Wearing an N95 Respirator Concurrently With a Powered Air-Purifying Respirator: Effect on Protection Factor

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OBJECTIVE: To determine if using an N95 filtering face-piece respirator concurrently with a loose-fitting powered air-purifying respirator (PAPR) offers additional protection to the wearer. METHODS: We used a breathing mannequin programmed to deliver minute volumes of 25 L/min and 40 L/min. We measured the baseline protection factor of the PAPR with its motor operational and then deactivated (to simulate mechanical or battery failure). We tested 3 replicates of 3 different N95 models. We glued each N95 to the breathing mannequin and obtained a minimum protection factor of 100 at 25 L/min. We then placed the PAPR on the mannequin and took protection factor measurements with the N95-plus-PAPR combination, at 25 L/min and 40 L/min, with the PAPR operational and then deactivated. RESULTS: The N95 significantly increased the PAPR's protection factor, even with the PAPR deactivated. The effect was multiplicative, not merely additive. CONCLUSIONS: An N95 decreases the concentration of airborne particles inspired by the wearer of a PAPR. *Key words: N95, respirator, powered air-purifying respirator, protection factor.* [Respir Care 2008;53(12):1685–1690]

Introduction

During the severe acute respiratory syndrome outbreaks of 2003, concerns about the lethality of the virus prompted medical professionals, institutions, and governmental agencies to promote the use of N95 filtering face-piece respirators (or the equivalent) concurrently with loose-fitting powered air-purifying respirators (PAPRs) during aerosol-generating medical procedures.[1-5] The rationale was that the N95 would supplement the respiratory protection to the wearer,[2] prevent the passage of unfiltered exhalation gases from the wearer to the immediate environment,[3,4] and serve as a backup in the event of PAPR mechanical failure (eg, motor problem or battery failure) or overbreathing (inhalation at a flow higher than the PAPR can provide, which creates negative pressure in the PAPR and entrains outside, unfiltered air).[6] The combination of an N95 and a PAPR is worn in special circumstances (eg, bronchoscopy, intubation, or autopsy on a patient with a virulent respiratory pathogen), and is not routinely used by most health care workers. The fact that permissible exposure limits have not been assigned for most pathogens[7] (some serious diseases, such as tuberculosis and influenza, require as few as 1–3 infectious particles to initiate infection[8]) underscores the need to maximize respiratory protection. Although the suggestion to combine N95 and PAPR seems logical, it has not been subjected to scientific scrutiny and is not approved by the National Institute for Occupational Safety and Health (NIOSH), the federal agency

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The authors report no conflicts of interest related to the content of this paper.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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responsible for respirator certification. Furthermore, all personal protective equipment places physical and psychological strain on the wearer and can impede effective communication.[9] Therefore, it would be useful to quantify whether the combination of N95 plus PAPR increases protection, and to weigh the merits against the increased burden to the wearer.

One method to quantify the protection afforded by a respirator is the protection factor, which is the ratio of contaminant concentration outside the respirator to that inside the respirator,[10] which represents the respirator's efficiency in removing air contaminants from the air breathed. We studied the effect of concurrent use of an N95 on the protection factor of a loose-fitting PAPR.

Methods

We used a breathing mannequin (Smartman, ILC Dover, Frederica, Delaware) composed of a hollow, cast zinc shell and a head-form that represents a static uniform surface that outlines a medium-sized, human male head, neck, shoulders, and upper chest stature. Anthropometric facial measurements (face width, face length) of the Smartman placed it in cell 10 of the recently-developed NIOSH Respirator Fit Test Panel.[11] We used a computer-controlled breathing simulator (Dynamic Breathing Machine, Warwick Technology, Warwick, United Kingdom) that houses a reciprocating piston that moves within a precision-machined cylinder and reproduces human (sinusoidal) breathing patterns. We programmed the breathing simulator at breathing rates and tidal volumes that created 2 deliver minute volumes ($\dot{V}_E$): 25 L/min and 40 L/min. We selected 25 L/min to represent a light work level in a health care worker, on the basis of the exhaustive literature evaluation by Caretti et al[12] (21.3–21.6 L/min during nursing activities). We selected 40 L/min to represent a moderate work level, as might be expected with surge of patients in a major catastrophe.

We tested one loose-fitting PAPR (BreatheEasy, 3M, St Paul, Minnesota) fitted with 3 gas filter canisters (FR-57, 3M, St Paul, Minnesota) that are rated as P-100 particulate filters (ie, they filter out at least 99.97% of particles > 0.3 μm). The airflow range of the Breathe Easy PAPR, when used with a loose-fitting hood, is 200–250 L/min (a NIOSH-certified loose-fitting PAPR must supply airflow of at least 170 L/min).[13] During the study we conducted routine airflow checks with a mass flow meter, and the flow always exceeded the 170 L/min minimum.

We tested 3 models of N95 (models 1860 and 1870, 3M, St Paul, Minnesota, and model N9504C, AO Safety, Chickasha, Oklahoma). The N95s were not pre-conditioned prior to use. We measured the protection factors with a respirator fit tester (Portacount Plus, TSI, Shoreview, Minnesota), which uses condensation nucleus counting technology to make optical density measurements of ambient and within-respirator particulates. This method detects particles as small as 0.02 μm in a range of 0.1–5×10^5 particles/cm^3. We used a particle generator (model 8026, TSI, Shoreview, Minnesota) that uses sodium chloride solution, and during the tests we maintained the room-air particle count at 16,000–30,000 particles/m^3, which is significantly greater than the mean particle count (2,311 particles/m^3) in hospital operating rooms,[14] but is in the preferred range (8,000–50,000 particles/m^3) for optimal functioning of the Portacount Plus.[15] We measured the protection factors for the normally functioning PAPR with and without the N95s, the PAPR during battery failure with and without the N95s, and the N95s alone.

Baseline PAPR

We placed the PAPR over the mannequin, draped the internal nape of the shroud over the mannequin torso, covered it with a standard medical laboratory coat, buttoned the coat, and draped the external nape of the shroud over the laboratory coat. That arrangement simulated actual wear in a medical facility. We activated the PAPR motor, started the breathing simulator at 25 L/min, and took 3 consecutive protection-factor measurements. We then repeated this test scenario with the breathing simulator set at 40 L/min.

PAPR With Battery Failure

For this test we turned off the PAPR to simulate PAPR battery failure or mechanical failure, and used the same test scenario (25 L/min and 40 L/min, and 3 protection-factor measurements).

N95 Only

To obtain a good seal, we glued the N95 to the mannequin face, as has been done in other studies. To avoid damage to the mannequin face we placed a layer of electrical tape where the N95 contacts the face. We then applied hot ethylene vinyl acetate polymer hydrocarbon resin glue (Electromatic TR550 glue gun, Arrow Fastener, Saddle Brook, New Jersey) evenly around the inside edge of the N95 and immediately placed it on the mannequin face. The glue-drying time was less than 1 min. We then visually inspected the glue-N95 interface for leaks, and applied additional glue if necessary. We then took 3 protection-factor measurements at both 25 L/min and 40 L/min. We then repeated the latter set-up and test procedure with 3 replicates of each N95 model (ie, we tested a total of 9 N95s). By gluing the N95 to the mannequin we achieved protection factors > 100 at 25 L/min.

Fig. 1. Breathing mannequin with an N95 filtering face-piece respirator and a loose-fitting powered air-purifying respirator.

N95 Plus Operational PAPR

After 3 consecutive protection-factor measurements > 100 at 25 L/min, we left the N95 on the mannequin and put the PAPR on over the N95 (Fig. 1). With the PAPR motor activated, we took 3 protection-factor measurements, at both 25 L/min and 40 L/min, with each of the 9 N95-plus-PAPR combinations.

N95 Plus Deactivated PAPR

In this experiment we deactivated the PAPR motor and took 3 protection-factor measurements with each of the 9 N95-plus-PAPR combinations, at 25 L/min and 40 L/min.

Statistical Analysis

We entered the data into a spreadsheet (Excel, Microsoft, Redmond, Washington) and conducted statistical analysis via single-factor and 2-factor (with replication) analysis of variance for the differences in protection factors. A *P* value of < .05 was considered significant.

Results

Table 1 shows the protection-factor data, and Table 2 shows the mean protection factors.

The PAPR's mean protection factor at 25 L/min (31,552 ± 8,758) was not significantly different than at 40 L/min (33,741 ± 8,930) ($P = .36$). The mean protection factor of the 9 N95s at 25 L/min (142.6 ± 38.2) was significantly greater than at 40 L/min (98.4 ± 28.9) ($P < .001$).

The mean protection factor of the N95-plus-operational-PAPR at 25 L/min (325,037 ± 127,739) was not significantly different from that at 40 L/min (320,185 ± 161,254) ($P = .90$) (Fig. 2). The mean protection factor of the N95-plus-PAPR combination was significantly greater than that of the PAPR alone, at both 25 L/min and 40 L/min ($P < .001$).

There was no significant difference in the mean protection factor with the PAPR deactivated at 25 L/min (7.7 ± 2.1) and 40 L/min (8.5 ± 2.3) ($P = .32$). The combination of N95-plus-deactivated-PAPR had a mean protection factor of 1,990 ± 1,208 at 25 L/min and 1,414 ± 621 at 40 L/min ($P = .22$) (Fig. 3).

The mean protection factor of the N95-plus-deactivated-PAPR combination was significantly greater than that of the deactivated PAPR alone at both 20 L/min and 40 L/min ($P < .001$). Two-way analysis of variance of delivered $\dot{V}_E$ and N95 model indicated that, without the PAPR, the different N95 models and the delivered $\dot{V}_E$ both significantly affected protection factor ($P < .001$), but their interaction was not significant ($P = .90$). Two-way analysis of variance of the N95-plus-PAPR combination and the N95-plus-deactivated-PAPR tests indicated that the N95 models were significantly associated with the protection factor ($P = .05$), but both $\dot{V}_E$ and their interaction were not significant associated ($P = .09$ and .45, respectively)

To improve the normality of the protection factors, we ran the analyses with a log transformation. Although quantile-quantile (Q-Q) plots seemed to reveal that the log-transformed data conformed better to a normal distribution, the *P* values were qualitatively unchanged; the largest differences observed, for instance, were $P = .27$ instead of $P = .36$, and $P = .53$ instead of $P = .90$, so these data are not shown here. We also ran mixed models whenever possible, to adjust for potential correlation with a given N95 (as 3 of each N95 model was tested 3 times). This analysis also found no qualitative differences, and therefore the data are not described further.

Discussion

The present study analyzes the protection factor with concurrent use of a properly-fitting N95 under a loose-fitting PAPR, which is a combination occasionally used

Table 1. Protection Factors of N95 Respirators, With and Without Powered Air-Purifying Respirator

N95 Model	N95 Only, at 25 L/min	PAPR Only, at 25 L/min	PAPR Plus N95, at 25 L/min	N95 Only, at 40 L/min	PAPR Only, at 40 L/min	PAPR Plus N95, at 40 L/min
3M 1860	107	35,200	255,000	71	31,900	214,000
	111	22,100	203,000	68	29,200	140,000
	107	35,700	399,000	67	28,400	241,000
	113	56,100	499,000	107	50,000	515,000
	117	37,700	502,000	113	67,000	676,000
	120	41,200	334,000	112	46,000	498,000
	108	28,700	582,000	68	34,800	193,000
	112	29,600	381,000	70	33,000	408,000
	113	28,500	154,000	67	29,200	235,000
3M 1870	166	30,000	238,000	136	42,000	424,000
	171	58,700	415,000	135	34,100	292,000
	181	29,500	410,000	140	34,700	286,000
	209	23,700	332,000	138	30,000	213,000
	223	25,200	265,000	142	29,400	259,000
	242	29,300	349,000	142	31,500	220,000
	163	23,300	147,000	119	31,600	118,000
	167	27,000	267,000	119	32,200	108,000
	170	26,400	116,000	122	31,200	124,000
AO Safety N95O4C	131	34,700	412,000	89	20,300	332,000
	133	23,600	229,000	91	29,900	536,000
	137	29,400	274,000	90	35,500	463,000
	109	32,800	235,000	64	36,900	493,000
	110	31,300	313,000	62	26,400	632,000
	102	29,200	184,000	58	28,300	279,000
	143	29,700	510,000	86	28,600	338,000
	141	29,600	237,000	93	28,500	285,000
	143	23,700	534,000	88	30,400	123,000

* PAPR = powered air-purifying respirator

Table 2. Mean Protection Factors

N95 Model	Deactivated PAPR, at 25 L/min	Deactivated PAPR Plus N95, at 25 L/min	Deactivated PAPR, at 40 L/min	Deactivated PAPR Plus N95, at 40 L/min
3M 1860	4.1	2,798	3.7	1,756
	7.9	2,056	8.2	2,096
	8.3	4,732	9.5	2,370
3M 1870	7.1	2,104	8.8	1,930
	9.1	1,868	9.9	1,226
	10.3	1,101	11.6	835
AO Safety N95O4C	8.7	1,158	9.9	1,045
	7.1	965	9.1	681
	4.4	1,127	5.9	782

* PAPR = powered air-purifying respirator

during potentially aerosolizing medical procedures (eg, endotracheal intubation, airway suctioning, aerosol administration) on patients with dangerous pathogens (eg, severe acute respiratory syndrome, influenza, tuberculosis). The N95-plus-PAPR combination has not been approved by NIOSH.[16]

The mean protection factors of the PAPR, deactivated PAPR, N95-plus-operational-PAPR combination, and

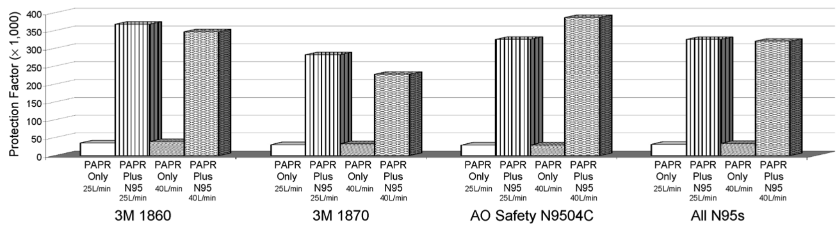

Fig. 2. Protection factors with a properly functioning, loose-fitting powered air-purifying respirator (PAPR) with and without N95 filtering face-piece respirators, at minute volumes of 25 L/min and 40 L/min.

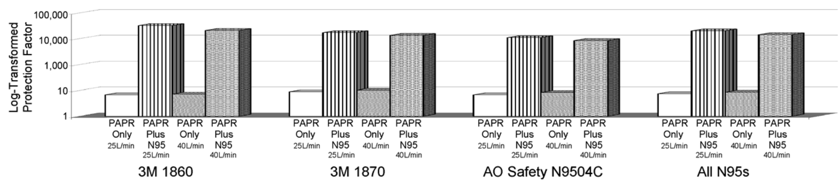

Fig. 3. Log-transformed protection factors with a properly functioning, loose-fitting powered air-purifying respirator (PAPR) with and without N95 filtering face-piece respirators, at minute volumes of 25 L/min and 40 L/min.

N95-plus-deactivated-PAPR combination were not significantly influenced by the 2 $\dot{V}_E$ we tested (25 L/min and 40 L/min). However, the N95s' protection factors at 25 L/min were significantly greater than at 40 L/min ($P < .001$). The protection factors with the N95-plus-PAPR and N95-plus-deactivated-PAPR were significantly greater than that of the PAPR alone or the deactivated-PAPR alone ($P < .001$ for both).

The N95s increased the mean protection factor of the functioning PAPR by approximately an order of magnitude (ie, protection factor of at least 100), at both 25 L/min and 40 L/min. The deactivated PAPR provided relatively little protection by itself (protection factor < 10), because its loose fit does not provide an adequate facial seal. That was highlighted in a recent study with humans, which found that a tight-fitting, negative-pressure, full-face-piece connected to a deactivated PAPR (same model as in the present study) had a protection-factor range of 38,000–46,500.[17] However, our data suggest that a properly-fitting N95 increases the mean protection factor of a deactivated PAPR by 2–3 orders of magnitude.

Limitations

The breathing mannequin we used delivers equal, regular respirations at a pre-programmed rate, whereas humans have variable respiration. However, it is noteworthy that our data, which indicate a protection factor of $> 20{,}000$ in all the trials of the functional PAPR at 25 L/min, are similar to the findings of a study with humans of the same PAPR model we tested, which found a 100% pass rate for protection factor 20,000 (with a corn oil aerosol).[18] The difficulty in obtaining a good seal between the respirator and mannequin face necessitated our use of glue to adhere the N95 to the breathing mannequin, as has been done in other studies.[19] Because protection factor depends partly on fit (and partly on filter-penetration), the use of glue to enhance respirator adherence to the mannequin face provides a better fit than is generally obtainable in actual use by humans,[20] and thus increases the prominence of filter-penetration in the protection factor. The influence of N95 fit in the present study was further diminished by the fact that the breathing mannequin cannot be fully fit-tested, because the mannequin can only perform 2 of the 8 fit-test exercises (normal breathing and deep breathing).[21] Thus, the protection factors of the N95-plus-PAPR combinations in the present study are largely a measure of N95 filter-penetration and PAPR leakage, so our protection-factor measurements may be superior to those that would be obtained with humans, where face-seal leakage would probably be greater.

Although a low particle count measured by a respirator fit tester may generate a higher protection-factor measurement, that higher protection factor may not correlate to additional protection. However, there may not be much practical difference between protection factors of 100,000 and 200,000, because in that situation there are so few particles, and the accuracy of protection-factor measurements $> 10{,}000$ with the respirator fit tester have not been well described.[15] Nonetheless, since no permissible exposure limits have been set for infectious agents that may be carried on airborne particles (some pathogens can generate a respiratory tract infection with as few as 1–3 organisms[8]), a higher protection factor may translate to greater protection. The 2 $\dot{V}_E$ we tested are within the operating range of a loose-fitting

PAPR and should not have resulted in negative-pressure in the PAPR, so we did not determine protection factors in an over-breathing scenario.[6]

Conclusions

Our study suggests that a properly-fitting N95 substantially increases the protection factor of a loose-fitting PAPR, even if the PAPR suffers mechanical or battery failure. This finding highlights the value of an N95 as an extra protective measure in case of PAPR malfunction. Inasmuch as the protection afforded by an N95 is highly dependent on fit at the face/respirator interface, and we glued the N95 onto the mannequin face, the protection factors we found may be superior to those that would be observed with humans, especially in a work environment.[20] Determining the true protection from the N95-plus-PAPR combination would require a simulated or actual health-care workplace protection-factor study, of the type previously carried out for other respirators.[22] Also, because with some pathogens very few infectious particles can create a respiratory infection,[8] we cannot state that the N95-plus-PAPR combination offers complete protection, irrespective of the significantly elevated protection factor the combination achieves. Nonetheless, the N95-plus-PAPR combination appears to significantly reduce aerosol exposure, over PAPR alone. It is not our objective to promote widespread use of the N95-plus-PAPR combination over the respiratory-protection methods currently practiced. This study addressed only the protection factor afforded by the N95-plus-PAPR combination. Additional experiments are necessary to quantify the effects of adding an N95 on physiological and psychology tolerability and communication.

REFERENCES

1. Khoo KL, Leng P-H, Ibrahim IB, Lim TK. The changing face of healthcare worker perceptions on powered air-purifying respirators during the SARS outbreak. Respirology 2005;10(1):107-110.
2. Kamming D, Gardam M, Chung F. Anaesthesia and SARS (editorial). Br J Anaesth 2003;90(6):715-718.
3. Wong KC, Leung KS. Transmission and prevention of occupational infections in orthopedic surgeons. J Bone Joint Surg Am 2004;86-A(5):1065-1076.
4. Shek HK J. Neonatal aspect of SARS. Hong Kong K Paediatr 2003; 8:242-253.
5. Ministry of Health and Long-Term Care, Province of Ontario. SARS directive to all Ontario acute care facilities for high-risk respiratory procedures (includes both non-outbreak and outbreak conditions). Directive HR03-12; October 22, 2003.
6. Mackey KR, Johnson AT, Scott WH, Koh FC. Over breathing a loose-fitting PAPR. J Int Soc Resp Protect 2005;22:1-10.
7. Johnson B. OSHA infectious dose white paper. Appl Biosafety 2003; 8:160-165.
8. Musher DM. How contagious are common respiratory tract infections? N Engl J Med 2003;348(13):1256-1266.
9. Szeinuk J, Beckett WS, Clark N, Hailoo WL. Medical evaluation for respirator use. Am J Indust Med 2000;37(1):142-157.
10. Kretchik JT. Respirators: assigned protection factors. Chem Health Safety 2003;10:26.
11. Zhuang Z, Bradtmiller B, Shaffer RE. New respirator fit test panels representing the current US civilian work force. J Occup Environ Hyg 2007;4(9):647-659.
12. Caretti DM, Gardner PD, Coyne KM. Workplace breathing rates: defining anticipated values and ranges for respirator certification testing. Edgewood Chemical Biological Center, US Army Research, Development and Engineering Command. Report ECBC-TR-316; September 2004.
13. 3M Technical Data Bulletin #180. Determination of service life for NIOSH CBRN approved 3M cartridges and canisters. http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660zjcf6lvs6evs66smvkcorrrq-. September 2007. *Accessed October 7, 2008.*
14. Landrin A, Bissery A, Kac G. Monitoring air sampling in operating theatres: can particle counting replace microbiological sampling? J Hosp Infect 2005;61(1):27-29.
15. Portacount Plus Model 8020 operation and service manual. http://www.tsi.com/en-1033/products/14020/portacount®_respirator_fit_tester.aspx.
16. Roberge RJ. Effect of surgical mask worn concurrently over N95 filtering facepiece respirators: extended service life vs increased user burden. J Pub Health Manag Pract 2008;14(2):E19-E26.
17. Harrison B, Harrison C, Liang S, Smith S, Croll L. Laboratory performance testing of powered air purifying respirators. J Int Soc Resp Protect 2007;24:42-48.
18. Seiple AD, Pappas AG. Protection factor testing of the 3M Breathe Easy (BE-10) powered air purifying respirator. Edgewood Chemical Biological Center, US Army Soldier and Biological Chemical Command. Report ECBC-TR-338; September 2003.
19. Balazy A, Toivola M, Reponen T, Podgorski A, Zimmer A, Grinshpun SA. Manikin-based performance evaluation of N95 filtering-facepiece respirators challenged with nanoparticles. Ann Occup Hyg 2006;50(3):259-269.
20. Crutchfield CD. Those fantastic fit factors. Respir Protect Update 1995;6(1):4-5.
21. US Department of Labor, Occupational Safety and Health Administration. Fit testing procedures (mandatory), 1930. Appendix A:134.
22. Coffey CC, Campbell DL, Myers WR, Zhuang Z, Das S. Comparison of six respirator fit-test methods with an actual measurement of exposure in a simulated health care environment: part I: protocol development. Am Indust Hyg Assoc J 1998;59(12):852-861.