Forces Generated by N95 Filtering Facepiece Respirator Straps

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ABSTRACT

The adequacy of the seal developed at the interface of a respirator and the user's face is an important factor in preventing inward leakage of contaminants into the user's breathing space. Restorative forces generated in response to the load produced by the elasticized straps of respirators during donning are responsible for the development of this seal, yet little data exist regarding the level of force developed by these tethering devices. Tensometer evaluations of six models of N95 filtering facepiece respirators indicated significant differences in forces generated by the tethering devices that were model dependent. Forces exerted on facial structures by N95 filtering facepiece respirators averaged <10 Newtons. Utilizing the Mooney-Rivlin hyper-elastic predictive model with vectors derived from three dimensional photogrammetry representations, force vector analyses were conducted on six models of N95 filtering facepiece respirator straps and indicated that this model can be useful in determining forces generated by these tethering devices. Tethering devices are integral to proper respirator function and data from this study may be useful in future research studies and for designers of protective facemasks that utilize similar tethering devices in determining minimal forces that are associated with passing quantitative respirator fit testing.

Keywords: N95 filtering facepiece respirators, straps, force vectors

INTRODUCTION

N95 filtering facepiece respirators (N95 FFRs) are the most common respiratory protective devices used by U.S. workers in private industry [U.S. Dept. of Labor, 2001] and are also the most common single-use (disposable) respirators in healthcare settings.[Martyny et al., 2002] The protection afforded by N95 FFRs is significantly related to the adequacy of the seal developed at the interface between the wearer's face and the FFR. The better the seal, the less likely is the ingress of contaminants into the breathing zone of the wearer. That seal is substantially developed by the restorative forces of the FFR's elasticized straps that occur in response to the initial load (applied force) associated with the strap stretching that takes place during donning. Despite decades of N95 FFR use by workers, little data exist on the forces generated by their straps, a critical component of FFR function and comfort. The National Institute for Occupational Safety and Health (NIOSH) certifies FFRs but does not evaluate the straps, fit, or comfort as part of the evaluation process.[Code of Federal Regulations, 2004] This investigation by the National Personal Protective Technology Laboratory of NIOSH focused on determination of forces generated by N95 FFRs and strap characteristics of N95 FFRs. A secondary objective of this investigation was to determine if it is possible to accurately model the behaviors of these straps and use this to predict the forces produced by the straps when only the strain of the strap is known.

METHODS AND MATERIALS

Experimental Equations

Hooke's law does not adequately describe the stress-strain relationship of highly-elastic materials because it states that at any level of strain, the amount of force applied is proportional to the distance the material stretches. Highly-elastic materials have a non-linear relationship which has been characterized in several ways including the Neo-Hookean model, the Mooney-Rivlin model and the Ogden model.[Peel and Jensen, 2000] It was important to determine the best model to accurately determine the relationship between the stress and strain of the FFR straps. The model was then used to predict the forces imparted upon the face by the FFR. Each model contains strain, stretch, and stress. These can be calculated using:

Strain: $\varepsilon = \Delta L/L$ (1)

ΔL is the change in length in meters and L is the initial length in meters.

Stretch: $\alpha = (L+\Delta L)/L = \varepsilon + 1$ (2)

Stress: $\sigma = F/A$ (3)

F is the force in Newtons (N) and A is the initial cross-sectional area in meters2.

The equations for the Hyper-elastic Models (Peel and Jensen, 2000) are:

Neo-Hookean:

$\sigma = 2C_1 (\alpha - 1/\alpha)$ (4)

Two-Coefficient Mooney-Rivlin:

$\sigma = ((2C_2)/\alpha)(\alpha - 1/\alpha^2)$ (5)

Three-Coefficient Mooney-Rivlin:

$\sigma = 2[C_1 \alpha - C_2/\alpha^3 + C_3 (1/\alpha^3 - \alpha)]$ (6)

In each equation, α represents stretch and C1, C2 and C3 are experimentally determined constants. These hyper-elastic models are designed to predict the relationship between stress and stretch. The Neo-Hookean model is best for describing behaviors at very low levels of strain in the range of 25%. The Two-Coefficient Mooney-Rivlin model is most accurate at describing incompressible materials up to a strain of 200%. Lastly the Three-Coefficient Mooney-Rivlin model is most useful for describing hyper-elastic materials that are both compressible and incompressible.[Peel and Jensen, 2000]

Study Trials - Tensometer Evaluations

Five trials each of top and bottom straps from the same manufacture lot for six models (two manufacturers) of NIOSH-certified N95 FFRs were conducted for strap tension: 3M 9210, 3M 9211 (3M, St. Paul, Minnesota, USA), Moldex 2200, Moldex 2201, Moldex 2300, and Moldex 2301 (Moldex, Culver City, California, USA). All of these N95 FFRs have non-latex (polyisoprene) elastomeric straps. Strap quality was demonstrated by the consistency of the load necessary to stretch the band to a strain (change in baseline length) of 200%. This 200% limit was chosen because it encompassed the range of strain a strap was under while worn by an adult during N95 FFR fit testing, as documented by photogrammetry measurements in a study examining physiological aspects of FFR wear [Roberge et al., 2012], as well as for silicone rubber harness straps used on a full facepiece air-purifying respirator.[Cohen, 1999] Also, 200% strain is the upper limit for the accuracy of the Mooney-Rivlin distribution. Straps were tested using a factory-calibrated Instron 5569A Tension Testing apparatus (Instron, Norwood, MA) equipped with a static load cell rated at 50 Newtons (N). Normally, single top and bottom straps are attached to the N95 FFR in two places so that, when the N95 FFR is donned, the center of the upper and lower straps essentially remains stationary at the back of the head and back of the neck, respectively, creating a situation where the strap is being stretched from both sides of the head. To mimic this situation, each study strap was cut in half and mounted in the Instron chuck in parallel, as shown in Figure 1. The lower chuck holding one end of the straps remains stationary, simulating the center of the strap remaining stationary, and the top chuck moves vertically to apply the programmed force. The Instron was programmed via proprietary software (Instron Bluehill) to apply 1 N of force to the strap per minute until it had reached a strain of 200% and subsequently reported the strain (extension) in mm, load in N, stress in kPa and the strain ratio (i.e., stress/strain). Because all straps of the same FFR model acted similarly, a trend-line based on the Mooney-Rivlin equation could be created to predict forces produced by all straps for a given type of FFR model

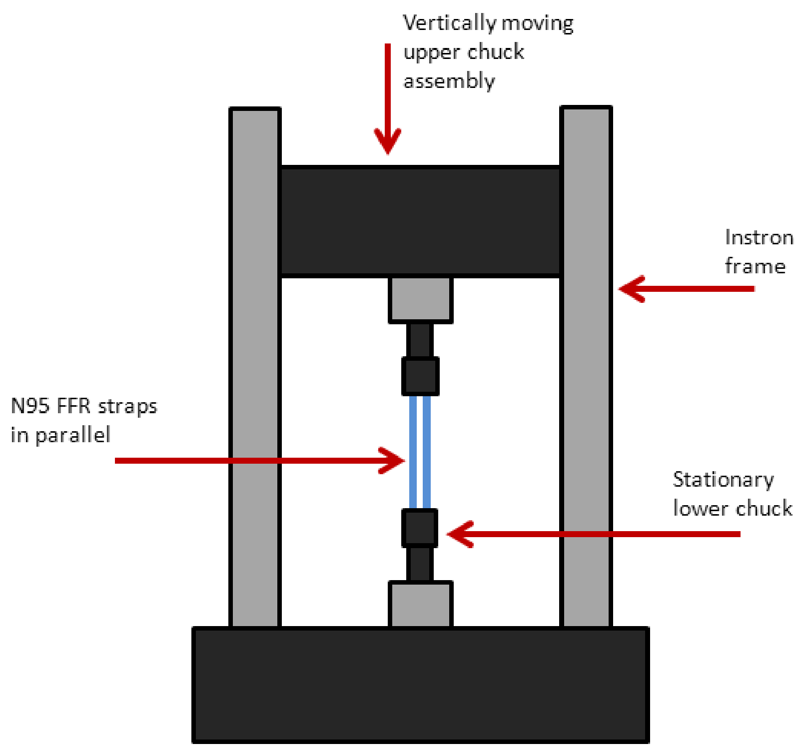

Figure 1. Instron 5569A Tension Testing apparatus with two halves of N95 FFR straps being subjected to stress.

In order to limit the number of data points on the plot, only the points at 0, 25, 50, 75, 100, 125, 150, 175, and 200% strain were used. An average of the stress at each level of strain was taken. The average stress and the strain values were entered into R statistical software. [Bates et al., 2011] Strain was converted to stretch and a non-linear least square function was applied to create both a Neo-Hookean and a Mooney-Rivlin fit to the data. Through a comparison of achieved convergence tolerances, the Mooney-Rivlin equation was found to more accurately model the strap behavior. Contained in R is a summary function that returns the values of the C1 and C2 coefficients, the standard errors and the t-statistic. [Battles, 2011] These coefficients, along with the two-coefficient Mooney-Rivlin equation, form the model needed to accurately predict how much force the straps are applying at any level of strain.

Study Trials - Human Subjects

Baseline (non-strained) and donned strap lengths were collected from 20 subjects in a previous study (approved by the NIOSH Human Subjects Review Board, and for which written and verbal consent was given by each subject) [Roberge et al., 2012] in which all 20 subjects had passing scores (i.e., fit factor ≥ 100) as established for quantitative fit testing by the Occupational Safety and Health Administration (OSHA).[OSHA, 1998] From this data, the strain and stretch values were calculated. Utilizing the averaged coefficients and the calculated stretch, the stress could be calculated and used to find the restorative forces. Images of each subject were captured using a three dimensional (3-D) photogrammetry unit (5 Face Cranial System, 3dMD, Atlanta, GA). The 3-D scans of the human subjects were evaluated with PolyWorks 11.0.4 software (InnovMetric, Quebec, Canada) and vectors for each strap were determined. The magnitude and direction of the resultant forces were determined through a simple vector analysis and the conversion of the vectors from Cartesian coordinates to a spherical coordinate system. The angle of the resultant force is measured in relation to a plane that passes through the center of the mask and is parallel to the Frankfort plane.

RESULTS

The average values obtained from the previously-tested 20 subjects for strain and stretch (elongation), as well as for the stress calculated from the Mooney-Rivlin equation, are presented in Table I. For all models tested there was no difference in C1 and C2 observed between the top and bottom straps. As a result, data from both the top and bottom straps were used together for fitting the model. Figure 2 shows the fitted models along with averages of the generated forces of the straps at given extension ratios. For all N95 FFR models, the Mooney-Rivlin equation was found to best fit the data using least-squares. It is clearly seen in Figure 2 that the respirator brand (3M, Moldex) was the major determining factor in strap properties. All four Moldex models were overlapping, distinctly separated from the two 3M models tested. It is possible that the similarity between models within a manufacturer is a consequence of the limited model choice. Further testing is needed to establish the range of variation in elastic properties for N95 FFRs in general.

Table I. N95 Filtering Facepiece Top and Bottom Strap Study Parameter Results

Top Strap						
Model	**2201**	**2200**	**2301**	**2300**	**9210**	**9211**
Mean Initial Length (mm)	304.27	305.40	315.29	309.60	193.70	193.70
Mean Final Length (mm)	478.20	513.20	479.14	508.80	463.10	462.70
Mean Strain (ε)	0.5716	0.6804	0.5197	0.6434	1.3908	1.3887
Mean Stretch (*a*)	1.5716	1.6804	1.5197	1.6434	2.3908	2.3887
C 1	304348	301842	261196	264067	106631	109227
C 2	128091	1242156	213993	207330	157850	202383
Mean Engineering Stress (σ)	897362	996572	870509	993159	727853	857670
Initial Cross-sectional Area (A)	6.184E-06	6.184E-06	6.184E-06	6.184E-06	4.356E-06	4.356E-06
Mean Predicted Force (N)	5.5491079	6.162601	5.3830526	6.141495	3.1705264	3.7360115
Bottom Strap						
Model	**2201**	**2200**	**2301**	**2300**	**9210**	**9211**
Mean Initial Length (mm)	262.67	261.80	265.43	263.00	194.35	193.90
Mean Final Length (mm)	329.00	337.40	323.85	337.60	313.00	309.74
Mean Strain (ε)	0.2525	0.2888	0.2201	0.2837	0.6105	0.5974
Mean Stretch (*a*)	1.2525	1.2888	1.2201	1.2837	1.6105	1.5974
C 1	304348	301842	261196	264067	106631	109227
C 2	128091	1242156	213993	207330	157850	202383
Mean Engineering Stress (σ)	486778	539736	464704	569363	497323	563746
Mean Cross-sectional Area (A)	6.184E-06	6.184E-06	6.184E-06	6.184E-06	4.356E-06	4.356E-06
Mean Predicted Force (N)	3.0101405	3.3376207	2.8736387	3.5208239	2.1663373	2.4556793

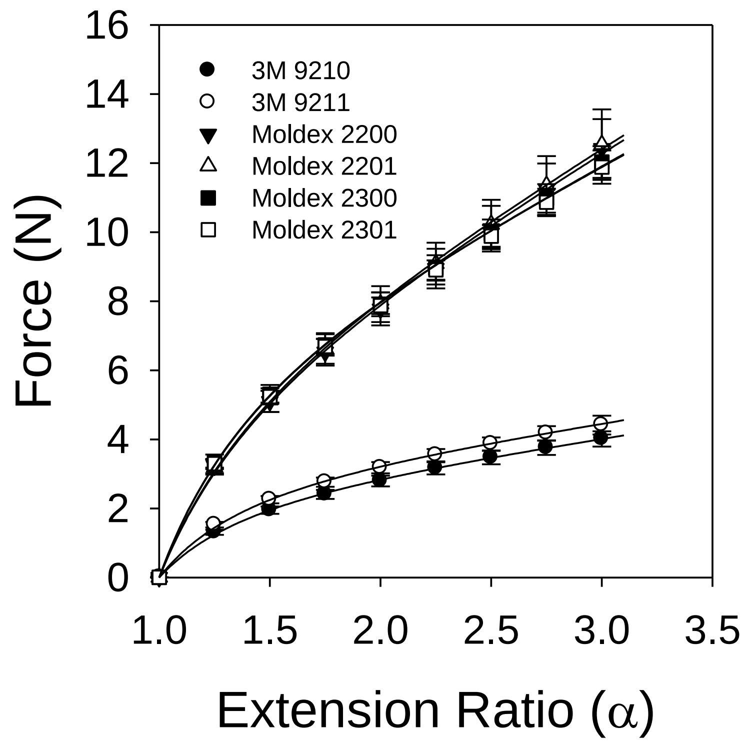

Figure 2. Comparison of experimental data points to fitted Mooney-Rivlin curves. Symbols are averages (n=5) for a given Extension Ratio. Error bars are standard deviation from the average.

Results of the vector analysis for the straps are shown in Figure 3 and summarized in Table II. From Figure 3, three groupings can be observed. The first is the cluster of 3M points at 5 N and 25° above the Frankfort plane. The second is the Moldex models centered at 8 N and 25°. The final group is one point from each of the 3M models and the two larger Moldex models that occurs at 47°. This third group originates from a single subject. No distinguishing dimension characteristics were noted for this subject over the rest of the subject pool. Further testing is needed to examine the effect of different facial dimensions and their impact on strap angle.

Table II. Vector Analysis of Straps from Six Models of N95 Filtering Facepiece Respirators

Respirator	Mean Force (Newtons)	Force Angle (°)
Moldex 2200	8.8621 (±1.15)	26.66 (±5.16)
Moldex 2201	8.0308 (±1.22)	22.28 (±9.60)
Moldex 2300	8.8875 (±0.96)	24.76 (±4.43)
Moldex 2301	7.5979 (±0.91)	23.85 (±8.34)
3M 9210	4.9713 (±0.32)	25.64 (±6.42)
3M 9211	5.5688 (±0.33)	25.24 (±6.27)

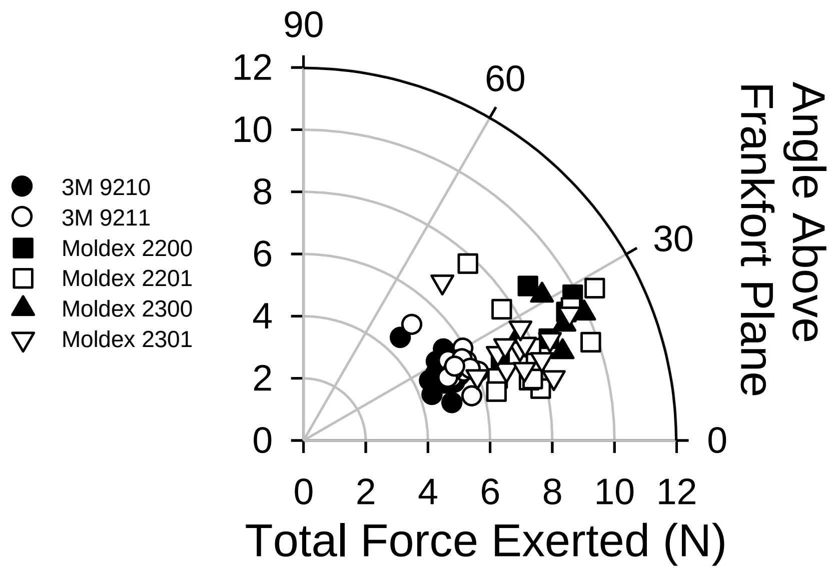

Figure 3. Force exerted (Newtons) as a function of strap angle above the Frankfort plane for all subjects included in this study. Symbol indicates FFR model.

DISCUSSION

This investigation has shown that there are differences in forces developed by straps of identical elastic material composition on different N95 FFR models and that, by use of the Mooney-Rivlin hyper-elastic model, it was possible to determine the forces applied to the face seal area of a FFR user donning one of the tested FFRs. This data is potentially of significance to researchers and FFR manufacturers in that the integrity and adequacy of the face seal are important in preventing ingress of harmful airborne contaminants into the breathing zone of the FFR user. Also, the facial pressure produced by the strap restorative forces has been identified as causing facial discomfort and, possibly, headaches associated with FFR wear that can impact FFR tolerance.[Baig et al., 2010; Lim et al., 2006; Radonovich Jr et al, 2009] The feeling of force on one's face is defined by a sensation and is experienced subjectively by the individual.[Snook et al., 1966] The specific function for sensing pressure against the face is Steven's Law (S=aI1.29) where S = sensation, a = constant, and I = intensity of pressure).[Piccione et al., 1997] Snook et al. [1966] reported that a low pressure (0.36 megadynes [3.6 N]) could be sensed in the perinasal regions of the face that are covered by an N95 FFR. Although the minimal pressure required for an adequate facial seal is not presently known, in the current study it has been shown that straps from the same manufacture lot of FFRs that had previously passed quantitative fit testing [Battles, 2011] generated relatively low restorative forces ranging from 4.97 N to 8.88 N (Table 2). The minimal FFR strap pressure required to obtain an adequate facial seal and minimize facial pressure discomfort for N95 FFR is not currently known, but the lowest value obtained in the current study (4.97 N) could be a starting point for such determinations, though numerous other variables (e.g., facial skin features, FFR structural features, strap materials, etc.) may also be operant. Cohen [1999] showed that, for a silicone rubber, full facepiece negative pressure air-purifying military mask (M40) with harness assembly, the minimum mean facial pressure required to pass a respirator fit test ranged from 0.06 kg/cm2 – 0.13 kg/cm2 (5,880 – 12,740 N/m2). Lei et al. [2012], utilizing a pressure transducer system composed of ultra-thin sensors combined with computational modeling, determined that a one-size only FFR model develops facial pressures that range (depending on facial characteristics) between 0.005 – 0.058 MPa (5,000 – 58,000 N/m2). In the current study, the dissimilarity in generated forces for molded style FFR (i.e., Moldex models) compared with flat-fold style FFRs (i.e., 3M models) imply that FFR-specific features (e.g., gasket seals, foam nose pads, etc.) will also impact the generated forces. Additionally, although the straps from the two manufacturers are identical in material composition (i.e., polyisoprene), they are dissimilar in length, thickness and cross sectional area, such that these differences also impact generated forces. Conceivably, the greater forces achieved by the Moldex respirators may be required in order to overcome the greater rigidity of those models that is related to their molded contour and the incorporation of a (non-filtering) mesh plastic support over the entire outer surface and between the inner and middle filter layers [Roberge et al., 2012] (Figure 2). Achieving an adequate contact area of the FFR to the wearer's face at lower tethering device pressures can reduce some of the negative effects (e.g., facial pressure) while possibly (depending on design) not affecting protection performance. Conversely, the application of too much strap tension can actually induce leakage (sometimes well within the user's tolerance level of comfort). Additional strap force research that includes a fit test component is warranted to determine the minimum force(s) required to maximize comfort while optimizing fit. Future research may be able to correlate objective data on forces (as obtained in the current study) with subjective data on user comfort.

The total force vector was used to determine how the straps applied force to the mask which, in turn, supplies the needed pressure to the face seal area. The objective was to understand how these straps in isolation worked, and to establish the amount of variation between FFRs from different manufacturers. Vector analysis in the current study indicated that the forces generated by the FFR straps are applied in an upward direction that is, on average, between 22.28 and 26.66 degrees, implying that the majority of the force is applied to the upper region of the maxilla and the nasal prominence (it should be noted that the upward angle at which the force is applied is directly related to the elevation of the top strap on the occiput [crown] of the head). One subject was found to have a strap angle that was significantly above the rest of the sample group. This was not found to be related to any measured facial dimensions, but may be the result of hair style. A study involving a larger number of subjects would be needed to assess this connection. Interestingly, a recent computer modeling study has indicated that the nasal and maxilla regions sustain the highest facial pressures from N95 FFRs.[Lei et al., 2010] Similarly, recent work using thermal imaging has shown that the maxilla and nasal regions are the sites of the majority of exhalation leaks when wearing N95 FFRs.[Roberge et al., 2011]

Limitations of the current study include its non-human nature; however, the strain data were obtained from fit test data of a prior human study [Roberge et al., 2012] and the tested FFRs were from the same production batches used in that study. Also, the evaluated straps were of only one material (i.e., polyisoprene) and we cannot comment on straps of different material composition. Similarly, our data may not be applicable to straps with different material characteristics (e.g., fixed straps, etc.) or those incorporating other features in their TDs (e.g., buckles, strap tensioners, cradle, single strap, etc.).

CONCLUSIONS

Restorative forces of N95 FFR straps are but one of many components that determine adequate fit, but it is important to investigate them in isolation in order to understand their interaction with other factors. The restorative forces generated by FFR straps are issues of importance with regard to protection and comfort, and the Mooney-Rivlin hyper-elastic model has been shown to be useful in determining these forces. FFR models investigated in the current study generated relatively low pressures that were sufficient to pass OSHA-mandated quantitative respirator fit tests. The data from the current study provides useful information that would be of interest to researchers and FFR manufacturers. Additional investigation is warranted to determine the lowest pressures required for passing respirator fit tests as this will ultimately also impact comfort and, by extension, tolerance and protection. Future research should correlate objective data with subjective responses on user comfort to determine if lesser force corresponds with better user acceptance of respirators.

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The findings and conclusions in this manuscript are those of the authors and do not necessarily represent the view of the National Institute for Occupational Safety and Health.

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