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Respirators

RESPIRATOR TOLERANCE

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RESPIRATOR TOLERANCE

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Table of Contents

Title Page	1
Table of Contents	2
List of Abbreviations	3
List of Figures	3
List of Tables	3
Significant Findings	4
Abstract	6
TECHNICAL REPORT	
Report format	8
Overview: General Approach	9
Overview: Future Work Needed	9
Methods	
Respirators	10
Use Situations	11
Exercise Regimens	12
Specific Aims	13
Results Organized by Specific Aims	14
Effects of model and actual respirators	14
Comparative effects of several types of respirator loads	15
Interrelationships among the physiologic, subjective, psychophysiologic, and work performance factors of respirator effects	16
Develop and validate a human volunteer panel technique	17
The short and long term stability of measured responses	18
Methods for testing individuals and respirators in field settings	19
Determining physiologic responses to respiratory pressure biasing	20
The effect of emergency use of respirators	21
Additional studies	22
Conclusions	23
References	24

List of Abbreviations

LSS:	Load scaling sensitivity to inspiratory resistance
PAPR:	Powered air purifying respirator
Ti:	Inspiratory time.
Ti:Ttot:	Duty cycle (ratio of inspiratory: total time).
SCBA:	Self contained breathing apparatus
CO2:	Carbon dioxide.
IR:	Inspiratory Resistance
ER:	Expiratory Resistance
PBB:	Pressure biased breathing. (SCBA in pressure-demand mode).
DS:	Dead space (respiratory).

List of Figures and Tables

Table 1. Methods: Actual vs. Surrogates

Table 2. Specific Aims

Abstracts and selected tables and figures are from the following papers:

1. Effects of respirator dead space, inspiratory resistance, and expiratory resistance ventilatory loads.
2. Physiologic and subjective effects of respirator mask type.
3. Subjective tolerance of respirator loads and its relationships to physiologic effects.
4. User response to single use respirator expiratory valve.
5. Respirator effects in pulmonary impaired subjects.
6. Effect of exercise level on ventilatory adaptation to respirator use.
7. Relationship of subjective tolerance of respirator loads to physiologic effects and psychophysical load sensitivity.
8. Effects of industrial respirators on respiratory timing and load sensitivity.
9. Determinants of pattern of breathing during respirator use.
10. Respirator testing in non-clinical settings: II. Global subjective questions.
11. Temporal pattern of adaptation to respirator use.
12. Respirator testing in non-clinical settings: I. Relative consistency of field versus laboratory measurements.
13. Non invasive measurement of respirator effect at rest and during exercise.
14. Relative effects of flow-resistive and pressure biased respiratory loading.
15. Respirator effect on oral-nasal flow partition.
16. Nasal-oral flow partition with respirator use.
17. Worker fitness and respiratory protective devices.
18. Respiratory physiology research: Answers in search of the question.
19. Respirator use in the work environment.

RESPIRATOR TOLERANCE

P. Harber

SIGNIFICANT FINDINGS

Respirators play a major role in protecting American workers from inhaled toxins. Proper understanding of their effects upon the user improves their design and the medical criteria for determining proper utilization. This project can improve the health of workers with potential exposure to a wide variety of toxins by development of respiratory protection systems which are effective and, equally importantly, will actually be used.

Unlike other workplace exposure controls, respiratory personal protection depends upon the volitional action of the worker in employing the device properly. This study has focused not only on the adverse physiologic effects of the devices but also upon identification of those factors which affect the workers' ability to tolerate the device, thereby directly affecting the likelihood of proper utilization. In this fashion, they have increased the probability that the devices will be employed and thereby protect workers.

1. Assessment of Ventilatory Limitation Effect is Inadequate

The study has clearly demonstrated that respirators have effects other than simply producing limitation of ventilation due to resistance to airflow. These effects include: subjective discomfort, mask effects, change in load sensitivity, change in respiratory control pattern, and a switch from nasal to oral airflow. Failure to consider these effects will lead to inadequate characterization of devices and workers. This was demonstrated empirically for certain devices (eg., PAPR's). This suggests that governmental regulations concerning certification of equipment (which are now largely based on resistance) should consider the other factors as well in order to assure safe and effective respirators.

2. Psychophysical Sensitivity Affects Tolerance

Individuals, even those who are physiologically normal, differ in their sensitivity to inspiratory resistance (load scaling sensitivity, LSS). This factor partially determines an individual's response to respirator use, both subjectively and in terms of respiratory pattern. This explains while routine pulmonary function tests, such as spirometry, are unlikely to successfully select those workers who will have poor tolerance. Therefore, policies (both clinical and regulatory) concerning evaluation for fitness in respirator use situations should not rely only upon such routine tests. So doing would potentially expose sensitive intolerant workers to respirator use.

3. Relatively Simple Methods May be Feasible for Worker Evaluation

RESPIRATOR TOLERANCE

P. Harber

The patterns of response of healthy volunteers, individuals with mild respiratory impairment, and actual respirator users are qualitatively similar. Therefore, standard methods can be developed for all users. Studies showed that subjective response was as stable and consistent as was physiologic response. In addition, measurements made during actual use in field settings was generally as consistent as in carefully controlled laboratory settings. This suggests that with only limited additional study, practical worker evaluation methods may be developed for workplace application. This is especially important now that the Americans with Disabilities Act mandates careful rational evaluation of impaired workers to assure their right to work.

4. Respiratory Timing Parameters are Useful for Characterization

Respiratory timing parameters (Inspiratory time, T_i , and duty cycle, $T_i:T_{tot}$) are useful for characterizing devices and workers. They are consistently affected, related to actual tolerance, affected in all subject subgroups, and affected by the different respirator loads.

In summary, this project has identified respirator and personal factors affecting tolerance to respirator use. Application of these data can foster development of objective measures to assure the proper respirator may be available for each worker to protect against inhaled toxins. Furthermore, understanding of the mechanisms of tolerance can assure that no worker is denied a job inappropriately because of concern about ability to use a respirator.

ABSTRACT

This project sought to determine those factors determining whether a worker will tolerate respirator use. In the past, respirators and users were assessed to determine whether the physical load imposed by the device is so great that the user cannot meet the ventilatory demand of the added work. The Respirator Tolerance project demonstrated both empirically and conceptually that respirator design and user evaluation must consider additional effects. Studies were conducted in normal volunteers, industrial workers, and persons with mild respiratory impairment.

The physiologic response to each type of respirator load (alone and in combination) was evaluated, including flow resistance (inspiratory and expiratory), dead space, and pressure biasing (as from pressure-demand SCBA). Inspiratory resistance produces the most prominent effects, although the other loads were significant.

The respirator effect on adaptation of respiratory control (to optimize work of breathing or to minimize sensation) was as important as total work of ventilation. Further studies illustrated that respiratory pattern adaptation is consistent across subjects and across levels of exercise; in addition, respiratory impaired workers showed a consistent response for these variables. Subjective response also correlates with respiratory timing adaptation. Thus, effects on respiratory pattern seem particularly useful for evaluating workers and respirators. Ventilation limitation alone does not explain respirator tolerance at submaximal exercise levels.

The studies of normal volunteers in the laboratory setting were complemented by studies on site in two industrial facilities (a foundry and an aerospace manufacturer). Furthermore, respiratory inductive plethysmography (RIP) was applied (with considerable effort) to respirator research, allowing measurement with actual unmodified respirators and in field activities, which are more similar to real life use. These confirmed and extended the laboratory studies. Use of actual respirators, in addition to laboratory surrogates, provides insight; for example, a powered air purifying respirator produced much less physiologic impact than a standard air-purifying device, but the adverse subjective effects were comparable.

Because the traditional effects on air-flow, etc. do not fully explain differences in tolerances among subjects, additional effects were evaluated. Partitioning of airflow between the nasal and oral routes is changed by respirator use, and absolute resting lung volume changes (FRC) were found to be increased by pressure demand (pressure biasing); both possibly account for poor tolerance. Subsequently, based on a pilot trial suggesting its importance, subjective response was also determined. Inspiratory flow resistance is more important than dead space loading. Pressure bias, as with pressure demand respirators, is also important both physiologically and subjectively.

Personal factors affecting tolerance were also studied.

RESPIRATOR TOLERANCE

P. Harber

Psychophysical load scaling sensitivity (LSS) is an objectively measured personal characteristic, describing growth of sensation with added resistances. Persons with high LSS tend to have greater subjective discomfort and also adapt a different respiratory pattern (which imposes greater actual loads) than do individuals with lower LSS. Differences in LSS (and consequent maladaptation of respiratory pattern) may partially explain differences in tolerance, even among physiologically normal persons who can overcome the respirator resistance itself. Furthermore, on the average, LSS declines with respirator use, thereby improving tolerance to the imposed load.

A series of subjects with mild-moderate respiratory impairment were studied; the pattern of response was comparable to that of normals. This suggests that the types of variables studied in normals are applicable to the impaired.

A group of industrial users self-classified themselves as tolerant/intolerant; there was a tendency for differences to persist on each of several subjective sub-scales and for the intolerants to have a higher LSS. A combined subjective index was useful for separating the tolerant and intolerants.

Subjective measures may be consistently measured, are related to physiologic response, and reflect two important personal characteristics (LSS and self-rated tolerance). They can distinguish respirator load types and provide complementary information to physiologic measures. The components of subjective response were assessed; perceived limitation of exertion and subjective discomfort may be dissociated. The data suggest that subjective response should be included in evaluations of both respirator designs and specific workers.

Extensive studies showed general comparability of volunteer, mildly impaired, and industrial populations. Field course testing showed results comparable to those of the laboratory and was consistent.

In summary, the project has shown that respirator effects cannot be considered merely as limiting ventilation and maximal exercise. Very important respiratory control adaptation and subjective effects were described, and the project evaluated interrelationships among various respirator loads, exercise level, personal characteristics, ventilatory, sensation, respiratory control, and subjective effects. These factors should be considered when comparing alternative respirators or testing workers. They also explain why some apparently "normal" workers have poor tolerance.

TECHNICAL REPORT

REPORT FORMAT

This project has had many facets and subprojects. Therefore, to facilitate this report, the summary report is organized into sections based upon the proposed specific aims, shown in Table 2.

The "Overview" section discusses the general problem. "Methods" provides the overall scheme of the investigation. "Specific Aims" summarizes the eight original project aims and succinctly describes results for each; where appropriate, reference for details is made to the published or in-progress papers. A summary of the actual "Data" is presented in a series of sections, each addressing a particular facet. Each of these sections includes an overview of the problem and results. Abstracts of papers¹⁻²¹ and selected tables and figures are included.

Overview: General Approach

Respirators play a major role in protecting american workers from inhaled toxins. Proper understanding of their effects improves their design and the medical criteria for determining proper utilization. This project can improve the health of workers with potential exposure to a wide variety of toxins by development of respiratory protection systems which are effective and, equally important, will be used in work situations. Effective respirator programs (respirator personal protection) depend upon actual utilization. This study has focused not only on the positive physiologic effectiveness of the devices but also upon identification of those factors which affect the workers ability to tolerate the device, thereby directly effecting the likelihood of proper utilization. Unlike other workplace exposure controls, respiratory personal protection depends upon the volitional action of the worker in employing the device properly. This study has directly assessed the factors which determine an individual's tolerance of the device. In this fashion, they have increased the probability that the devices will be employed and thereby protect workers.

Overview: Future Work Needed

There is a need in the area of well founded criteria for defining permissible physical loads imposed by the respirators and in defining the types of medical evaluations. The current OSHA regulation (1910.134) is not specific for the type of medical evaluation, leaving considerable opportunity for inadvertent discrimination against mildly impaired workers and, in addition, permitting false assurance that use will be safe in some individuals.

Although the planned work was completed, additional study is needed. Now that the specific factors which determine tolerance have been identified, future studies can use the quantitative methods developed to generate rationale quantitative guidelines for acceptable limits for respirator design and worker certification.

There is now a need to use the information developed in this project and by other investigators in order to accomplish the following:

1. Identify which of the many demonstrated effects are really most important.⁷
2. Establish quantitative measures for each of the important effects.
3. Develop an integrated model for all respirator effects.
4. Determine acceptable limits for the major effects and

RESPIRATOR TOLERANCE

P. Harber

loads as a guide for regulatory and clinical policy.

METHODS

This study was performed to assess respirator effects in human volunteers. This section describes the methods used.

Respirators:

The study used either actual respirators or surrogates. Actual respirators included single use masks, full face mask dual cartridge respirators, self contained breathing apparatus (SCBA), and powered air purifying respirators (PAPR). Surrogates allow providing carefully designed and quantitative loads alone or in combination. The table shows relative advantages and disadvantages.

Table: ACTUAL VS SURROGATES	<u>ACTUAL</u>	<u>SURROGATE</u>
Types of Load	-Single Use -Dual cartridge full face mask -SCBA -PAPR	-Insp Resistance -Exp Resistance -Dead Space -Pressure Bias
Relevance	directly relevant to actual use	not directly comparable to any real respirator
Load Characterization	difficult	quantitative
Physiologic measures	difficult (cannot connect to measuring equipment; must use plethysmographic methods).	Easier and more direct
Generalizability	possibly model specific	relevant to other similar loads
Consistency of load	actual load may differ among subjects	controlled and constant
Integrative Value	integrates all effects	might miss an important effect if the particular load is not suspected

RESPIRATOR TOLERANCE

P. Harber

Table: ACTUAL VS SURROGATES	<u>ACTUAL</u>	<u>SURROGATE</u>
Specificity of Effect	a measured effect may have several causes	effects can be assigned to specific loads by use of factorial design
Ease of experimentation	difficult	easier
Use method	mask	mouthpiece

For certain protocols, a mixed approach was used, in which actual masks were employed, but the fittings were modified to allow direct attachment to measuring devices such as pneumotachographs.

USE SITUATIONS:

The effects were studied under several circumstances.

In the laboratory setting (lab), conditions were carefully controlled. Exercise level was directly controlled (eg, by setting the resistance on the bike ergometer). Measurements could be made using the full range of equipment. The disadvantage of this setting, however, is that it is somewhat unrealistic and might theoretically not fully reflect actual use conditions. In addition, recruitment of workers who regularly use respirators to come to a laboratory is more difficult because they must leave their worksites.

Field course (Field) work is performed on a carefully specified field course. The subject is accompanied by a staff member throughout. The activities, although specified, are all "natural" (eg., stair or hill walking). To provide consistency, there are markers and time cards along the course. Nevertheless, there is a possibility of greater exercise variability than in the lab. Furthermore, measurements are more difficult since the usual respiratory ventilation equipments cannot be used, but rather, tape recording and plethysmography are needed. This disadvantage is offset by the greater relevance to actual worksites. Furthermore, in the future, "field courses" could be established in clinics and worksites for evaluation of workers.

Worksite laboratories (worksite) involve controlled exercise as in a lab setting, but conducted at a worksite facility. For example, in part of the study, major components of the on-campus lab were moved to an aerospace manufacturing facility's on-site

RESPIRATOR TOLERANCE

P. Harber

clinic. This permitted studying actual respirator users (and similar non-user controls) efficiently without the biases potentially present in volunteers who are able to come to a University lab.

Exercise Regimens:

In general, the project utilized submaximal, exercise levels. We elected to specify the exercise level rather than adjust exercise level to adjust the subject's ventilation or O_2 consumption to a set value (ie, the speed and grade of the treadmill, not the achieved ventilation, was set).

Exercise periods were 6-8 minutes in length for each condition in most protocols. For some purposes, when the study required that the subject be evaluated at many exercise levels, rapidly incremental protocols were employed using 1 minute intervals.

In addition, for those studies involving determination of a subject's peak level, incremental exercise to maximal was employed.

Table 2. SPECIFIC AIMS

Specific aims of this project include:

- 1. Determine effects of model and actual respirators upon the physiologic, psychophysiologic, subjective, and work performance characteristics of users.**
- 2. Compare effects of several types of respirator loads on the above variable classes. Determine the extent to which laboratory studies with respirator surrogates are comparable to actual respirator use in non-laboratory conditions.**
- 3. Assess the inter-relationships among the physiologic, subjective, psychophysiologic, and work performance factors of respirator effects. Assess the degree to which easily determined objective physiologic tests relate to the other factors of respirator tolerance.**
- 4. Develop and validate a human volunteer panel technique for providing integrated measures of respirator effects. Such a method should be useful as a standardized respirator evaluation technique.**
- 5. Describe the short and long term stability of measured responses to respirator use. Delineate intra-personal from inter-personal differences in pattern of adaptation. (Such information is necessary for interpreting any evaluation of an individual worker and for "man testing" of respirators).**
- 6. Develop methods for testing individuals and respirators in field settings; such methods might subsequently be employed on a "non-research basis". Compare laboratory, field course, and worksite methods.**
- 7. Determine the physiologic response to respiratory pressure biasing (similar to that of pressure demand respirators).**
- 8. Describe the effects of Emergency Use of respirators (in contrast to regular, prolonged use).**

RESPIRATOR TOLERANCE

P. Harber

Results Organized by Specific Aims

1. Determine effects of model and actual respirators....:

The effects of respirators, both actual and surrogate load, were carefully evaluated.

Different loads were compared, and it appears that inspiratory resistance is most significant both physiologically and subjectively. However, other loads also contributed to adverse effect.

As previously shown by the investigators, flow resistance decreased peak flow rates and peak exertion levels. A major new finding was the extremely consistent effect on respiratory control. Uniformly, there was prolongation of the inspiratory time (T_i) and of the duty cycle ($T_i:T_{i+tot}$) by inspiratory resistive loading, and conversely, expiratory loading had the opposite effect. Average flow rates also were decreased. It is notable that the change to the timing parameters did not necessarily decrease the total ventilatory work.

Subjective responses were measured using two visual analog scales, and the effects of different types of loads could be compared. As shown below in more detail, resistive loads were more significant than dead space loads.

The specific effects of pressure biasing loads are discussed under aim seven below.

2. "Comparative effects of several types of respirator loads....determine the extent to which laboratory studies with respirator surrogates are comparable to actual respirator use in non-laboratory conditions."

Extensive studies under field conditions were performed. The study required the use of respiratory inductive plethysmography. These studies demonstrated that comparable results were obtained under field conditions using actual respirators and in laboratory settings using surrogates. This is reassuring, allowing utilization of laboratory data from our other studies as a guide to "real-life" effects.

The results suggest that it is important to evaluate both subjective and "objective" physiologic effects. For example, we studied powered air purifying respirators (PAPR). There was a significant disparity between the subjective responses (which were adverse) and the physiologic responses (which were not). Focusing only on the physiologic effects of the respiratory loads (which are minimized with PAPR's) would have inappropriately labelled these as especially valuable.

3. Assess the interrelationships among the physiologic, subjective, psychophysiologic, and work performance factors of respirator effects....

These studies demonstrated that there are clear interrelationships among the different categories of effect.

Psychophysiologic studies provided insight into the mechanisms of tolerance beyond those involving actual ventilatory work. An individual's psychophysiologic load sensitivity is an objectively measurable parameter (LSS), showing how quickly sensation grows in proportion to increased loads. It differs significantly even among normal individuals. Studies demonstrated the following:

- a. There are significant differences in LSS among normal individuals.
- b. An individual's LSS partially determines the subjective response to a given load. Individuals who are highly sensitive tend to be more uncomfortable.
- c. LSS partially determines the pattern of respiratory response to respirator loading. Individuals with high LSS scores tend to adapt a somewhat "non-functional" respiratory pattern when faced with certain loads.
- d. In normal individuals, LSS "down adapts" during respirator use. That is, over the course of an extended experiment, the LSS scores actually decreased for individuals, thereby allowing them to better tolerate the effects of the respirator.
- e. In industrial worker populations, there is a trend towards greater global discomfort ratings by individuals with higher LSS scores.

Taken together, the psychophysiologic (LSS) data help explain why some individuals report poor tolerance. Individuals with higher innate sensitivity to added respiratory loads may tend to be increasingly uncomfortable. In addition, in order to minimize sensation, they adapt respiratory patterns which tend to increase the actual work. Finally, it is possible (although we have not proven it) that there are individuals who do not decrease their load sensitivity in the course of respirator use; such individuals may be particularly sensitive.

We have also examined the relationship between subjective responses and physiologic responses. It is reassuring that there are, indeed, such relationships. Generally, this suggests validity of worker comments concerning respiratory tolerance even if subjective.

4. Develop and validate a human volunteer panel technique...

Throughout the recent studies, human volunteers have participated on multiple occasions and have displayed consistent results. The consistency is described under aim five, below. Use of human volunteer panels may be advantageous in respirator assessment, particularly since there has been increased recognition (through this project and work of other investigators) of the importance of subjective as well as objective responses. Development of a stable human rating panel was feasible and could be applied in a general manner.

5. Describe the short and long term stability of measured responses...

The stability of responses was examined. Responses appear equally stable in field and laboratory settings. Furthermore, somewhat surprisingly, subjective responses are as stable as "objective physiologic responses". This is important because simple tests using subjective responses may be useful for respirator evaluation. Furthermore, it further supports the potential use of human panel studies.

6. Develop methods for testing individuals and respirators in field settings. Compare laboratory, field course, and worksite methods.

This study made extensive use of several different testing settings. As discussed above, results tended to be consistent and comparable in the different settings. Furthermore, practical field courses, such as those developed herein, could be established in many industrial settings.

In the course of the work, several groups of subjects were compared. These included normal volunteers, individuals with mild respiratory impairment (studied in the earlier project), workers who used respirators regularly, industrial workers who do not use respirators, and workers who claim they are particularly uncomfortable. Notably, the pattern of response in each of these populations was qualitatively the same. This suggests that the same types of evaluating procedures may be used.

Comparison of the industrial workers who self classified themselves as "tolerant" to those who were "intolerant" exhibited interesting phenomena: They differed on many individual scales of particular types of discomfort or intolerance. Furthermore, there was a trend (but not statistically significant in the sample size used) for the self classified intolerant workers to have greater psychophysiologic sensitivity and to state that they tended to use their respirators less. If this is true, then there would be a clear link between actual use and subjective response.

7. Determine physiologic responses to respiratory pressure biasing (similar to that of pressure demand respirators)....

Pressure biasing was specifically studied in laboratory settings. It is clear that pressure biasing does produce significant physiologic and subjective impact. The degree of intolerance is comparable to that of a moderately large inspiratory resistance - dead space load. Furthermore, the mechanism identified was probably being related to an increase in the resting lung volume. This suggests that pressure demand SCBA's must be used with caution and that they must be evaluated for more than ventilatory effects.

8. Describe the effect of emergency use of respirators:

We were not able to adequately describe emergency use. Studies using "naive" subjects were unable to demonstrate any significant differences from those who had been studied with any prior experience. It is possible that this was related to ethical considerations in the study: we were not ethically able to have naive subjects use respirators without any explanation. It is therefore possible that by the time the study was actually performed, they were somewhat acculturated.

9. Additional studies:

Additional studies, not fully described in the specific aims were carried out.

The partition between nasal and air flow was studied based on the preliminary observation in the course of the study that changes occurred. Work in other laboratories suggested that this might be an important factor, and we therefore incorporated such studies using a thermal sensing method (thermocouple in front of the nose). The studies demonstrated that there is indeed a significant effect of respirator use upon the switch from nasal to oral breathing. Normal individuals shift from nasal to oral breathing as exercise level increases. In the respirator use situation, this occurs much earlier in the exercise regimen, and this may significantly contribute to adverse symptoms.

CONCLUSIONS

The ability to use respirators safely and effectively is multifactorial. Proper evaluation of both respirators and users must recognize all of the important factors. The study suggests that human panel testing can have a major role in the objective evaluation of respirators. Practical workplace testing of respirator users in a rational manner is likely to be feasible in the future.

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RESPIRATOR TOLERANCE

P. Harber

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