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Interoffice Communication

VISTA

TO: Distribution

FROM: T. G. Grumbles
DATE: September 24, 1991
SUBJ: **COMPARISON OF FIT BETWEEN NATURAL AND SILICONE RUBBER FACEPIECES**

The attached article describes a study comparing the fit factors obtained by natural and silicone rubber facepieces. In summary, the fit factors for the silicone rubber facepiece were found to be significantly greater than those for natural rubber face pieces. However, the variability of fit factors was higher for the silicone facepieces.

This data should be considered when evaluating new respirators.

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Attachment

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Comparison of Fit Provided by Natural and Silicone Rubber Facepieces of the Same Brand of Half-Mask Respirator

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The fit provided by natural and silicone rubber facepieces of the same brand and size of half-mask respirator were compared by performing multiple fit tests in random order with both facepieces on 45 subjects. The tests consisted of a six-exercise protocol while measuring the penetration of ambient room aerosols with a condensation nuclei counter fit test device. Fit factors obtained by the two facepieces were compared by nonparametric statistical methods because fit factors for the silicone rubber facepiece were not lognormally distributed. The fit factors for the silicone rubber facepiece were found to be significantly greater than those for the natural rubber facepiece. Although the difference was statistically significant, it was not of the same magnitude as reported in previous studies. It was noted that the maximum and minimum fit factors obtained with the natural rubber facepiece were higher than those for the silicone rubber facepiece. The variability of fit factors for the silicone rubber facepiece was also found to be higher than that of the natural rubber facepiece. This would affect the calculation of fit factor lower tolerance limits and should be considered in estimating the lowest likely fit provided by a respirator for an individual or a group of wearers. **Oestenstad, R.K.; Zwissler, A.M.: A Comparison of Fit Provided by Natural and Silicone Rubber Facepieces of the Same Brand of Half-Mask Respirator. Appl. Occup. Environ. Hyg. 6:785–789; 1991.**

Introduction

During the past decade there have been significant changes in respirator technology that have resulted in increased comfort and efficiency of these devices. These changes include: improved filter materials to reduce breathing resistance; better sealing surfaces from changes in facepiece design; the availability of sized facepieces; improved weight distribution by using crown straps and facepiece yokes; and the use of silicone rubber to provide more comfortable facepieces. Silicone rubber facepieces have been promoted extensively by manufacturers as being significant improvements to their product lines. They cite a more comfortable fit, lighter weight, ease of cleaning, and better durability as advantages.

If properly formulated, silicone rubber is more pliable, superior in chemical resistance, and just as durable as natural black rubber. However, natural rubber may have better tear resistance. Because of their increased pliability, it would be reasonable to expect that silicone rubber facepieces would conform better to wearers' faces and provide more effective faceseals than their natural rubber analogues. However, there is only limited information in the literature to support this assumption.

As part of quantitative fit tests (QNFT) to develop performance data for self-contained breathing apparatus (SCBA), Hyatt[1] reported results of tests on silicone and neoprene rubber full facepieces made from the same mold. Fit factors (FFs) for the two facepieces equipped with demand regulators were measured with DOP aerosol while subjects performed a five-exercise test protocol. The test panel consisted of 31 firemen selected according to face length and face width criteria of the Los Alamos full-face respirator test panel.[2]

Hyatt found that 95 percent of the subjects achieved a FF $\geq$ 100 while wearing the silicone rubber facepiece, whereas only 87 percent achieved a FF $\geq$ 100 with the neoprene rubber facepiece.[1] Log-probability plots of the data from this study indicate that the FFs for both facepieces were approximately lognormally distributed. The geometric mean for the silicone facepiece was about 23,000, and the geometric mean for the neoprene facepiece was only 570. The researcher described the silicone facepiece as being soft and pliable and the neoprene facepiece as being hard and rigid.

As part of a report of the effectiveness of an anthropometrically designed half-mask respirator, Jones *et al.*[3] compared the fit obtained with medium-sized facepieces made of silicone and natural rubber. They determined FFs for the two facepieces using a corn oil aerosol while subjects performed a six-exercise test protocol. The test panel consisted of 25 subjects (12 female and 13 male) who were selected according to face length and lip width criteria of

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the Los Alamos half-mask test panel.[2]

The range of FFs for the silicone rubber facepiece was 174–18,750 with an average of 2735.[3] The range of FFs for the rubber facepiece was 20–838 with an average of 214. The researchers attributed the better fit to silicone's lower coefficient of friction that allowed it to seal/conform better to facial surfaces. The researchers did not report tests for the distribution of FFs or for the difference between the mean FF for the two facepieces.

These studies[1,3] would lend strong support to the assertion that respirators made of silicone rubber provide a much more efficient faceseal than those made of natural rubber. However, there are limitations in the study designs that might restrict interpretations of those results. Neither study accounts for intrasubject variability in fit because only one QNFT was performed by each subject with each respirator. daRoza *et al.*[4] found that the fit obtained by one subject with a given facepiece was defined by a lognormal distribution and that the geometric standard deviation for that distribution varied widely among individuals. Therefore, multiple QNFTs must be performed on the same subject/respirator combination to make an estimate of that distribution. The FF for that subject can then be defined as the geometric mean, or the probability of experiencing a minimum FF can be calculated from the geometric mean and geometric standard deviation.

The variation of FFs for a group of subjects has also been shown to be lognormally distributed.[4,5] Failure to test for this distribution and perform the appropriate transformations when comparing FFs obtained by subjects wearing different respirators can be misleading and can result in the use of inappropriate statistical tests. It is not clear from the data reported by Jones *et al.*[3] if these factors were considered. The means they reported for the two facepieces were not identified as arithmetic or geometric.

The purpose of the present study was to compare the fit obtained by silicone and natural rubber facepieces of the same model and size of a half-mask respirator while accounting for intrasubject fit variability of the test subjects. This was accomplished by conducting replicate tests with each facepiece on 45 subjects and by testing for the significance of any observed difference between FFs.

Materials and Methods

Respirator

The respirators used in this study were size medium, U.S. Safety® (United States Safety Service Co., Kansas City, Missouri) Series 100 silicone rubber and Series 200 natural rubber half-mask facepieces equipped with HEPA filters. Each facepiece was fitted with a sampling port on the midline at a location between the subject's nose and mouth. The facepieces were disassembled, cleaned, reassembled, and inspected after the tests on each subject.

Subjects

The 45 subjects used in this study were university students, staff, and faculty. Of these, 23 were male and 22 were female, 20 had previous experience wearing a respirator for more than one hour at least once in a workplace setting, and 25 did not have that experience. Persons with facial features that would have resulted in obvious faceseal leaks were not used in the study. Subjects were not selected on the basis of anthropometric dimensions of the Los Alamos respirator test panel.[2] The rationale for this selection criteria was to compare the fit of the two facepieces over a wide range of FFs, recognizing that one size facepiece would not be expected to provide a good fit for every member of a group of wearers.[6]

Quantitative Fit Test Methods

Respirator fit tests were conducted with the Portacount® Respirator Fit Tester (TSI, Inc., St. Paul, Minnesota). This device is a continuous flow condensation nuclei counter (CNC) that utilizes ambient room particles as a test aerosol. The CNC increases the size of sampled aerosols as small as 0.02 μm to about 0.1 μm by condensing isopropanol on the particles. The resulting droplets are then counted by a light-scattering laser photometer. It can measure particle counts in the range of 0.1 particles/cm^3 to 5×10^5 particles/cm^3. Willeke *et al.*[7] first proposed the use of the CNC for fit testing with nonhazardous submicrometer aerosols. The CNC has since been found to provide good agreement in measuring FFs when compared with the traditional DOP aerosol photometer method.[8,9]

Test Protocol

A series of six fit tests were performed on each subject: three tests while wearing the silicone rubber facepiece and three tests while wearing the natural rubber facepiece. The type of facepiece worn in each test was randomly selected by the flip of a coin until one type had been tested three times. A positive pressure check was performed before each test, and an initial measurement was made with the CNC to confirm a FF > 10. FFs were measured while the subjects performed each of the following exercises for 1.5 minutes: normal breathing, deep breathing, moving the head side-to-side, moving the head up-and-down, talking, and normal breathing. The respirator was removed at the end of each test, and the sealing surface was wiped with an alcohol swab. The subjects also wiped their faces with paper towels to remove any accumulated perspiration.

Results and Discussion

Data from each test were entered into a SOLO® database (BMDP Statistical Software, Inc., Los Angeles, California) for sorting and for performing necessary transformations and appropriate statistical analyses.[10] The overall FF for each test was calculated by the following equation:[11]

$$\text{Overall FF} = \frac{6}{\sum_{i=1}^{6} \frac{1}{\text{Exercise FF}_i}} \quad (1)$$

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The geometric mean of the three FFs for each facepiece on each subject was used as the best estimate of the FF

Subject Fit Factors

Subject Number	Natural Rubber Facepiece Test 1	Test 2	Test 3	GM[A]	GSD[B]	Silicone Rubber Facepiece Test 1	Test 2	Test 3	GM[A]	GSD[B]
1	713	53	311	228	3.76	7038	8749	5385	6921	1.28
2	32233	29321	29127	30194	1.06	33477	33575	30214	32384	1.06
3	3790	1975	1875	2412	1.48	24135	19985	16081	19795	1.23
4	3626	5548	5657	4845	1.29	63786	14703	10965	21746	2.57
5	17031	10173	9760	11914	1.36	29970	19698	20527	22969	1.26
6	15912	30059	4998	13371	2.48	6008	18340	14413	11667	1.80
7	457	2055	5349	1713	3.45	35350	17279	32827	27167	1.48
8	57829	9952	32024	26415	2.45	31324	27143	24127	27374	1.14
9	12740	12704	7870	10840	1.32	61	36	13	31	2.18
10	8211	4135	2827	4578	1.72	8	2159	50	96	17.09
11	8270	8521	6509	7712	1.16	264	4019	1997	1284	4.11
12	188	5128	2472	1335	5.68	4277	7107	6688	5880	1.32
13	14333	8768	8213	10106	1.36	3531	3881	2681	3324	1.21
14	4404	1208	1025	1760	2.22	15755	32777	12322	18531	1.66
15	2287	2399	1944	2201	1.12	24380	27654	2697	12205	3.70
16	12944	10697	8959	10745	1.20	2332	2972	3001	2750	1.15
17	27116	48835	37763	36841	1.34	2086	309	2921	1235	3.36
18	2891	2058	1919	2252	1.25	35840	16564	17685	21897	1.53
19	6505	5197	3072	4700	1.47	29209	5522	9360	11472	2.34
20	389	463	1727	678	2.26	11362	5164	7729	7683	1.48
21	3324	1834	12628	4254	2.69	26368	29543	18277	24237	1.29
22	9982	7714	7665	8388	1.16	15794	16571	14246	15507	1.08
23	2097	2357	1362	1888	1.33	2106	18935	218	2055	9.33
24	1385	4059	3663	2741	1.81	7741	7957	7981	7892	1.02
25	922	338	2440	913	2.68	1120	120	19	136	7.78
26	11221	15036	28220	16824	1.60	18319	22415	18607	19695	1.12
27	46813	42726	18582	33376	1.66	21581	15610	13552	16589	1.27
28	23148	18120	22412	21105	1.14	27425	40086	17577	26834	1.51
29	6389	7224	5125	6184	1.19	6458	5844	9400	7079	1.28
30	16050	10141	10358	11902	1.30	2451	13557	646	2779	4.60
31	6650	7790	10666	8206	1.27	543	10832	10650	3971	5.60
32	2329	5494	4981	3995	1.60	42913	35653	13470	27417	1.86
33	12083	9248	6348	8933	1.38	2466	13622	12329	7454	2.61
34	4083	517	9463	2714	4.46	218	210	1022	361	2.47
35	1104	1975	8445	2641	2.85	27022	10236	16426	16563	1.62
36	513	554	2186	853	2.26	7391	2202	6292	4678	1.93
37	3097	481	1687	1360	2.58	10770	7877	1887	5430	2.53
38	10637	7390	18999	11431	1.61	13143	20439	16194	16324	1.25
39	2903	568	596	994	2.53	9622	9663	563	3742	5.15
40	10475	8830	2337	6001	2.27	10193	13631	8747	10672	1.25
41	11442	6834	7087	8214	1.33	18968	12869	9810	133778	1.39
42	6933	5539	5894	6094	1.12	4265	15808	16585	10380	2.16
43	6649	6499	5634	6244	1.09	6828	6620	6877	6774	1.02
44	12160	12985	2425	7262	2.59	1212	13172	15268	6247	4.14
45	15349	5289	3931	6833	2.05	10730	2990	9160	6648	2.01

[A]GM = geometric mean.
[B]GSD = geometric standard deviation of n = 3 replicates.

for that subject/facepiece combination. This method of calculation was intended to account for intrasubject variability of fit as identified by daRoza *et al.*[4] The FFs for the three tests with both respirators and the geometric mean and the geometric standard deviation of those tests for all subjects are shown in Table I.

A review of the data revealed that the geometric standard deviations for the silicone rubber facepiece for Subjects 10 and 23 were 17.09 and 9.33, respectively. These values were much higher than expected;[4,5] therefore, Natrella's test[12] was applied to the variances of the three log FFs for the silicone facepiece to determine if the data for the two subjects could be classified as outliers. That test rejected the variance for Subject 10 as an outlier ($\alpha = 0.05$). As a consequence, all the data for that subject were excluded from subsequent statistical analyses.

The cumulative distributions of the mean log FFs for both facepieces on the remaining 44 subjects are shown in Figure 1. It was noted that the values for the natural rubber facepiece followed an approximately straight line indicating a lognormal distribution. However, the values for the silicone rubber facepiece deviated substantially from a straight line. The Martinez and Inglewicz test[13] was applied to test the data for normality. That test found the log FFs for the natural rubber facepiece to be normally distributed ($\alpha = 0.05$), but the distribution of the log FFs for the silicone rubber facepiece was not. Therefore, nonparametric statistical tests were used to compare FFs ob-

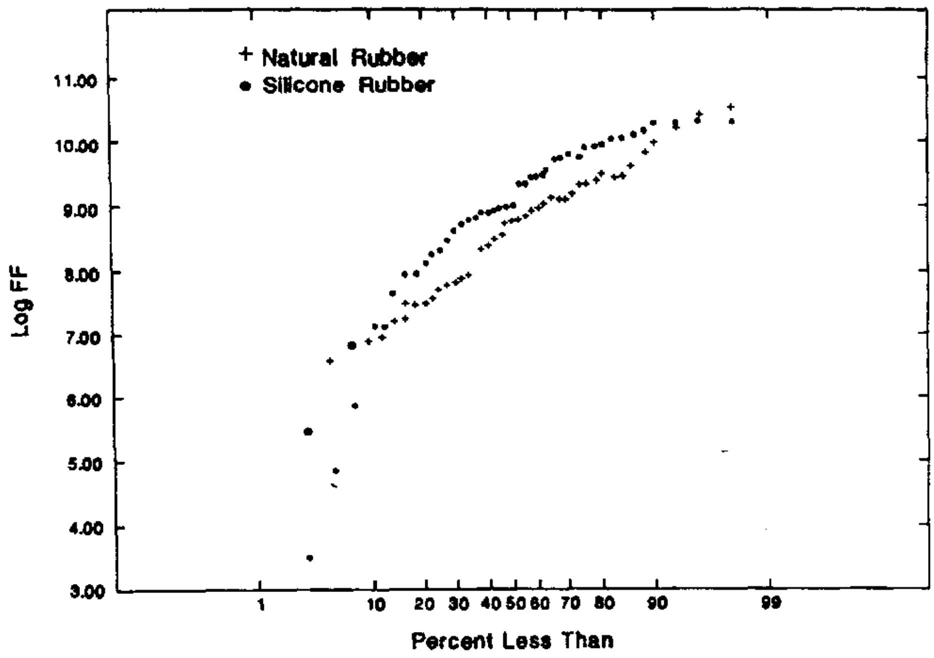

FIGURE 1. Cumulative distributions of log FFs for the natural rubber and silicone rubber facepieces.

tained with the two facepieces.

The observation that log FFs for the silicone rubber facepiece were not normal was unexpected and does not follow previous studies that found FFs to be lognormally distributed.(1,4,5,14) It is not known why this distribution was observed with the silicone rubber facepiece only, because fit tests on both facepieces were performed in a random sequence at the same time. When the mean log FFs for the silicone rubber facepiece were sorted by gender, it was found that the distribution for males was lognormal, whereas that for females was not.(13) Therefore, this phenomenon may be due to the gender differences in critical facial dimensions identified by Johnson(15) and to the gender differences in faceseal leak sites observed by Oestenstad *et al.*(16)

Correlation coefficients were determined as a test of the possible effect of room particle count on the observed FFs. Spearman's correlation coefficient was 0.25 for room particle count and the natural rubber FFs, and it was 0.15 for room particle count and the silicone rubber FFs.(10) Therefore, it was assumed that room particle count had no effect on measured FFs.

In a sequence of fit tests, it is possible that repeated donning of a respirator might result in a learning effect producing higher FFs for the last tests. To test for this effect, the FFs for both facepieces were sorted into the six-test sequence in which they were performed on each subject, and a Kruskal–Wallis ANOVA was performed.(10) That test indicated there was no significant difference within the six-test sequence ($p = 0.470$). Therefore, it was assumed that a learning effect did not influence the FFs obtained with the two facepieces.

Examination of Table II indicates that the maximum geometric mean FF obtained by a subject with the natural rubber facepiece was higher than that obtained with the silicone rubber facepiece, and the minimum value for the silicone rubber facepiece was lower than that for the natural rubber facepiece. However, the median and mean FFs for the silicone rubber facepiece were higher than their respective values for the natural rubber facepiece. It was also noted that the variation in fit was greater for the silicone rubber facepiece as indicated by higher maximum, median, and mean values of the geometric standard deviation for replicate tests on each subject. Variations in standard deviations would affect the lower confidence levels determined for the two facepieces.

The 95 percent lower tolerance limit is the value above which it could be predicted with some level of confidence that 95 percent of the FFs in a population would lie, and this value has been used to determine assigned protection factors from workplace protection factor data.(17) If both distributions were lognormal, the mean of the logs and their standard deviations could be used to calculate the 95 percent lower tolerance limits for FFs for the two respi-

TABLE II. Summary of Facepiece Fit Factors

	Natural Rubber Facepiece		Silicone Rubber Facepiece	
	GM[A]	GSD[B]	GM[A]	GSD[B]
Maximum	36845	5.68	32386	9.33
Median	6140	1.54	9136	1.60
Mean	8401	1.94	11800	2.34
Minimum	228	1.06	31	1.02

[A]GM = geometric mean of three replicates with the same respirator on the same subject.
[B]GSD = geometric standard deviation of replicates with the same respirator on the same subject.

those values would be 456 for the natural rubber facepiece and 352 for the silicone rubber facepiece at a confidence level of 95 percent. This indicates that the rubber facepiece would be expected to provide a better fit for 95 percent of the subjects wearing that respirator. Although these values exceed the commonly accepted assigned protection factor of 10 for half-mask respirators,[18] this point illustrates the importance of using quantitative respirator fit testing for selecting the best-fitting respirator for a subject and performing multiple tests of the respirator/subject combination to determine the variation of fit.[4]

The statistical significance of differences between FFs for the two facepieces was tested by the Wilcoxon Sign Rank Test and the two-sample sign test.[10] The Wilcoxon Sign Rank Test showed that the FFs for the silicone rubber facepiece were significantly greater than those for the natural rubber facepiece ($p = 0.0134$). The two-sample sign test found that the probability of observing higher FFs for the silicone rubber facepiece in 30 of the 44 pairs was 0.0113.

Conclusions

The median FF for the natural rubber facepiece was 6140 and the mean was 8401; corresponding values for the silicone rubber facepiece were 9136 and 11,800, respectively. Both independent and matched nonparametric tests found the FFs for the silicone rubber facepiece to be significantly greater than those for the natural rubber facepiece. Although these differences are statistically significant, they do not confirm the order of magnitude differences reported by Hyatt[1] and Jones *et al.*[3]

The results of this study indicate that this brand of half-mask silicone rubber facepiece provided a better average fit than its identical natural rubber twin in a laboratory study. The study was designed to account for intrasubject variability in making the comparison. Fit was compared over a wide range of FFs and an anthropometric test panel was not utilized. It was assumed that if any sampling bias due to conditions beneath the respirator facepiece was present,[19] it was consistent between respirators.

The observation that the log FFs for the silicone rubber facepiece were not normally distributed contradicts the accepted assumption that FFs are lognormally distributed. If that assumption were accepted in this study, parametric t-tests would have found no significant difference between the mean log FFs for the two facepieces ($p = 0.2150$): an outcome that is opposite of that found with the nonparametric tests used in this study. This would indicate that distributions of FFs should be tested before comparing the fit provided by different respirators for a group of subjects.

Although the silicone rubber facepiece provided higher mean and median FFs, it was noted that the natural rubber facepiece provided higher maximum and minimum FF values. In addition, variation in fit for the silicone rubber facepiece was greater than that for the natural rubber facepiece. This would affect the calculation of FF lower or tolerance limits and should be considered in estimating the lowest likely fit provided by a respirator for an individual or a group of wearers. In this case, if the distribution of mean log FFs for the silicone rubber facepiece had been normal, the 95 percent lower tolerance limit would have been lower than that for the natural rubber facepiece. Persons selecting respirators are cautioned to consider the variation of fit as well as the FF.

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