

Final Performance Report

(Option 2)

NIOSH Grant 5-R01-OH03244

Characteristics of Respirators Protecting against TB

Project Period: 02/01/95 - 01/31/98, extended to 07/31/98

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Publications: Total number: 18
Eleven peer-reviewed publications
Seven non-peer-reviewed publications

Date: August 28, 1998 (sent again December 23, 1998)

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PUBLICATIONS RESULTING FROM THIS GRANT

A. Peer-Reviewed Publications

1. Willeke, K., Qian, Y., Donnelly, J., Grinshpun, S., and Ulevicius, V. "Penetration of Airborne Microorganisms through a Surgical Mask and a Dust/Mist Respirator" *Am. Industrial Hygiene Assoc. J.*, 57:348-355 (1996).
2. Terzieva, S., Donnelly, J., Ulevicius, V., Grinshpun, S.A., Willeke, K., Stelma, G.N., and Brenner, K.P. "Comparison of Methods for Detection and Enumeration of Airborne Microorganisms Collected by Liquid Impingement", *Applied and Environmental Microbiology*, 62:7:2264-2272, (1996).
3. Willeke, K. and Han, D-H. "Quantitative Fit Testing Techniques for Respirators Protecting the Human Respiratory System against Environmental Aerosols", in: "*Aerosol Inhalation: Recent Research Frontiers*" (J. C. M. Marijnissen and L. Gradon, editors), pp. 225-234, Kluwer Academic Publishers, Dordrecht, The Netherlands, (1996).
4. Han, D-H., Willeke, K. and Colton, C.E. "Quantitative Fit Testing Techniques and Regulations for Tight-Fitting Respirators: Current Methods Measuring Aerosol or Air Leakage, and New Developments", *American Industrial Hygiene Association Journal*, 58:219-228, (1997).
5. Qian, Y., Willeke, K., Ulevicius, V., and Grinshpun, S.A., "Particle Reentrainment from Fibrous Filters," *Aerosol Science and Technology*, 27:394-404, (1997).
6. Qian, Y., Willeke, K., Grinshpun, S.A., and Donnelly, J. "Performance of N95 Respirators: Reaerosolization of Bacteria and Solid Particles", *American Industrial Hygiene Association Journal*, 58:876-880 (1997).
7. Huang, C., Willeke, K., Qian, Y., Grinshpun, S., and Ulevicius, V. "Method for Measuring the Spatial Variability of Aerosol Penetration through Respirator Filters", *American Industrial Hygiene Association Journal*, 59:461-465, (1998).
8. Qian, Y., Willeke, K., Grinshpun, S.A., Donnelly, J. and Coffey, C. "Performance of N95 Respirators: Filtration Efficiency for Airborne Bacteria and Solid Particles," *American Industrial Hygiene Association Journal*, 59:128-132, (1998).
9. Willeke, K. and Qian, Y. "Tuberculosis Control through Respirator Wear: Performance of National Institute of Occupational Safety and Health-Regulated Respirators" *American Journal of Infection Control*, 26:139-142, (1998).
10. Wang, Z., Reponen, T., Willeke, K., and Grinshpun, S.A. "Survival of Bacteria on Respirator Filters", *Aerosol Science and Technology*, in print (1999).

11. Reponen, T.A., Wang, Z., Willeke, K., and Grinshpun, S.A. "Survival of Mycobacteria on N-95 Personal Respirators", *Infection Control and Hospital Epidemiology*, in print (April 1999).

B. Non-Peer-Reviewed Publications

12. Grinshpun, S.A., Willeke, K., Ulevicius, V., Qian, Y., and Donnelly, J. "Aerodynamic Particle Sizing of Airborne Bacteria" *J. Aerosol Sci.* 26: S879-880 (1995).

13. Qian, Y., Willeke, K., Donnelly, J., Grinshpun, S.A., and Ulevicius, V. "Penetration of Rod-Shaped Bacteria of Different Aspect Ratio through Filter Media Used in Respiratory Protection Devices" Abstract of 14th Annual Meeting of the American Association for Aerosol Research, p. 14, Pittsburgh, PA, October 9 -13, 1995.

14. Qian, Y., Donnelly, J., Ulevicius, V., and Willeke, K. "Re-Aerosolization of Microorganisms from the Filter Media of Health Care Respirators" Abstract of 1996 American Industrial Hygiene Conference and Exposition, Washington, DC, May 20-24, 1996 .

15. Qian, Y., Willeke, K., Ulevicius, V., Grinshpun, S., Donnelly, J., Reponen, T., and Huang, C. "Particle Reentrainment from Fibrous Filters" Abstract of 1996 15th Annual Conference of the American Association for Aerosol Research, p. 298, Orlando, FL, October 14-18, 1996.

16. Willeke, K. And Qian, Y. "Filtration of Airborne Microorganisms: Collection and Reaerosolization Characteristics", in *Advances in Filtration and Separation Technology*, Vol. 11, Baumann, E.R. and Weiset, L., editors, American Filtration and Separation Society, p. 396, 1997.

17. Wang, Z., Reponen, T., Willeke, K., and Grinshpun, S.A. "Survival and Growth of Bacteria on Respirator Filters", Abstract of the 1998 American Industrial Hygiene Conference and Exposition, Atlanta, Georgia, paper #291, 1998.

18. Reponen, T., Wang, Z., Willeke, K., Qian, Y., Grinshpun, S., and Jankowska, E. "Behavior of Bacteria on Respirator Filters - Reentrainment and Survival", Abstract of 1998 175th Annual Conference of the American Association for Aerosol Research, p.314, 1998.

SIGNIFICANCE AND USEFULNESS OF RESULTS

In 1995 NIOSH issued new regulations for respirators. All nine new respirator categories are permitted in health-care facilities for the prevention of the transmission of tuberculosis. The N95 respirator is the most frequently used. It has been evaluated as to its efficiency for collecting TB-size bacteria. The study results show that N95 respirators collect 0.1 to 0.3 μm particles with efficiencies of 95% or higher. TB-size bacteria of 0.8 μm and larger, however, are collected with much higher efficiencies: 99.5% or higher. Furthermore, the study results show that no bacteria are reentrained during normal exhalation. Only at low humidity flow conditions, corresponding

to violent coughing or sneezing, has reaerosolization of 0.1% or less been observed.

The survival and potential growth of several bacteria were investigated on polypropylene respirator filters which are the most common among the NIOSH-certified respirators. *Mycobacterium smegmatis*, a biochemical simulant of *Mycobacterium tuberculosis* (Mtb), and the other test bacteria did not grow on the tested respirators, even when the respirators were stored at temperature, humidity and nutrition conditions most favorable for microbial growth. However, *Mycobacterium segmatis* could survive on respirators for up to three days during storage. The culturability of *Mycobacterium segmatis* was not affected by the air flow simulating respirator wear under medium work load conditions.

It is concluded that all of the new NIOSH-certified respirators, including the N95 respirators, offer good protection against TB bacteria. A significant number of bacteria can enter the respirator wearer's breathing space only through face seal leaks. Bacteria collected by the respirator filter will not reaerosolize during normal exhalation. This study shows that Mtb surrogate bacteria collected on a respirator can remain viable only under conditions that are not usually encountered in hospital wear. Reaerosolization of a very small fraction of collected bacteria can occur only at low humidity under extreme conditions of violent sneezing or coughing. Thus, minimal infection risk is expected from the reaerosolization of Mtb collected on respirators. Emphasis for respiratory protection in environments that may contain airborne Mtb, thus, needs to focus on appropriate fit of the respirator to the wearer's face.

SATISFACTION OF SPECIFIC AIMS

Note: Reference is made to the peer-reviewed publications listed above.

Specific Aim 1a. Development of a dynamic aerodynamic sizing technique for measuring the filter penetration of microorganisms and microorganism-containing droplets in the size range of 0.3 μm to several micrometers. (Year 1)

A new aerodynamic particle size spectrometer, the Aerosizer by Amherst Process Instruments Inc., has been modified for this purpose, see publication #1.

Specific Aim 1b. Development of a technique for dynamically measuring the microbial fragments below 0.3 μm . (Year 1)

The LAS-X laser aerosol size spectrometer by Particle Measuring Systems Inc. has been modified for this purpose, see publication # 1.

Specific Aim 1c. Development of method for electrostatic charging of microorganisms and discharging of respirator filter material. (Year 2)

This part is included in publication #5.

Specific Aim 1d. Modification of present test facility to accommodate the new methods. (Year 1)

& 2)

This has been done to perform the tests reported on in publication #1. Further modifications and results are presented in publications #5 and 8.

Specific Aim 2a. Selection of Mycobacterium species test microorganisms and their aerosolization. (Year 1)

Specific bacterial species were selected for the penetration testing of bacteria of different shapes, see publication #1. Different species have been selected for the re-aerosolization and survival testing. The latter are discussed in publications #5, 6, 10 and 11.

Specific Aim 2b. Development of experimental technique for measuring the bacterial concentrations up- and down-stream of respirators, utilizing new agar-impaction and liquid-impingement bioaerosol samplers. (Year 1)

These techniques and modifications of them have been used in publications #2, 5, 6, 7, and 8.

Specific Aim 2c. Development of experimental techniques for studying bacterial injury after filter penetration, and bacterial repair and survival after storage. (Year 2)

These techniques have been developed, as described in publication #2.

Specific Aim 3. Selection of Respirators and Statistical Considerations. (Years 1 & 2)

Publication #1 lists some of our statistical considerations used in the work leading to that publication. Statistical procedures are developed by us for each experimental step and are reported on in each journal publication. Our tests with new respirators under the new Regulations 42CRF Part 84 are reported in publications #2, 5, 6, 8, and 9.

Specific Aim 4a. Bacterial penetration studies with off-the-shelf respirators. Studies of off-the-shelf respirators with neutralized, aerosolized microorganisms. (Year 2)

This aim is the subject of publications 1, 2, and 8. Since aerosol penetration not only occurs through the filter material, but also through face seal leaks, additional publications #3 and 4 have been written to address face seal leakage.

Specific Aim 4b. Studies of new respirators with charged, aerosolized microorganisms. (Year 2)

Instead of charged versus discharged microorganisms, tests were conducted with charged versus discharged filter media, see publication #5. Since microorganisms have their natural charge while airborne, the testing with charged versus discharged filters is considered to be more important.

Specific Aim 4c. Studies with discharged respirators. (Year 3)

Same publicaions as in 4a and 4b.

Specific Aim 4d. Studies at different humidity levels. (Year 3)

Same publicaions as in 4a and 4b.

Specific Aim 5. Studies of Bacterial Aerosolization from Respirators after Exposure to Airborne Microorganisms. (Years 2 & 3)

Many of these tests were conducted on filter samples cut out of full-size respirators. That was necessary for the complex test procedure. Publication #7 was undertaken to investigate the representativeness of such a filter sample. Data on reaerosolization and data interpretation are given in publications #5, 6, and 9.

Specific Aim 6. Bacterial Injury Studies. (Years 2 and 3)

The test procedures have been described in publication #2. The test data are given in publications #10 and 11.

Specific Aim 7. Evaluation of Research for Future Standards of Certification and Quality Assurance Testing of Respirators Protecting against TB and other Infectious Agents.

All listed publications are relevant for future standard setting, in particular publications #6, 8, 9, 10, and 11.

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