece are little elastic and not structurally easy to wear tightly, so it may be difficult to provide a good fit for a wearer. To solve this problem, as the way of a better fit for filtering facepieces, Shinyongsa Co. in Korea has developed a tight fitting net (TFN) (see Fig. 1). The TFN consists of a flexible plastic net connecting to the strap, which covers the exterior surface area around the filtering media. Pulling the strap will tighten the contact inner part of the filter media to the wearer's face, ensuring a tight fit. The TFN has several patents from many different countries including Korea (Patent No. 10-1013242), the U.S. (Patent No. 9079051B2), the U.K. (Patent No. 2425875), and China (Patent No. 12844080).

Meanwhile, fit performance of RPE can be explained by fit factor (FF) determined by quantitative fit test (QNFT). FF means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn[2]. Although the FF is not measured when RPE is used in the workplace[7, 8], it is one of the most fundamental and important parameters that describe fit performance of respirators: it provides some indication, albeit incomplete, of the expected performance of the respirator for the wearer in the workplace[9].

This study aimed to evaluate whether the TFN improves fit performance in a filtering facepiece when wearing it using a QNFT.

Materials and Methods

Two types of single-use filtering facepieces

Figure 1 shows two types of filtering facepieces used in the present study. They are the same model respirators (SY2500) (Shinyongsa Co., Korea), which consist of the cup-typed filter media, exhalation valve, and strap. Filter media are the first class in Korea, the same as the P2 filter of BS EN 143[10], capturing at least 94% of airborne particles at the airflow of 95 L/min. Nose clip made of aluminum is generally used to match the wearer's face with the mask on the bridge of the nose. A non-woven sponge form is attached in the inner surface to increase fit performance. The difference between two types is that one has nose clip and felt sponge form without the TFN (hereafter referred to as 'existing mask'), while the other is attached the TFN without nose clip instead (hereafter referred to as 'TFN mask'). The TFN is made of flexible plastic, the strap tab on which can be freely adjusted for an appropriate face-fit by the wearer her/himself.

Development of Korean 25-member male and female facial size category for half-mask fit test (KFCH)

Korean 25-member male and female half-mask test panel (KMFHP) was developed by Han in 1999[11], but it was neither officially approved by governmental authority nor used by manufacturers. It was necessary to determine Korean representative facial size for male and female and members for half-mask fit test in the present study. So using recent data Korean 25-member male and female facial size category for half-mask testing (KFCH) was developed on the basis of face length and lip length as the similar methodology of previous researches (bivariate approach)[11–14]. Facial dimension data were chosen from the general Korean population (male 1822, female 1846) aged between 19 to 70 yr old in 2003 to 2004[15]. To establish the limits for faces that included approximately 95% of the males and females, the upper limits for face length and lip length were set by adding two standard deviations (SD) to male subject mean values. The lower limits were similarly defined by subtracting two SD from the female subject means. The upper limit for face length was 131.5 mm, and for lip length 60.5 mm. The lower limit for face length was 89.5 mm, and for lip length 36.5 mm. The rect-

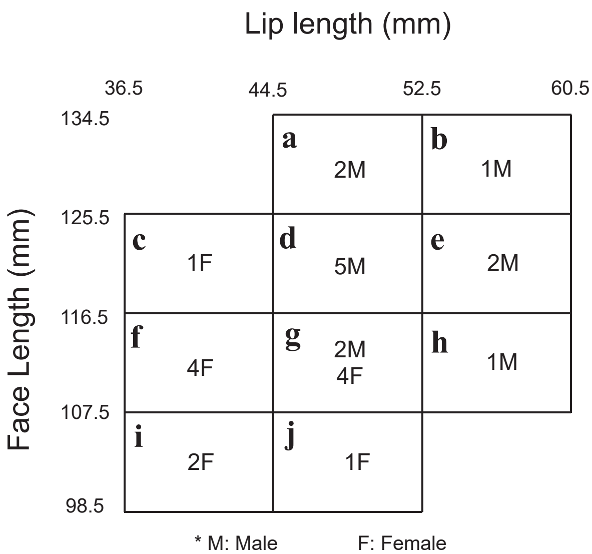

Fig. 2. Korean 25-member male and female facial size category for half-mask fit test (KFCH) in the present study.

angle enclosed by these limits is conveniently subdivided into 10 categories by 10.5 mm for face length and 8.0 mm for lip length. The numbers of each category were determined by the percentage proportion of male and female occupied in general population (see Fig. 2).

Subjects

A total of 125 student volunteers aged between 19 and 27 yr old were recruited from Inje University. The participants, who had hardly any experience of wearing respirators, had no scars and infirmity on their faces. Since the EN standard requires that the faces of the test subjects shall be described (for information only) by four facial dimensions[16], four facial dimensions (length, width, depth of the face and length of the mouth) were measured using a spreading and sliding caliper (Siber Hegner, Zurich, Switzerland). Every participants did not match exactly each facial size category numerically in KFCH. There was a surplus of participants in some categories, whereas there was a shortage of participants in the other categories. One hundred subjects (male 52, female 48) of the 125 participants were ultimately selected to match fourfold in KFCH.

Fit performance testing

Since fit factor (FF) is the measure of the sealing of a respirator to the face of the wearer, as determined by quantitative fit test (QNFT), the quantity of FF can explain how to face-fit, in other words, fit performance. QNFT was tested using Portacount®Pro+8038 respirator fit tester (TSI Inc., Shoreview, Minn.) and conducted according to the protocol written in the Occupational Safety and Health Administration (OSHA) regulations for the United States[2]. Before fit-testing, all subjects were taught to conduct how to wear RPE properly and user's seal checks because FF was influenced by RPE education program[17]. Positive-pressure seal checks were performed putting palm on the exhalation valve and blowing to determine whether the respirator was properly adjusted to the face of the subject. If a subject experienced a leakage between the skin of the face and the mask facepiece, the subject donned the respirator again, and the seal check was repeated. Aerosol sampling probe was located at the center between mouth and nose. During the fit test, the subjects were asked to perform seven fit-test exercises: (1) normal breathing, (2) deep breathing, (3) head movement from side to side, (4) head movement up and down, (5) reading, (6) bending, (7) normal breathing. Each exercise was performed for 60 sec. The three QNFTs for each mask on a subject were conducted in crossed-order succession of the existing mask followed by the TFN mask (existing→TFN→existing→TFN), with a 5-min break between successive fit-tests.

Questionnaire survey

After fit testing, all subjects were asked to respond the simple questionnaire, in which comfort differences between two masks, main leak point(s), difficulty in breathing, pains from strap tightening and so on, were written.

Statistical analyses

The goodness-of-fit-test was conducted using the LogNorm2 statistical package (InTech Software Corp., Tulsa, Okla.). The geometric mean of fit factors (GMFFs) and geometric standard deviation (GSD) were determined for comparison. Natural logarithm-transformed fit factors (ln-FFs) were assessed before statistical analysis and used for all subsequent analysis. The differences of the means of ln-FFs between males and females were compared using a two-tailed *t*-test. A paired *t*-test was conducted to determine if ln-FFs of the existing mask differed from those of the TFN mask. A single pair involved one subject and was the mean of the subject's three ln-FFs with the existing mask and the mean of the same subject's three ln-FFs with the TFN mask. An ANOVA test was conducted to compare the means of the ln-FFs among the different facial size categories. The statistical tests were conducted using the SPSS statistical package (IBM Corp., Armonk, NY).

Table 1. Descriptive statistics of fit factors between two models

	Existing mask						TFN mask						
	Male (N=52)		Female (N=48)		Total (N=100)		Male (N=52)		Female (N=48)		Total (N=100)		
	GM[a]	GSD[b]	GM	GSD	GM	GSD	GM	GSD	GM	GSD	GM	GSD	
Maximum	114	1.43	104	1.58	114	1.43	198	2.16	174	1.80	198	2.16	—
Mean	45	1.73	37	1.60	42	1.62	71	1.58	60	1.60	67	1.63	p=<0.001[c]
Median	38	1.41	32	1.45	37	1.43	66	1.48	55	1.45	61	1.43	p=<0.001[c]
Minimum	11	1.03	9	1.04	9	1.03	16	1.23	12	1.16	12	1.16	—
	$p=0.024$[d]						$p<0.016$[d]						
The numbers of subjects for the existing mask having higher GMFFs than the TFN mask were six only.													

[a] GM: geometric mean of three replicates with the same mask on the same subject
[b] GSD: geometric standard deviation of three replicates with the same mask on the same subject
[c] The results of *t*-test between the existing and the TFN masks
[d] The result of *t*-test between males and females

Ethics

Prior to conducting research, the research design and procedure were approved by the Inje University Institutional Review Board. Every subject passed physical examination at Paik's Hospital of Inje University before wearing a respirator.

Results

Comparison of fit factors between two masks

The results of normality test demonstrated that the aggregated fit factors of the existing mask and the FTN mask had both log-normal distributions. The result agreed with those reported in previous researches[18–20]. Accordingly, statistical analysis of the paired *t*-test was conducted using ln-FFs. Table 1 shows descriptive statistics for the two masks. Since the GM and GSD were determined by three tests on the same subjects for each mask, and thus the numbers of GM and GSD were the same numbers of subjects (male 52, female 48). The maximum, mean, median and minimum were calculated from each GM and GSD.

The existing mask had a mean GMFF of 42 and a median GMFF of 37 for aggregated values for all subjects; in comparison, the TFN mask had a mean GMFF of 67 and a median GMFF of 61. The paired *t*-test using ln-FFs showed that both of mean and median of the GMFFs for the TFN mask were significantly higher than those for the existing mask ($p=<0.001$). Most of the individual GMFFs (94%) of the three tests conducted on the same subjects for the TFN mask were much higher than those for the existing mask excluding six subjects. Consequently, most of the TFN mask would show a better fit performance than the existing mask: namely, the TFN can generally improve fit performance when wearing filtering facepieces.

The mean of GMFFs for male subjects were significantly higher than the corresponding values for females in all two masks ($p=0.024$ for the existing mask, $p=0.016$ for the TFN mask).

Fit factors with KFCH

To better clarify how fit performance would be influenced by facial size, fit factors in KFCH were analyzed. Figure 3 shows that the number of subjects, GMFFs and GSDs of the existing mask and TFN mask, were calculated according to individual GMFFs and GSDs calculated from three fit-tests on the same subject. The values out parenthesis were calculated by the existing mask, while those in parentheses were determined in the TFN mask.

In the case of the existing mask, the facial size category "g" had the subject number of 24 (male 8, female 16) and the highest GMFF of 65, the category "d" having the subject number of 20 and the second-high GMFF of 60, followed the category "e" the third-high of 54. They had relatively high GMFFs compared with the mean GMFF of 42 for all the subjects, as shown in Table 1. In the results of Duncan testing, there was a statistically significant difference among ten facial categories ($p=0.027$). The results imply that the existing mask would be better fit those with common or medium facial dimensions rather than distinct ones-larger or smaller facial sizes.

In contrast with the existing mask, the TFN mask did not appear to be influenced by ten facial size categories. There was neither consistent tendency of GMFFs nor statistically significant difference according to facial size category. In other words, the TFN mask seemed to be regardless of facial size.

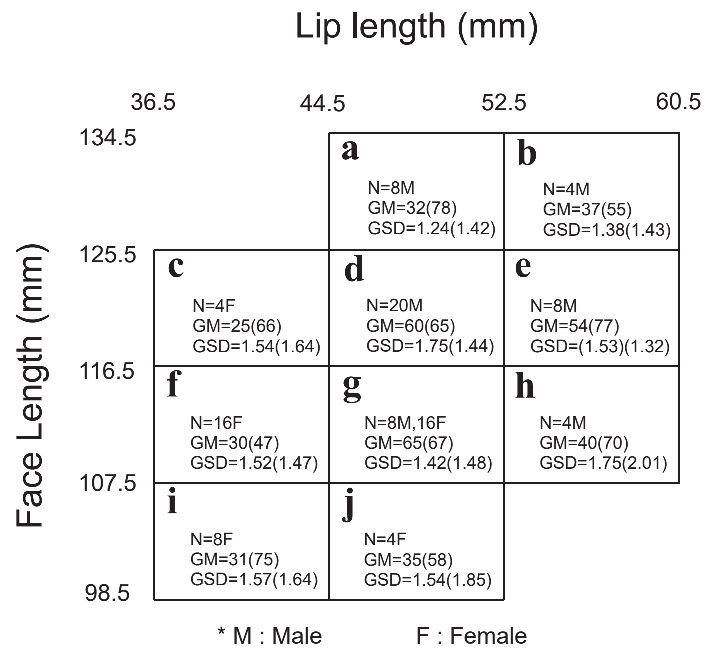

Fig. 3. Number of subjects, geometric mean of fit factors (GMFFs) and geometric standard deviation (GSD) in KFCH. Values out parenthesis are for the existing mask and those in parenthesis for the TFN mask. Statistically significant difference among 10 categories in the existing mask was observed (*p*=0.027), but no difference in the TFN mask.

Discussion

No respirator can provide perfect performance if it leaks, and one of the main sources of leakage is a poor fit of the mask on the face. One of the best ways of solving the poor fit issue is to fit test at the initial selection stage[2–5]. However, in most Asian countries including Korea, there is no regulation for fit test; therefore, another way should be found to solve leakage problem. One is to design the respirator facepiece that would provide the wearer with a better fit[6], however, due to the lack of elasticity of mask material to support face-fit, designing a filtering facepice having a good fit is likely to be limited compared with creating an elastomeric mask facepiece. The other is to find the way how to provide a better fit while wearing a respirator, namely, how to wear it more fittingly and tightly using a tool or not. This study is to find a simple tool to support good face-fit. The TFN for filtering facepieces was invented from understanding the point that putting more pressure on the contact surface of the face seemed to improve fit performance while donning it.

As the method of respirator certification test in Korea is nearly identical to the EN standards, a panel of ten clean-shaven persons shall be measured on four facial dimensions and described for information only when conducting a certification test[21]. In the present study two parameters, namely, face length and lip length were used to match with KFCH, which was developed on the basis of anthropometric data of Korean general population as the same method of previous studies[11–14]. Many data of two parameters for male and female could be obtained on line website of Korean anthropometric data, ‘sizekorea’. The latest statistics available were for 2015, but since there were no data of face length unfortunately, the data for 2003 to 2004 only were used[15]. Recently, new respirator fit test panels were developed by NIOSH for U.S. workers using face length and width[22, 23]. The new panels have been widely used by manufacturers worldwide. However, NIOSH test panels could not be directly adopted for Korean people because there were different and various races in U.S. compared with almost one ethnic race in Korea. In the present study the point that fit test panels representing current Korean workers were not used could be a limitation, which should be studied in the future.

As expected, our results revealed that mean and median of the TFN mask had higher FFs than those of the existing mask and significant differences were observed (both of them, $p=<0.001$). The reason why the TFN mask yielded higher FFs than the existing one can be related to the point that the TFN would put pressure evenly on the entire contact face area to improve fit performance. By applying TFN, GMFF improved from 42 to 67. That is, the inward leakage decreased from 2.4% to 1.5%, which might be a slight advantage in practical use. However, applying the TFN can be one of the very important solutions of reducing faceseal leakage, since in filtering facepieces unlike elastomeric masks improving the fit performance is very difficult. In both the existing and the TFN masks the GMFFs of male were higher than those of female and there were statistically significant differences ($p=0.024$ for the existing mask, $p=0.016$ for the TFN mask). The main reason why male subjects had better FFs than females is probably caused by the fact that most filtering facepieces may be designed for male rather than female.

The FFs of the existing mask for subjects with the most common facial dimensions were higher than those for subjects with distinctive dimension, as shown in Fig. 3 ($p=<0.001$). This indicates that the shape of the existing mask was to be designed to have a better fit for the large percentage of people with common facial dimensions rather than the small percentage of those with distinctive dimensions such as larger or smaller ones. However, the TFN mask was a contrast to the existing one. In the case of the TFN mask, there was neither consistent tendency of FFs among ten facial size categories nor statistical significant difference. Although two masks were of the same cup-shape and size, the fact that the TFN mask was not greatly influenced by facial size but fitted better than the existing mask can be explained to be attributed to a pressure evenly and tightly on the contact area of facial skin. These results imply that one type design of a filtering facepiece may not provide a good fit for everyone with various facial sizes, but use of the TFN can supply a good fit for almost everyone regardless of facial sizes when wearing it.

Since the TFN used in the study was manufactured to be applicable for the mask SY2500 only, it cannot be applicable for all filtering facepieces. In other words, the exact applicable range of the TFN should be limited to the mask SY2500 at this time, but it may be applicable for any filtering facepieces with the same size and shape after thorough studies. Because all subjects were also composed of Koreans only, further study to apply for people worldwide should be conducted.

Although ninety four subjects for the TFN mask (94%) had higher FFs than the existing mask, six subjects of them (6%) were lower than the corresponding values of the existing mask. The result suggests that, in order to get a better face-fit than now, new TFN should be also designed by facial size such as small, medium and large, even if use of the TFN was found to hardly affect the fit performance by facial size or shape. This suggestion is supported by the fact that many subjects whose values of the bridge of the nose were higher than those of average subjects reported that the main face seal leakage was through the area around the nose.

Finally, the results of questionnaire analysis demonstrated that there was no significant difference between two masks in terms of discomfort while wearing them. Any problems from wearing the masks were not found.

Conclusions

The results of this study suggest one of the best ways to get a better fit performance of a filtering facepiece when wearing it. Attaching a simple tight fitting tool, a TFN, on the exterior surface of the mask and pulling a strap were to be found to get a better fit than the existing mask attached by an aluminum clip only on the outside of the nose bridge. Since this performance was found to not only be hardly influenced by facial size but also yield a better fit than the existing mask, it can be an alternatives to design a filtering facepiece getting a good fit. However, we suggest that to obtain a better fit than now new TFN should be also produced taking into account facial size like mask designing.

Funding

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Appendix: Questionnaire

Before QNFT (Medical supervision)

1. Have you ever been short of breath on exertion, such as (a) climbing a flight of stairs, (b) walking up a slight hill, or (c) walking with other people of your own age, at an ordinary space on level ground?
2. Have you ever had chest pains?
3. Have you ever had asthma or emphysema?
4. Do you frequently have difficulty breathing?
5. Do you smoke?
6. Do you have chronic skin problems of the face?
7. Do you wear glasses or contact lenses?

Before QNFT (User's seal check)

Do you feel leaking between the skin of the face and the mask facepiece while wearing the mask? Yes/No

If "yes", please take off the mask and don it again, and then repeat user's seal check.

After QNFT

1. Did you have pains from strap tightening while fit testing? Yes/No
2. Did you have difficulty in breathing while fit testing? Yes/No
3. Did you experience comfort differences between two masks? Yes/No
   If "yes", which one was more discomfort? The existing mask/the TFN mask
4. Did you feel leaking between the skin of the face and the mask facepiece while fit testing? Yes/No
   If "yes", where do you think a main leak point is? Nose bridge/Nose valley/Chin/Cheek/Others

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