

User Response to Single Use Respirator Expiratory Valve

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Respirators

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Introduction

Single use ("disposable") quarter mask respirators are extensively used in industrial settings when the hazard does not require a high protection factor. Some of these masks contain an expiratory valve, decreasing the resistance to outflow during the expiratory phase of breathing.

This study empirically assesses whether there are measurable physiologic and/or subjective benefits to this arrangement.

Methods:

_____ normal volunteers participated in this study as approved by the UCLA Human Subject Protection Committee. Each subject underwent a limited physical examination and a medical interview, completed a health questionnaire, received a full explanation of the study, and signed an informed consent statement to participate. Each subject received a nominal fee for participation. These subjects included _____ males; the average age was ____ years (range ____ to ____).

Subjects participated in a protocol which involved carrying out six to eight minutes of moderate walking exercise in a standardized field course. The field course was designed with specific times between relatively frequent checkpoints in order to insure uniformity. A research staff member accompanied the subjects. The field course included walking on the level and on slight inclines. The experimental protocol was repeated using several different respirators. The order varied. Results relating to the use of powered air pure fine respirators and dual cartridge full face mask devices have been separately reported in that they included extensive replication and more detailed physiologic analysis. This study reports on the periods involving no respirator use, a single use dust-mist quarter mask and a similar single use quarter mask device with a single expiratory valve. (The specific models are not identified here to avoid implications for these specific ones, but they were comparable in terms of mask size and other features except for

the presence of the valve.)

During the course of exercise, respiratory physiologic measurements were performed with an ambulatory Respiratory Inductive Plethysmograph (RIP). Details of this method have been described elsewhere (_____). In general, the subject wears a compliant band around the chest and abdomen. Changes in chest configuration are reflected in changes in the inductance of the bands. This inductance signal is D modulated and recorded on a lightweight portable board channel FM recorder. (RIP is produced by Ambulatory Monitoring Incorporated, Ardsley, New York; the recording system is by Oxford Medical, ?, England.) (2WWB; 2BOH900). The tapes are played back using a replay unit [Oxford, XXX] digitized (metrabyte, _____, MA) and analyzed using specific computer programs which we developed for this purpose. (_____). In addition, heart rate was obtained from an electrocardiographic trace recorded on this unit.

Subjective responses were measured using two visual analyzed scales, in which a subject marked a position on a continuous line representing the continuum of effect. The two scales were EXERT, asking "How long can you keep working like this?", and DISCO, inquiring about the level of discomfort. The former is a projective scale (asking about an estimated future feeling), whereas the latter is a state descriptive scale. The responses were recorded as the distance in millimeters from the base line. This method has been used in prior studies (_____ _____).
_____).

Data management was performed using Dbase (Ashton Tate, Torrance, CA), and statistical analyses were performed using BMDP (_____) on a personal computer. Analysis of variance with repeated measures was performed and a $P < .05$ was considered statistically significant and $.05 < P < .10$ of borderline significance.

Results:

Table 1 shows the results obtained. In this table, the results for the noer(??) respirator load (NL)??????, mask-no valve (MN), and the mask with valve (MV) are shown. Physiologic variables include heart rate and respiratory rate. In addition, minute ventilation (liters per minute) and title volume (liters) are shown. In addition, inspiratory time (Ti) (seconds) was calculated and analyzed because prior studies with other respirators have shown this to be a sensitive parameter of effect.

As may be seen in the table, the MV and MN periods showed little or no difference. The lack of difference is not simply due to a small sample size since there is no evident trend.

Table 2 shows the results for the two subjective variables. As it demonstrates, the valve mask was not different from the no-valve mask subjectively either. (Sounds a little awkward.)

Discussion:

Single use respirators are commonly used in many industrial settings, but they have received relatively little research attention regarding their effects on the user. Such information may be helpful in two ways: first, it may facilitate improvement of respirator design, making the device more tolerable to the user, and therefore more likely to be properly utilized. Second, such information can help select appropriate medical evaluative procedures for determining if a worker can and should use a respirator.

This study has shown that single use masks have relatively little direct physiologic impact. This contrasts with the effects of other respirator types previously studied (_____). In addition, as this study shows, self contained breathing apparatus devices have very significant physiologic impacts. Because single use devices have so little physiological impact, it is unlikely that there would be any significant benefit to physiologic testing of workers for respirator medical certification if they will use only single use masks.

This study also showed that there was no significant objective physiologic or subjective difference with or without an expiratory valve. Therefore, at least for the model studied there appears to be little reason to select such a device. Theoretically, an expiratory valve might be preferable for two reasons: first, it might provide a lower expiratory resistance, not requiring that air be forced through the filtering surface

itself. Second, it is theoretically possible that the expiratory valve would be particularly important in allowing the terminal portion of the exhaled breath to escape rather than remain within the mask. Because the terminal portion of the breath is particularly rich in carbon dioxide (representing the air from the alveoli), this might theoretically decrease the amount of dead space (re-breathing). Despite these two theoretical advantages, no significant effects of the valve were seen. It is likely that the resistance of the respirator was sufficiently low that there was no marginal benefit to the expiratory valve. Furthermore, the expiratory valve provides no benefit during inspiration, yet it is the inspiratory portion of the respiratory cycle in which most of the work of the respiratory muscle is performed. Previous studies have shown that inspiratory resistance is particularly important as a factor determining respirator subjective and objective affect, and therefore the decrease of expiratory resistance would be likely to have much less benefit than a change in inspiratory resistance. For similar reasons, the purely theoretical benefit in decreasing effective mask dead space is also likely to be of minimal impact. There generally is only a little dead space in a small quarter mask, particularly since air can exit throughout the entire surface rather than only through small valves (as occurs in other respirators with air impermeable masks).

There are two theoretical disadvantages to expiratory valves. The first is the possibility that they may become partially incompetent, not closing completely with inspiration.

This would allow the worker to inhale a portion of the ambient air without appropriate filtration, thereby decreasing the effective protection factor of the device. Bellin and Hinds (_____) have studied the effect of small leaks in expiratory valves (as might occur with a very small amount of paint on the valve), and they have found it to be significant in some instances. The second theoretical disadvantage is that the valve respirator may be more costly.

There were no significant subjective differences between the MV and MN masks. However, respirator masks have been shown to have different preference levels in the empiric study of _____. Furthermore, although the single use respirators have been shown to have different preference levels in the empiric study of _____. Furthermore, although the single use respirators have minimal physiologic impact, they may have significant subjective and psychologic impact on some individuals. The studies of Gwosdow et al have shown that temperature of inhaled air and the temperature of the upper lip very much affect subjective comfort. Respirator masks may lead to increased temperature within the mask, and this factor may account for differences in worker tolerance, particularly if the mask is worn in a particularly hot, humid environment. Hence, although there may be minimal physiologic impact, the respirator user should be asked about subjective response. Workers who report that they tolerate the respirator particularly poorly may require special attention in the medical certification process. For example, they may require counseling and evaluation to

determine if their subjective intolerance is so great that they will not actually comply with the proper use.

Hence, for users of single use respirators, the use of a simple questionnaire, asking about subjective effects, may be preferable to physiologic testing. While purely subjective responses in the absence of more detailed evaluation certainly should not be used to make a job placement decision, these questionnaire approaches can be used to select the very small number of workers who require more in-depth interview and examination. Unfortunately, in some clinical and industrial settings, the availability of physiologic testing (e.g., spirometry) detracts from attention which should be given to asking the worker his/her subjective opinion. Similarly, assessment of subjective response should be an inherent part of respirator testing to compare alternate designs. Reliance on physiologic measures only, or even to a greater extent, upon pressures, flows, etc. on ventilated manikins can be significantly misleading if this does not acquire the full range of subjective response information.

The authors thank _____ for preparing the manuscript.

Move**** In addition, subjects used self-contained breathing apparatus (SEBA) (Model _____ from _____) for two experimental periods: in one, the device was used in the demand mode (SE), and in another period, the device was used in the pressure demand mode (SP), in which the mask maintained a positive pressure throughout the respiratory cycle).

Unfortunately, in several subjects, the device supports (straps, etc.) interfered with the RIP bends?? preventing accurate data collection. Therefore, for this portion of the study, the sample size was too small to meaningfully compare SC and SP results. These were combined for analysis and comparison to the ML situation.

Table 3 shows the analysis of variance comparing the no load to the SEBA (combined SP and SD) data. As may be expected, there were significant physiologic and subjective effects of the respirator upon the subjects.

This study was performed using two specific types of single use disposable respirators, and the method should be extended to study others. It does demonstrate that there is a specific technique for evaluating such responses. Furthermore, the study was performed using clean respirators. After extensive use, the resistance of the device may increase as the pores are obstructed by inhaled dust. However, under such circumstances, the respirators should be replaced rather than relying upon the worker to overcome the added resistance period.

Abstract:

_____ number of volunteers participated in a study investigating the physiologic and subjective effects of single use (disposable) respirators during moderate exercise on a calibrated field course. Measurements were made non-invasively using respiratory inductive plathesmography, and subjective responses were evaluated with visual analysis?? scales. The presence of a expiratory valve on the respirator did not appear to have any measurable significant effect on physiologic response or on subjective response. For comparison, self-contained breathing apparatus affects were studied and were significant both physiologically and subjectively. This study suggests that routine inquiry about subjective effects of single use disposable respirators is advisable, but that reliance upon physiological testing alone may be misleading.

To the Editor:

Please consider the enclosed manuscript, " _____
_____ " for industrial and environmental hygiene. It addresses
a specific question regarding the use of single use disposable
respirators.

In this manuscript, we do not identify the specific devices by
manufacturer so as not to imply too much about the specific
product. In actuality, the devices employed were _____ and
_____.

Thank you for your consideration of this manuscript. Please let
us know if we can provide any further information.

Please address all correspondence to the return name and address.
Sincerely,

Philip Harber, M.D., M.P.H.
Associate Professor of Medicine

PH:kk

COMPARISON OF PAPER AND VALVED MASKS

VAR	NO LOAD		PAPER		VALVED		P
	mean	st dev	mean	st dev	mean	st dev	
HR	142.2	16.12	139.2	17.76	135.7	26.25	0.72
Ti	1.032	0.274	1.230	0.203	1.225	0.222	0.10
RR	32.76	6.001	29.06	6.278	28.25	5.315	0.11
Vt	1.115	0.344	1.984	2.252	1.700	1.612	0.19
Ve	36.74	13.78	37.56	7.979	34.05	9.769	0.53
EX	5.227	1.571	4.808	1.528	4.646	1.590	0.08
DI	2.242	0.670	2.500	0.744	2.508	0.598	0.26

ANOVAS contrasting Paper, Valved and No Mask were done. It appears that the difference between No Mask and Mask is greater than the difference between Paper and Valved. It is also obvious that not very many variables came out statistically significant.

MASK AND LOCATION DIFFERENCES

VAR	MASK TYPE				LOCATION							
	Similar		Different		Field		Lab		Both			
	mean	n	mean	n	mean	n	mean	n	mean	n		
HR	17.75	24	7.13	17	**	8.42	12	13.34	18	18.57	11	ns
Ti	0.41	47	0.34	32	ns	0.17	31	0.65	21	0.43	27	**
RR	5.97	50	3.65	33	*	3.01	31	5.11	23	7.14	29	**
Vt	0.33	50	0.32	33	ns	0.23	31	0.22	31	0.52	27	*
Ve	10.37	47	6.50	33	+	4.85	30	10.92	23	11.29	27	*
EX	0.59	51	1.03	29	**	0.60	29	0.85	21	0.83	30	ns
DI	0.61	52	0.98	29	*	0.66	29	0.72	23	0.84	29	ns

ANOVAS were done on the differences between periods which were categorized by Mask Type, and Location. These differences were categorized according to the following table:

DIFFERENCE	MASK TYPE	LOCATION
FFD-FFN	Similar	Field
FSA-FSE	Similar	Field
FFN-FSA	Different	Field
LID-LFN	Similar	Lab
LID-LP	Different	Lab
FFN-LID	Similar	Both
FFN-LFN	Similar	Both
FSA-LID	Different	Both

THE WONDERFUL WORLD OF SCBA'S

(... or do we really want to check this out?)

VAR	LOAD		NO LOAD		P	SA		SE		P
	mean	st dev	mean	st dev		mean	st dev	mean	st dev	
HR	302.9	59.75	268.0	51.32	0.02	147.7	26.53	155.2	16.61	0.11
Ti	2.110	.0450	2.669	0.600	0.01	1.351	0.092	0.318	0.108	0.62
RR	53.56	10.81	66.10	12.34	0.01	25.94	5.210	27.62	5.952	0.10
Vt	3.292	0.893	2.447	0.819	0.03	1.704	0.503	1.588	0.430	0.22
Ve	85.79	30.62	78.18	25.13	0.38	43.16	14.65	42.62	16.38	0.75
EX	7.031	1.793	11.35	2.776	0.00	3.588	0.877	3.444	0.949	0.29
DI	7.850	1.038	3.819	0.943	0.00	3.900	0.569	3.950	0.555	0.75

ANOVAS of SA vs SE were done for each Variable, and ANOVAS of (SA+SE) vs (No Load) were done.

It is the table collator's humble opinion that this indicates that the SCBA user doesn't care if the Tank is on Air on demand or Positive Pressure. It matters far more if they are using a SCBA at all. Since the positive pressure offers more protection from seepage through the seal around the face, it would seem to be better. (but it must use the air supply faster)