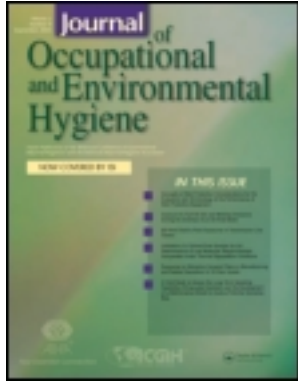


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Analysis of Forces Generated by N95 Filtering Facepiece Respirator Tethering Devices: A Pilot Study

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The restorative forces of elasticized tethering devices on N95 filtering facepiece respirators (N95 FFR), that occur in response to the application of a load (applied force) during donning, create the requisite pressure to effectively seal the respirator against the face and prevent excessive inward migration of harmful elements. Many workers don and doff the same N95 FFR multiple times in the course of a single workday, yet little is known regarding the possible degradation of these restorative loads and, by implication, protection with multiple donnings. This laboratory pilot study evaluated the degradation in loads of tethering devices of three models of N95 FFRs subjected to the strain of five wear periods of 15 min interspersed with 15-min periods without wear. Data indicate that there were load degradations at each donning that differed significantly with the FFR model ($p = <0.001$), the greatest of which occurred with the first donning. The N95 FFR model with the lowest restorative loads was able to pass fit testing in a previous study, indicating that lower loads, perhaps coupled with FFR model-specific features, are sufficient to provide an adequate face/FFR interface seal. Tethering devices are importantly related to issues of comfort and protection afforded by N95 FFR and additional research is warranted.

Keywords degradation, loads, N95 filtering facepiece respirators, tethering devices

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INTRODUCTION

Filtering facepiece respirators (FFRs) are the most commonly used negative pressure respirators in industry and health care, and the N95 class of FFRs (N95 FFR) is the most popular overall.^(1,2) For FFRs to serve their protective

function effectively, an adequate seal must be maintained at the face/respirator interface to minimize inward leakage of contaminants. The seal is brought about primarily through the design of the facepiece seal as well as the tension developed by restorative forces after a load (stress) is applied during FFR donning by the stretching of the tethering device(s) (TD), the majority of which (e.g., straps, bands, and so on) are constructed of elastic or elastomeric materials that have recoil properties as their force generator (the seal is also related to the position of the TD, their length, and proper donning). If the applied load exceeds the limits of its elasticity (elastic limit), the TD will not return to its original, non-stressed condition, and its load capacity is variably diminished.⁽³⁾

Disposable N95 FFRs are sold as limited use devices; however, many individuals work in occupations where multiple donning and doffing of a single N95 FFR occur over the course of the workday (e.g., construction trades, health care, and so on). These workers need to be assured that the tension developed by the FFRs' TD remains adequate throughout the course of its use to maintain a satisfactory seal. Currently, little TD load data exist for N95 FFRs, despite decades of use. The National Personal Protective Technology Laboratory of the National Institute for Occupational Safety and Health undertook this laboratory-based pilot study to evaluate the loads generated by the TDs of different models of N95 FFRs. This information, disseminated through publication and presentation at national conferences dealing with respiratory protection, could be useful to various stakeholders (e.g., FFR manufacturers, designers, users, and researchers).

METHODS AND MATERIALS

Two cup-shaped models (Model 1860S; 3M, St. Paul, Minn., and Model 2301; Moldex, Culver City, Calif.) and one flat-fold model (Model 9210; 3M) of N95 FFRs were selected for the current study (Figure 1). The TD of the 3M 9210 and Moldex 2301 models consists of single upper and lower non-latex (polyisoprene) elastomeric bands, whereas the 3M 1860S has two braided (polyester) straps that each house



FIGURE 1. N95 filtering facepiece respirators (left to right), Moldex 2300, 3M 9210, and 3M 1860S models

four thin non-latex (polyisoprene) elastomeric bands running in parallel.⁽⁴⁾

These models were selected because they had been utilized in a previous study⁽⁵⁾ that collected data on subjects undergoing respirator fit testing. In that study, TDs were marked with 1-cm gradations along their length. Following donning by the subjects (as per manufacturers' instructions, with the lower TD encircling the posterior neck, and the uppermost TD encircling the occiput [crown]), the position and length of the TD were captured with a three-dimensional photogrammetry unit (3dMD, Atlanta, Ga.) that offers superior surface detail to arrive at a percentage of increase in strain (donning length) over control values (e.g., change in length/length) (Figure 2). Mean strains for top/bottom TDs during fit testing were 140 and 61%, 75 and 35%, and 52 and 22% above controls, respectively, for subjects wearing the 3M 9210 (n = 20), 3M 1860S (n = 5), and Moldex 2301 (n = 20) models. These strains were subsequently employed in the current study.

For the current study, unused models of N95 FFRs were taken from the same production batches that had passed fit testing in the previous study,⁽⁵⁾ and a modified stress-relaxation study was carried out. The upper and lower TD of each N95 FFR were removed *in toto* and cut into two identical halves. The free ends of each of the TDs were then inserted in parallel (to approximate their position on each side of the head when worn) into the upper and bottom crosshead of a Model 5569A electromechanical tensometer (Instron, Norwood, Mass.) that was within the manufacturer's calibration specifications, having been calibrated by a certified technician in the year of the study. The aforementioned previously determined N95 FFR model-specific strains for the top and bottom TDs were programmed into proprietary software (Instron Bluehill) that controls the tensometer. TD were strained continuously for 15 min at the predetermined level specific to the N95 FFR model, followed by no strain for 15 min, to mimic the activities of workers who might don and doff N95 FFR multiple times in the course of a workday (e.g., health care personnel, construction workers, and so on). Five replicates of upper and lower TDs from each of the three N95 FFR models were tested five times each to simulate multiple donning, doffing, and wear periods during the course of a workday. At the point (0 minute) where the Instron initially reached the predetermined strain

and after 15 min of continuous strain, recordings of the load (force), in Newtons, that developed at those time points were taken and serve as the database for this study.

Statistical Analysis

Forces on top and bottom TDs were evaluated with a two-way repeated measures analysis of variance (ANOVA, respirator type × donning). When necessary, the Greenhouse-Geisser correction for sphericity was used to designate a level of significance. For a significant F-ratio obtained from repeated measures, post-hoc pairwise comparison was then performed with the least significant difference (LSD) adjustment. A statistical significance was accepted when $p < 0.05$, and all analyses were performed using a statistical software package (SPSS version 19; IBM, Somers, N.Y.).

RESULTS

Bottom TD

The interaction of the simulated load of donning (0-min load) and the resultant decrease in restorative forces by FFR model was significant for the bottom TD, $F = 2.678$, $p = 0.016$. However, there was no significance of this interaction ($F = 0.728$, $p = 0.597$) or donning alone ($F = 2.444$, $p = 0.099$) for the 15-min load measurements. Loads imparted by each FFR model at 15 min were significantly different from one another ($F = 344.157$, $p < 0.001$), with the 3M 9210 straps having the lowest loads and those on the 3M 1860S having the highest loads (Table I). Mean decrements in loads from the initial simulated donning (0 minute) to the end of the fifth 15-min simulated donning were 23.5%, 6.4%, and 17.9%, respectively, for the 3M 9210, Moldex 2301, and 3M 1860S models.

Top TD

The interaction of the simulated load of donning (0-min load) and the resultant decrease in restorative forces by FFR model was significant at each donning of the top TD ($F = 9.324$, $p < 0.001$). This interaction for the top TD after the 15-min load was not significant ($F = 0.728$, $p = 0.597$), but donnings themselves were significant ($F = 19.696$, $p < 0.001$). A pairwise comparison of the loads showed that Donning 1



FIGURE 2. Test subject wearing an N95 filtering facepiece respirator with tethering straps marked in one centimeter increments

was not significantly different from Donnings 2 or 3, which themselves were significantly different from Donnings 4 and 5. The loads imparted by each FFR model at 15 min were significantly different from one another ($F = 1265.3$, $p < 0.001$), with the 3M 9210 straps having the lowest loads and the 3M 1860S having the highest loads (Table II). Mean decrements in loads from the initial simulated donning (0 minute) to the end of the fifth 15-min stress were 29.1%, 12.5%, and 19.3%, respectively, for the 3M 9210, Moldex 2301, and 3M 1860S models.

DISCUSSION

Our study data indicate that there was a progressive decline in the loads generated by the top and bottom TDs of the three models of N95 FFR tested over the course of multiple simulated donning, doffings, and wear periods in a 2.5-hr span. The greatest decrement in the loads occurred within the first 15 min of stress irrespective of FFR model, and

the magnitude of load decline was FFR model-dependent for top and bottom TDs (Table I and II). As anticipated, greater loads were developed by the top TD because the normally lengthier trajectory to the occiput, compared with the lower TD trajectory to the posterior neck, results in greater strain. Nonetheless, the relative decrements in loads over time were somewhat similar for top and bottom TDs of the same model. Elastomers are polymer chains that display a spiral pattern that, when deformed due to the application of a force, assume a linear structure with cross-links at some points along their axes. The modification of the spiral standard to linear occurs due to weak secondary connections, while the recovery of a polymer's initial structure is due to the existence of cross-links. Permanent deformation occurs only when the polymer is stretched beyond its elastic limit causing cross-link breakage.⁽⁶⁾ Because the study data demonstrated a progressive decline in the forces generated by the applied stress, our assumption is that some cross-link breakage occurred.

TABLE I. Forces Generated by the Bottom TD of Three Models of N95 FFRs

	Simulated Donning			Simulated Donning			Simulated Donning			Simulated Donning					
	1 0-Min Load	15-Min Load	% Decrease	2 0-Min Load	15-Min Load	% Decrease	3 0-Min Load	15-Min Load	% Decrease	4 0-Min Load	15-Min Load	% Decrease	5 0-Min Load	15-Min Load	% Decrease
3M 9210^A															
#1	2.780	2.120	23.7	2.598	2.094	19.4	2.580	2.109	18.2	2.599	2.150	17.2	2.537	2.083	17.9
#2	2.816	2.147	23.7	2.655	2.162	18.5	2.524	2.065	18.1	2.573	2.118	17.6	2.625	2.178	17.0
#3	2.879	2.189	23.9	2.729	2.199	19.4	2.652	2.185	17.6	2.651	2.191	17.3	2.638	2.170	17.7
#4	2.675	2.018	24.5	2.688	2.195	18.3	2.612	2.143	17.9	2.593	2.134	17.7	2.572	2.130	17.1
#5	2.863	2.204	23.0	2.649	2.148	18.9	2.616	2.128	18.6	2.652	2.191	17.3	2.627	2.168	17.4
Moldex 2301^B															
#1	3.133	2.993	4.4	2.992	2.904	2.9	2.950	2.824	4.2	2.924	2.869	1.8	3.001	2.857	4.8
#2	3.135	2.921	6.8	3.164	3.043	3.8	3.145	3.007	4.3	3.134	2.998	4.3	3.125	3.060	2.0
#3	3.060	2.887	5.6	3.057	2.983	2.4	3.004	2.871	4.4	2.992	2.929	2.1	2.961	2.876	2.8
#4	2.951	2.780	5.7	2.851	2.810	1.4	2.973	2.925	1.6	2.854	2.799	1.9	2.830	2.787	1.5
#5	2.997	2.782	7.1	2.903	2.826	3.5	2.900	2.856	1.5	2.878	2.776	3.5	2.799	2.723	2.7
3M 1860^C															
#1	3.697	3.091	16.3	3.515	3.050	13.2	3.448	2.988	3.3	3.503	3.054	2.8	3.469	3.038	12.4
#2	3.654	3.018	17.4	3.648	3.185	12.6	3.567	3.135	12.1	3.529	3.114	11.7	3.505	3.058	12.7
#3	3.558	2.984	16.1	3.489	3.031	13.1	3.441	2.993	13.0	3.400	2.955	13.0	3.339	2.926	12.3
#4	3.668	3.053	16.7	3.571	3.130	12.3	3.540	3.116	11.9	3.478	3.047	12.3	3.465	3.034	12.4
#5	3.708	3.137	15.3	3.533	3.099	12.2	3.475	3.039	12.5	3.444	3.053	11.3	3.371	2.960	12.1

^AStress of 61% over baseline applied.

^BStress of 22% over baseline applied.

^CStress of 35% over baseline applied.

TABLE II. Forces Generated by the Top TD of Three Models of N95 FFRs

	Simulated Donning 1			Simulated Donning 2			Simulated Donning 3			Simulated Donning 4			Simulated Donning 5		
	0-Min Load	15-Min Load	% Decrease	0-Min Load	15-Min Load	% Decrease	0-Min Load	15-Min Load	% Decrease	0-Min Load	15-Min Load	% Decrease	0-Min Load	15-Min Load	% Decrease
3M 9210 ^A															
#1	4.207	3.092	26.5	3.745	3.198	14.6	3.687	3.231	12.4	3.525	3.094	12.2	3.447	3.056	11.3
#2	4.075	3.105	23.8	3.583	3.059	14.6	3.355	2.946	12.2	3.349	2.968	11.4	3.283	2.910	11.3
#3	4.324	3.301	23.7	3.834	3.270	14.7	3.689	3.236	12.3	3.588	3.192	11.0	3.570	3.156	11.6
#4	4.464	3.291	26.3	3.834	3.330	13.2	3.689	3.234	12.3	3.588	3.133	12.7	3.570	3.067	14.1
#5	4.152	3.115	25.0	3.795	3.220	15.2	3.597	3.148	12.5	3.507	3.102	11.5	3.463	3.075	11.2
Moldex 2301 ^B															
#1	5.790	5.282	8.7	5.514	5.244	4.9	5.417	5.196	4.0	5.370	5.147	4.1	5.378	5.175	3.7
#2	5.937	5.427	8.5	5.504	5.268	4.2	5.450	5.228	4.0	5.341	5.113	4.2	5.348	5.133	4.0
#3	5.602	5.113	8.7	5.214	4.988	4.3	5.077	4.916	3.1	5.113	4.921	3.7	5.071	4.865	4.0
#4	5.300	4.831	8.8	5.058	4.824	4.6	4.939	4.755	3.7	4.879	4.700	3.6	4.820	4.660	3.3
#5	5.345	4.897	8.3	4.975	4.767	4.1	4.826	4.669	3.2	4.826	4.669	3.2	4.811	4.657	3.2
3M 11860 ^C															
#1	4.591	3.827	16.6	4.591	3.961	13.7	4.659	4.067	12.7	4.665	4.068	12.8	4.540	3.944	13.1
#2	5.300	4.397	17.0	5.027	4.362	13.2	4.870	4.260	12.5	4.772	4.168	12.7	4.748	4.145	12.7
#3	5.052	4.213	16.6	4.825	4.210	12.7	4.740	4.128	12.9	4.702	4.097	12.9	4.636	4.041	12.8
#4	5.265	4.381	16.8	5.017	4.377	12.8	4.925	4.322	12.3	4.894	4.322	11.7	4.854	4.269	12.0
#5	5.211	4.322	17.1	5.050	4.427	12.3	4.946	4.357	11.9	4.914	4.313	12.2	4.706	4.100	12.9

^AStress of 140% over baseline applied.^BStress of 52% over baseline applied.^CStress of 75% over baseline applied.

However, without a microscopic examination of the TDs this remains an assumption on our part. Our data indicate a lack of significant decrease in top TD loads for Donnings 1 and 2, suggesting that for the three models tested under the donning time conditions of the study, a minimum of two donnings would be possible without a significant decrement in the recoil force. Nonetheless, it is feasible that the load decrements noted in Donnings 3–5, though statistically significantly different from Donnings 1 and 2, are still sufficient to pass a fit test. A human subject study with fit testing at each of five 15-min periods would be required to validate our supposition. This hypothesis shares some concordance with a recent study looking at fit factors ≥ 100 (a passing score on an Occupational Safety and Health Administration (OSHA) quantitative respirator fit test⁽⁷⁾) during multiple (20) FFR donnings that concluded that if a failure rate of 5% should not be exceeded in the workplace, five donnings could be performed before discarding the FFR.⁽⁸⁾

Similarly, another study, addressing the impact of various decontamination methodologies on FFR fit that involved multiple donnings (4) of three models of surgical N95 FFRs for ~5-min durations, reported passing fit test scores on 96.9% (698/720) of donnings.⁽⁹⁾ Comparisons between Bergman and colleagues'⁽⁸⁾ findings and the current study must be made cautiously given some differences in the models of FFRs studied and the cumulative time of wear for five donnings (25 min vs. 75 min, respectively). Nonetheless, the relatively small decrements in TD force over five donnings noted in the current study offer some potential support for Bergman and colleagues' findings, though FFR features other than merely TD forces are likely operant in developing acceptable fit (e.g., adjustable nasal bars, presence of inner flanges, and so on). Based on the available evidence, no recommendations can currently be made on the number of donnings that can be safely undertaken with a disposable N95 FFR. We observed that there was more FFR-to-FFR variability in the length of the Moldex 2301 TDs than the other FFRs. The lower loads developed by the 3M 9210 that in the aforementioned previous fit testing study⁽⁵⁾ were associated with passing fit testing are interesting in that it would be of value to determine the minimum load required to pass fit testing, as this would potentially have ramifications on issues such as comfort and tolerance.

The topic of FFR TD is one of considerable import for a variety of reasons other than the loads required for a proper face/FFR interface seal. Excess tension on TDs that are held in place by staples that perforate the filter media can increase the dimensions of the perforations and result in increased leakage into the FFR.⁽¹⁰⁾ Some models of FFR (e.g., 3M 9210) have staples placed outside the confines of the filter area material and would not be impacted by leakage due to staple-related perforations in the filter. Other models do not use staples but instead are welded so that the filter integrity is not impacted. The material composition of the TD can impact comfort (e.g., rubberized TDs pulling on hair, facial skin irritation, excess facial pressure). The top TD is likely more important in terms of comfort related to facial pressure of FFR inasmuch as prior investigations have shown that the nasal and malar regions

of the face are those associated with the highest pressures and exhalation leakage.^(11–13) Slippage of the top TD from its position at the occiput (a common occurrence) is likely to decrease the tension that develops since the degree of strain will be less below the prominence of the occipital ridge.

The composition of the TD of various FFRs may dictate differences in donning. For example, manufacturer's donning instructions are for pre-stretching the TD prior to donning for one model of N95 FFR (3M 8210) that has fixed thermoplastic straps,⁽¹⁴⁾ whereas for elasticized TDs, stretching beyond its "elastic limit" will preclude the TD from returning to its original, unstressed state⁽³⁾ and baseline load. The impact on TDs of decontamination of disposable N95 FFR (a potential strategy during times of limited supplies such as pandemics) utilizing such techniques as ultraviolet irradiation, microwave-generated steam, and moist heat, is a consideration⁽¹⁵⁾ and is an area of research that has only recently received attention.⁽⁴⁾ Last, the ability to re-use N95 FFR has important economic ramifications in terms of cost savings to users.

Limitations of the current study include its non-human nature; however, the strain data were obtained from a prior human study and the tested FFRs were from the same production batches used in a prior fit testing study. Only three models of N95 FFR were tested, and the conclusions of the study may not be generalizable to other N95 FFRs. The TDs evaluated were of elastomeric material, and our data may not be applicable to TD constructed from other materials (e.g., thermoplastic fixed straps) or those incorporating other features in their TD (e.g., buckles, strap tensioners, cradle, single strap). The simulated donnings in the current study were all of equal strain, whereas different strains might be applied by a wearer with each donning. Donning and doffing periods were of 15-min length, and the data obtained may not reflect periods of longer wear. Other TD features (thickness, area, and so on) other than length alone impact loads and were not evaluated. Last, the load of the TD is only one component of the development of an adequate FFR/face interface seal; the evaluation of the distribution of that force over the faceseal area needs investigation, as does the impact of TD tension upon FFR fit factors. It should be emphasized that the test procedure and data from this non-human study may not be indicative of the performance of N95 FFR TDs under actual use conditions.

CONCLUSIONS

There is model-specific variability in the top and bottom TD loads developed with donning of N95 FFRs, even when TD elastomeric component materials are similar. For the tested N95 FFRs, the greatest decrement in the loads generated by top and bottom elastomeric-type TD occurs with the first donning. Subsequent decrements occur with each subsequent donning, but total decrements over five donnings are less than 1 Newton. The issue of TD is a complex one and should be investigated further.

