DOI: 10.11910/j.issn.2791-2043.2025.2.08

Fit Testing of Medical Respirator and Its Determinants

Lili Guo, Jingyi Lyu, Ying Huang*

(*Nanjing Hospital of Chinese Medicine affiliated to Nanjing University of Chinese Medicine*)

ABSTRACT: Objective This study performed a fit testing of medical respirators so as to guide medical personnel to choose suitable medical respirators based on the test results and achieve the optimized protection effect. **Methods** The study applied a 3MTM FT-30 qualitative fit testing using a test solution of denatonium benzoate. The personnel wearing the Winner Medical Respirator were tested for the fit and sensitivity (taste). **Results** A total of 649 personnel participated in the fit testing, of whom 614 (94.6%) were qualified, and 35 (5.4%) failed. Those who failed the test had smaller faces, higher nasal bridges, and lower body mass indices. **Conclusion** The fit testing of medical respirators enables medical personnel to correctly select and use medical respirators that meet protection requirements, ensuring the optimal protective effect.

KEY WORDS: Medical respirator; Sensitivity testing; Fit testing

Respiratory infectious diseases are caused by various pathogens that invade the human respiratory mucosa (such as the nasal cavity and throat) through droplets. Their transmission mode is easily achieved in interpersonal interactions, and the pathogens of respiratory infectious diseases update rapidly, are numerous in variety, and have the characteristics of fast spread speed and strong infectivity[1]. Clinical prevention and control experience shows that targeted respiratory protection measures (selecting appropriate types of respirators for different scenarios) effectively block transmission routes and reduce the transmission probability of respiratory diseases[2]. Commonly used respirator types in clinical settings include medical surgical respirators and medical respirators. Among them, the medical respirators are the most effective protective equipment for preventing respiratory infectious diseases, because they can filter more than 95% of non-oily particles and have a good blocking effect on droplets with a diameter greater than 0.5 μm[3]. However, the fit of such respirators is greatly affected by the wearer's facial characteristics[4]. How to select the appropriate respirator based on the wearer's facial features becomes particularly important. Respirator fit testing enables wearers to assess the fit of medical respirators, assisting medical staff in testing the fit of the respirators they wear and reducing the risk of infection[5]. More and more medical institutions are recognizing the importance of fit testing for medical respirators and applying qualitative or quantitative methods to conduct the test[6-7]. Qualitative testing determines whether the respirator fits the face based on the subject's reaction to the test agent, while quantitative testing not only assesses whether the respirator fits the wearer's facial contours but also verifies the respirator' sealing performance[8-9]. However, quantitative testing equipment is costly. When medical institutions are dealing with epidemics, a qualitative method is faster and easier to implement than a quantitative method. Therefore, this study conducted a fit testing on medical staff to evaluate whether wearing Winner Medical Respirator can meet the protection needs against respiratory diseases, to explore determinants affecting respirator fit, and to provide practical evidence for personal protection.

1 Objects and Methods

1.1 Test subjects and respirators

Medical personnel from Nanjing Hospital of

Corresponding author: Correspondence to Ying Huang at 1119625376@qq.com

Chinese Medicine affiliated to Nanjing University of Chinese Medicine were selected as the study subjects, including staff from the Tuberculosis Department, Respiratory Department, and Office Support Department. The fit testing was conducted at the hospital from January to June 2022. Before testing, the personnel received training on the proper wearing of medical respirator and knowledge related to fit testing and were required to shave any facial hair and remove facial accessories affecting the test within 24 hours. The respirators used in the test were Winner Medical Respirators (foldable type), complied with the GB 19083—2010 standard.

1.2 Fit testing method

The qualitative fit testing was implemented according to the standard *Selection, use and maintenance of respiratory protective equipment* (GB/T 18664—2002) issued by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China[10]. The 3MTM FT-30 kit was used for sensitivity testing and fit testing. This kit includes a hood, sensitivity test solution, fit testing solution, and a dedicated sprayer. The qualitative fit testing procedure includes two stages: sensitivity testing and fit testing. Before testing, the subject dons the medical respirator correctly, is checked by the tester to ensure the gas-tightness.

1.2.1 Sensitivity (taste) testing

The subject needs to expose their nose and mouth, slightly stick out their tongue, and breathe through their mouth while the sensitivity test solution is sprayed. Once the subject perceives the bitter taste, the number of sprays should be recorded immediately. Subjects who pass the sensitivity testing, after clearing the bitter taste from their mouth, will proceed to the fit testing.

1.2.2 Fit testing

The subject needs to wear the medical respirator and use the dedicated test hood. Based on the subject's sensitivity level, the tester will spray a different number of sprays of the fit testing solution into the hood. After spraying, the subject shall perform the following exercises: normal breathing, deep breathing, turning the head side to side, moving the head up and down, reading a passage aloud, bending at the waist and then returning to upright, and normal breathing again. Each exercise lasts 1 minute. To maintain the aerosol concentration inside the test hood, half the number of initial sprays of reagent is replenished every 30 seconds. If the subject tastes the bitter taste during any exercise, the subsequent test steps are stopped immediately since it indicates a respirator leakage.

1.3 Handling of Test Failures and Cause Analysis

Failing the fit testing twice indicated that the Winner Medical Respirator was not suitable for the subject. The reason for failure was recorded, and the subject was switched to wear a Sinovo D920 Medical Protective Respirator to continue testing. If the test failed again, the failed individuals were further divided into a group to analyze potential determinants.

1.4 Statistical analysis

Stata 17.0 statistical software was used for data processing. Measurement data conforming to a normal distribution were described using mean ± standard deviation and compared using the t-test; measurement data not conforming to a normal distribution were described using the median (interquartile range) [M (P25, P75)]. Group comparisons were conducted using non-parametric tests (such as the Wilcoxon rank-sum test). Count data were expressed as number (percentage) [n (%)], and group comparisons were conducted using the chi-square (χ^2) test or Fisher's exact test. A two-sided test with α=0.05 was used as the significance standard, with P<0.05 considered statistically significant. Multivariate analysis was performed using logistic regression analysis.

2 Results

2.1 General information

A total of 649 medical staff were tested, including 223 males and 426 females. The average age was 38.2±9.8 years, the average height was 161.77±5.11 cm, the average weight for males was 68.5±11.2 kg, and the average weight for females was 54.3±8.7 kg. In terms of occupational composition, nursing staff were the most numerous, with 469 persons, accounting for 72.3%. Among them, 412 were female nurses, accounting for 87.8% of the nursing staff, and 57 were male nurses, accounting for 12.2%. Medical technicians accounted for 24.5% (159/649), including laboratory, imaging, pharmacy, and other technical personnel. Office support staff accounted for 3.2% (21/649), mainly cleaning, maintenance, and other support personnel.

2.2 Sensitivity (taste) testing results

Based on the number of sprays at which the subjects perceived the taste, sensitivity was divided into four levels: Level 1 meant perceiving the taste at 1~10 sprays; Level 2 at 11~20 sprays; Level 3 at 21~30 sprays; if the taste was not perceived after 30 sprays, the subject was deemed unsuitable for testing with this reagent (Level 4). Sensitivity testing with hood was conducted on 649 subjects, and the results are shown in Table 1. 97.5% of subjects were Level 1 sensitive, only 2.0% and 0.5% were Level 2 and Level 3 sensitive, respectively, with very few Level 3 sensitive individuals. No one reached Level 4 sensitivity.

Table 1 Sensitivity (taste) test results.

Sensitivity level	Performance criteria	Number of people	Proportion (%)
Level 1	Sprays≤10	633	97. 5
Level 2	Sprays≤20	13	2. 0
Level 3	Sprays≤30	3	0. 5
Level 4	Sprays>30	0	0

2.3 Fit testing results

A total of 649 individuals wore Winner Medical Respirators. Among them, 614 (94.6%) passed the test, and 35 (5.4%) failed. The number of failures and reasons for each item in the fit testing are shown in Table 2. The 35 individuals who failed with the Winner Medical Respirator were switched to the Sinovo D920 Medical Protective Respirator for testing. Among them, 5 passed the test after switching to the Sinovo D920 Medical Protective Respirator, while 30 still failed. Those who failed were not assigned to work in isolation wards.

2.4 Analysis of determinants for test failure

Further analysis of determinants for test failure compared differences between groups based on demographic characteristics such as gender, age, occupation, height, and weight. The results found that age was negatively correlated with the qualified rate, suggesting that the older the age, the tendency for the qualified rate in the fit testing decreased. Qualified rates also differed among different occupation groups, with nursing personnel having the highest qualified rate. Furthermore, height, weight, and body mass index were also associated with the qualified rate; those who failed the test had relatively lower body mass indices (Table 3).

Further multivariate logistic regression analysis showed that only weight and height had significant independent effects on the outcome of the fit testing. For every 1 kg increase in weight, the likelihood of failing decreased (OR=0.920, 95% CI: 0.885~0.957, *P*=0.001); for every 1 cm increase in height, the probability of failing increased (OR=1.161, 95% CI: 1.078~1.254, *P*=0.001); the details are shown in Table 4.

3 Discussion

Fit testing is a key link to ensure the protective effect of using medical respirators. Those 30 individuals who failed the test are most males.

Table 2 Fit testing results for Winner Medical Respirator.

No.	Test item	Passed	Failed	On-site failure reasons
1	Normal breathing (step 1)	641	8	Gap at the chin
2	Deep breathing	635	6	Small face shape
3	Turning head side to side	631	4	High nasal bridge
4	Moving head up and down	624	7	Lower edge of respirator not sealed when looking up
5	Talking aloud	619	5	Gap appearing at chin when talking
6	Bending and straightening up	614	5	Respirator gap appearing when bending
7	Normal breathing (step 7)	614	0	-

Table 3 Analysis of determinants for test failure.

Variable	Category	Qualified group (N=614)	Failed group (N=35)	Statistic (χ^2/F/t)	*P* value
Gender	Male	212	11	0. 186	0. 666
	Female	402	24		
Age*	≤30 years old	149	7	4. 231	0. 040
	31~40 years old	274	13		
	41~50 years old	153	9		
	>50 years old	38	6		
Occupation	Nursing	448	21	6. 725	0. 035
	Medical tech	148	11		
	Office support	18	3		
Height (cm)		161. 63±5. 04	164. 94±5. 93	3. 74	0. 001
Weight (Kg)		59. 91±10. 42	54. 65±7. 87	-2. 94	0. 003
Body mass index		22. 86±3. 37	19. 99±1. 54	-5. 01	<0. 001

Note: * Ranked data tested using rank-sum test.

Table 4 Multivariate logistic regression analysis of determinants for test failure

Variable	OR value	95% confidence interval	*P* value
Weight (kg)	0. 920	(0. 885~0. 957)	0. 001
Height (cm)	1. 161	(1. 078~1. 254)	0. 001
Gender (female vs. male)	1. 053	(0. 582~1. 905)	0. 867
Age (31~40 yrs vs. ≤30 yrs)	0. 721	(0. 325~1. 597)	0. 428
Age (41~50 yrs vs. ≤30 yrs)	0. 892	(0. 398~1. 998)	0. 785
Age (>50 yrs vs. ≤30 yrs)	1. 235	(0. 489~3. 119)	0. 662
Occupation (medical tech vs. nursing)	2. 345	(1. 352~4. 063)	0. 002
Occupation (office support vs. nursing)	1. 876	(0. 568~6. 192)	0. 305

Males typically have larger facial dimensions, including facial length, width, and higher nasal bridges. Larger facial dimensions may increase the difficulty of achieving a good gas-tightness between the respirator and the face, especially when wearing dome-shaped respirators, resulting in a relatively lower qualified rate for the testing. Females, however, are more suited to wearing fold-flat respirators due to their relatively uniform facial contours. Moreover, some males have fast stubble growth; although they were required to shave within 24 hours, some stubble could still affect the gas-tightness during testing. Fold-flat respirators have better moldability and can better adapt to facial contours, hence the relatively higher qualification rate among females.

The qualified rate of the fit testing directly reflects the degree of fit between the respirator and the wearer's face. The compatibility of respiratory protective equipment refers to how well these items match the wearer's face shape, thereby affecting the protective effect. It mainly depends on the match between the shape and size of the respiratory protective equipment and the wearer's face shape[11]. Because every individual has distinct facial characteristics, medical respirators cannot fully adapt to each different face shape, so the fit varies from person to person, and thus the risk of leakage still exists[12]. Different groups of medical personnel show significant differences in fit testing. This difference may be caused by various determinants, including gender, age, facial features: face length, face width, nasal bridge width, the width between the two mandibular angles, and nasal prominence, which reflect human head and facial characteristics[13]. The results of this study show that nasal bridge width and face width are the main determinants affecting fit testing. Different brands and models of respirators have differences in size and design. Five subjects failed the test wearing the Winner Medical Respirator but passed it after switching to the Sinovo Medical Protective

Respirator. However, the hospital involved in this study had a limited selection of respirator models, and the scope of investigation can be expanded in future studies to further explore the fit testing of different types of medical respirators for medical staff in medical institutions. This would better provide scientific and effective guidance for medical institutions when selecting respirators. Some protective respirators made in China are designed according to Western faces, such as the 3M's TM1860 Particulate Respirator. Some protective respirators cannot be promoted for use in medical institutions due to a series of problems, such as excessive size or poor gas-tightness at the nasal bridge. The qualitative methods for fit testing have the advantage of their simple to operate, taking less time, and being convenient to carry out in relevant workplaces. However, there are certain limitations. Qualitative testing relies on the subject's subjective sensation. The subject insensitive to the test reagent may cause test failure. The qualitative method only provides a "qualified" or "failed" result, and its accuracy depends on the cooperativeness of the subject.

Currently, medical respirators on the Chinese market are almost the same in size, only distinguishing between children's and adult versions, which means that the wearers cannot choose suitable models according to individual needs. Medical respirators from different brand companies, whether headband or earloop type, have slight differences in vertical and horizontal lengths, which provides some selectivity for people with different face shapes and body sizes. Conducting fit testing not only helps medical staff find protective respirators that match them, but also ensures that every clinical medical staff member wears the respirator correctly. It has been proven that standardized training and guidance for wearers on correct respirator usage significantly improve respirator fit and thereby increase the qualified rate of fit testing[14]. Furthermore, this study found that certain movements of the head and neck, such as nodding up and down, speaking loudly, and bending at the waist, have a significant impact on the respirator' gas-tightness. This indicates that even when respirators are worn correctly, performing certain movements or talking during work may still affect the respirator's gas-tightness, posing potential health risks to the wearer. Therefore, these movements should be minimized and avoided during work, especially when caring for patients with respiratory diseases. When performing operations while wearing protective respirators, try to keep movements small in amplitude. This is particularly important for high-risk exposure personnel, such as all staff working in wards, ICUs, and observation rooms for patients with novel coronavirus pneumonia (confirmed or suspected cases), including clinical doctors, nurses, nursing assistants, cleaners, and handlers of the deceased; doctors and nurses in fever clinics of designated medical institutions in epidemic areas; and public health physicians conducting epidemiological investigations on confirmed or suspected cases. Such personnel should choose medical respirators and undergo fit testing to prevent occupational exposure caused by improper respirator wearing. In special circumstances when there is a short supply of medical respirators, fold-flat respirators have a higher qualified rate in fit testing in high-risk environments due to their good moldability and comfort. Alternatively, self-contained filtering respirators (full-face or half-face) equipped with particulate filters, or powered air-purifying respirators can be used, which offer better protection. For critically ill patients where nursing and treatment operations are intensive, and for infectious diseases of unknown cause or highly contagious diseases, a full-face respirator is recommended.

During work, the frequency of facial movements by medical personnel may affect respirator fit. For example, frequent talking, turning the head, or bending over may cause the respirator to shift, thereby reducing the qualified rate of fit testing. Different groups of medical personnel show significant differences in the fit testing. These differences are mainly caused by determinants such as gender, age, facial features, respirator type, and working environment. To improve the protective effect of respirators, medical institutions should select appropriate respirator types based on the individual characteristics and conduct fit testing before purchasing respirators to ensure tight seals between the respirator and the wearer's face. In addition, respirator manufacturers should develop and design medical respirators of different models, sizes, and specifications based on the facial characteristics of the Chinese population to meet the needs of different medical staff. In summary, the importance of fit testing for medical respirators is increasingly gaining widespread recognition among professionals, and the demand for such testing among medical staff continues to grow[15]. It is recommended that medical staff responsible for treating respiratory infectious diseases should correctly select and use appropriate protective respirators by taking fit testing as a benchmark so as to obtain the optimal protective effect, thereby ensuring their own safety.

References

[1] WU X Q, SU J J, WANG W X, et al. Analysis on epidemiological characteristics and trends of respiratory infectious diseases in Nanjing City from 2004—2019 [J]. Occup Health, 2021, 37(18): 2513-2517.

[2] CHOPRA J, ABIAKAM N, KIM H, et al. The influence of gender and ethnicity on facemasks and respiratory protective equipment fit: a systematic review and meta-analysis[J]. BMJ Glob Health, 2021, 6(11): e005537.

[3] WANG L H, ZHAO X, ZHANG J L, et al. Rational selection and application of medical masks[J]. Chin J Nosocomiology, 2011, 21(18): 3908-3909.

[4] ZHUANG Z Q, COFFEY C C, ANN R B. The effect of subject characteristics and respirator features on respirator fit[J]. J Occup Environ Hyg, 2005, 2(12): 641-649.

[5] JIANG L, LI LY, WU AH, et al. 2019 novel coronavirus: appropriate rather than undue protection[J]. Chinese Journal of Internal Medicine, 2020, 59(9): 662-664.

[6] XUE J Y, CAI X X, TIAN Y J, et al. Qualitative suitability test of medical protective masks and influencing factors[J]. Chin J Nosocomiology, 2022, 32(10): 1586-1589.

[7] JIANG N, ZHANG Y C, JI X F, et al. Investigation on the fitness of masks for public health emergency personnels in Shanghai[J]. Chin J Disinfect, 2019, 36(7): 516-518.

[8] HU M H, JIA H X, YAO X, et al. Fit testing of respirators for health care workers in several hospitals[J]. Chin J Infect Contr, 2022, 21(1): 1-7.

[9] LIU B, WANG L, JIN W, et al. Fitness test of medical staff wearing three types of medical protective masks [J]. Chin J Disinfect, 2022, 39(7): 530-533.

[10] General Administration of Quality Supervision. Inspection and Quarantine of the People's Republic of China. Selection, Use and Maintenance of Respiratory Protective Equipment: GB/T18664—2002[S]. Beijing: Standards Press of China, 2004.

[11] LI C Q, YIN Y. Suitability survey on N95 filter masks for public health emergency personnel[J]. Shanghai J Prev Med, 2020, 32(7): 571-576.

[12] SHEN W, HE J F, SU Y, et al. Study on barrier property of medical protective clothing and protective mask [J]. Chin J Disinfect, 2005, 22(4): 386-390.

[13] DU L L, ZHUANG Z Q, GUAN H Y, et al. Head-and-face anthropometric survey of Chinese workers [J]. Ann Occup Hyg, 2008, 52(8): 773-782.

[14] YU Y Y, JIANG L M, ZHUANG Z Q, et al. Fitting characteristics of N95 filtering-facepiece respirators used widely in China[J]. PLoS One, 2014, 9(1): e85299.

[15] REGLI A, SOMMERFIELD A, VON UNGERN-STERNBERG B S. The role of fit testing N95/FFP2/FFP3 masks: a narrative review[J]. Anaesthesia, 2021, 76(1): 91-100.