

Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering Facepiece Respirator Fit: Part III – Two Year Assessment of Fit Changes

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Objectives

- The objectives of this study are to assess changes in respirator fit and facial dimensions as a function of time for a representative sample of subjects wearing filtering facepiece respirators (FFRs) (Figure 1) and to investigate factors (e.g., weight change) that affect change in fit.



Figure 1. Examples of FFR.

Background

- Over three million American workers are required to wear respirators and receive annual fit tests in accordance with the 1998 Occupational Safety and Health Administration (OSHA) standard 29 CFR 1910.134.
- Four commenters were considered in establishing the OSHA annual fit test requirement:
 - Texas Chemical Council: found that virtually no individuals fail fit tests a year after initial test.
 - Exxon Company: < 1% annual fit test failure rate.
 - Lord Corporation: < 1-3% annual fit test failure rate.
 - Hoffmann-La Roche: 7% switch to different sizes and/or models after 2 years.
- The National Institute for Occupational Safety and Health initiated a three-year study to assess changes in respirator fit and facial dimensions as a function of time to improve the scientific basis for the periodicity of fit testing.
- A representative sample of 229 subjects was initially enrolled in the study. To date, 149 subjects have completed the 2nd year of testing. The results from baseline through the second year of testing are presented.

Materials and Methods

- Subjects were trained to don and doff FFRs using standardized videos.
- Inward leakage (IL) was measured with the TSI PORTACOUNT® instrument during five-exercise fit tests. Filter penetration was measured to calculate face seal leakage (FSL).
- The study included only subjects who (a) passed one of the first three fit tests and (b) demonstrated, through a series of nine donnings, that they achieved adequate fit. A subject was considered to have achieved adequate fit if 90th percentile FSL was 5% or less.
- On each subsequent visit, subjects repeated the series of nine five-exercise fit tests for their specific style, model and size respirators.
- Three-dimensional (3-D) scans of subjects were captured; height, weight and 13 facial dimensions were measured using traditional measurement techniques.

Results

- For all follow-on visits (Visits 2-5), the mean FSL from V1 and the mean change in FSL from V1 were larger for subjects whose fit became unacceptable compared to those whose fit was remained acceptable (Table 1).
- A weight loss of ≤ 20 lbs. or weight gain of ≥ 20 lbs. was experienced by 4%, 12%, 12%, and 14% of subjects on the 2nd, 3rd, 4th, and 5th visits, respectively. An unacceptable fit was associated with 8% of these occurrences.

Table 1. Changes in Weight and FSL by Visit*

Visit 2 (V2): 6 Month Visit											
ACCEPTABLE						UNACCEPTABLE					
	n	Mean	SD	Min	Max		n	Mean	SD	Min	Max
FSL V1 (%)	178	0.65	0.34	0.11	2.13	FSL V1 (%)	21	0.98	0.44	0.32	2.01
Weight V1 (lb)	178	181.53	41.25	98.41	311.35	Weight V1 (lb)	21	196.69	48.90	131.62	305.61
ΔFSL (V2- V1) (%)	178	0.11	0.40	-1.09	1.72	ΔFSL (V2- V1) (%)	21	2.48	3.52	-0.63	16.01
Δ Weight (V2-V1) (lb)	177	2.47	10.17	-30.58	46.75	Δ Weight (V2-V1) (lb)	21	-1.33	12.85	-30.43	18.90
Visit 3 (V3): 12 Month Visit											
ACCEPTABLE						UNACCEPTABLE					
	n	Mean	SD	Min	Max		n	Mean	SD	Min	Max
FSL V1 (%)	168	0.66	0.34	0.11	2.13	FSL V1 (%)	19	0.95	0.51	0.26	2.01
Weight V1 (lb)	168	180.94	40.75	98.41	305.61	Weight V1 (lb)	19	199.51	57.13	131.62	311.35
ΔFSL (V3- V1) (%)	168	0.05	0.37	-1.32	1.50	ΔFSL (V3- V1) (%)	19	1.68	1.56	-0.28	6.30
Δ Weight (V3-V1) (lb)	167	-0.57	12.66	-40.24	45.62	Δ Weight (V3-V1) (lb)	19	-6.55	24.60	-92.28	33.89
Visit 4 (V4): 18 Month Visit											
ACCEPTABLE						UNACCEPTABLE					
	n	Mean	SD	Min	Max		n	Mean	SD	Min	Max
FSL V1 (%)	170	0.67	0.35	0.11	1.84	FSL V1 (%)	5	0.96	0.67	0.43	2.01
Weight V1 (lb)	170	182.76	43.44	98.41	311.35	Weight V1 (lb)	5	183.87	32.69	144.71	219.40
ΔFSL (V4- V1) (%)	170	-0.09	0.38	-1.04	1.43	ΔFSL (V4- V1) (%)	5	3.62	4.73	0.78	11.98
Δ Weight (V4-V1) (lb)	169	-3.45	15.15	-96.80	46.42	Δ Weight (V4-V1) (lb)	5	6.80	10.97	-5.47	24.70
Visit 5 (V5): 24 Month Visit											
ACCEPTABLE						UNACCEPTABLE					
	n	Mean	SD	Min	Max		n	Mean	SD	Min	Max
FSL V1 (%)	145	0.65	0.35	0.11	1.84	FSL V1 (%)	4	1.28	0.52	0.80	2.01
Weight V1 (lb)	145	180.95	43.03	98.41	311.35	Weight V1 (lb)	4	164.44	32.46	144.71	212.63
ΔFSL (V5- V1) (%)	145	-0.11	0.38	-1.32	1.22	ΔFSL (V5- V1) (%)	4	2.39	2.37	0.36	5.69
Δ Weight (V5-V1) (lb)	145	-2.27	15.78	-76.62	56.45	Δ Weight (V5-V1) (lb)	4	-1.14	7.04	-8.93	7.32

*V1 is baseline visit.

Results Continued

- The mean FSL for the baseline visit (Visit 1) was 0.7% (SD=0.4%) with a range of 0.1% to 2.1% (Figure 2).
- An unacceptable fit (90th percentile FSL > 5%) was shown for 10.6%, 10.2%, 2.8%, 2.7% of subjects for Visits 2, 3, 4, and 5, respectively.
- Only one subject had an unacceptable fit for all follow-on visits.

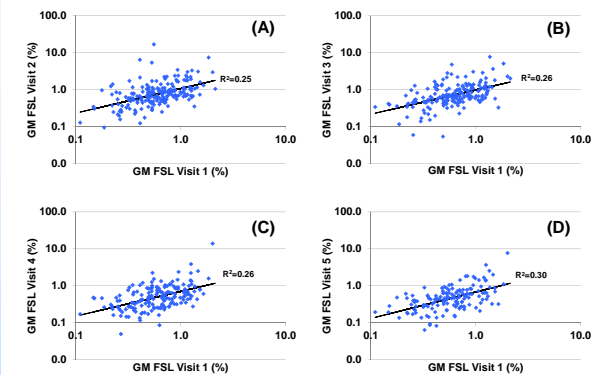


Figure 2. Plot of Geometric Mean (GM) FSL for Each Subject for Visit 1 against Visit 2 (A), Visit 3 (B), Visit 4 (C), and Visit 5 (D).

Conclusions

- These preliminary results indicate significant changes in fit during the first year for ~10% of subjects. Significant changes were seen for fewer subjects (~3%) during the second year.
- Additional work is needed to understand the cause of changes in fit over time.

Future Work

- Complete the third year of data collection with the remaining subjects.
- Conduct an elastomeric pilot study with 10 subjects in conjunction with the overall study.
- Assess 3-D data to determine ability to capture changes in facial characteristics over time.