Effect on Breathing Resistance of a Surgical Mask Worn over a N95 Filtering Facepiece Respirator

Mark R. Vojtko[1], Marc R. Roberge[1], Richard J. Vojtko[2], Raymond J. Roberge[1], and Douglas P. Landsittel[1,3]

[1] National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236 USA
[2] EG & G Technical Services, Inc., Pittsburgh, PA 15236 USA
[3] Department of Mathematics of Duquesne University§, Pittsburgh, PA

Correspondence author: Raymond J. Roberge, MD
E-mail: dtn0@cdc.gov

ABSTRACT

Concerns over potential shortages of filtering facepiece respirators in the face of a pandemic influenza have prompted suggestions that the use of a surgical mask as an outer barrier might prolong the useful life of the respirator, but the effect on breathing resistance of this tandem respiratory protection has not been scientifically evaluated. Utilizing pressure transducers coupled to a breathing mannequin programmed at low-to-moderate and moderate-to-high breathing volumes, the current study measured baseline inspiratory and expiratory pressures of N95 filtering facepiece respirators before and after placement of a surgical mask over the respirator. The use of a surgical mask concurrently with a N95 filtering facepiece respirator results in a statistically significant increase in breathing resistance over that of the respirator alone.

Keywords: N95 filtering facepiece respirator, surgical mask, breathing resistance

INTRODUCTION

Respiratory protection is a key issue when dealing with aerosols of highly pathogenic biological agents (e.g., SARS, tuberculosis, avian flu, etc.) and N95 filtering facepiece respirators (N95FFR) are the most commonly-employed filtering facepiece respirators in healthcare settings (Yassi and Bryce, 2004). Prior experience during the SARS outbreaks documented that one 1300-bed medical center in Toronto utilized 18,000 filtering facepiece respirators/day (Rubinson et al, 2005) and that requests from medical facilities in Taiwan (population 23 million) to that country's Department of Health amounted to 100,000 N95FFR/day (Lu, 2003).

The Centers for Disease Control and Prevention (CDC) has estimated that 90 million N95FFR and 1.5 billion medical masks (procedural and surgical masks) would be required for a 42-day pandemic influenza scenario (Institute of Medicine, 2006). Others have suggested that billions of these respiratory protective devices would be required (Schmit, 2006; Wein, 2006). These projected needs, coupled to stockpiling efforts by many nations (e.g., in 2006, France began efforts to stockpile 685 million N95FFR for its healthcare workers) have severely impacted the ability of respirator manufacturers to keep up with demand (Wein, 2006).

In response to this potential shortage of N95FFR, the Institute of Medicine (IOM) and the CDC have proposed that the use of a surgical mask as an outer barrier over a N95FFR might extend the respirator's useful life (IOM, 2006; CDC, 2006). However, this combination of respiratory protective equipment has not undergone scientific scrutiny such that its effects on the wearer (e.g., breathing resistance, speech clarity, facial discomfort, etc.) are currently unknown. This study evaluated the breathing resistance associated with the concurrent use of a surgical mask over a N95FFR.

METHODS AND PROCEDURES

A Smartman (**Si**M**u**lant **A**gent **R**esistant **T**est **MAN**ikin) mannequin (ILC Dover, Frederica, DE), composed of a hollow, cast zinc shell and headform representing a static, uniform surface that outlines a human male head, neck, shoulders, and upper chest configurations, was utilized as a human surrogate. Anthropometric facial measurements of the Smartman placed it in cell #10 of the newly-developed National Institute for Occupational Safety and Health (NIOSH) Respirator Fit Test Panel (Zhuang et al., 2007). A Dynamic Breathing Machine (Warwick Technology Ltd, Warwick, U.K), a computer- controlled apparatus housing a reciprocating piston moving within a precision machined cylinder that is capable of reproducing real life human (sinusoidal) breathing patterns, was employed in-line through the mannequin/headform to deliver equivalent, non-variable breathing rates and breathing volumes at 25 L/min. (low/moderate breathing volume) and 40 L/min. (moderate/high breathing volume). The 25 L/min. breathing volume was selected as being representative of the light-to-moderate work levels associated with healthcare workers on the basis of the exhaustive literature evaluation by Caretti et al (Caretti et al., 2004) that noted estimated breathing volumes of 21.3 – 21.6 L/min. reported for nursing care activities; the 40 L/min. breathing volume, indicative of moderate-to-high work levels, was included for those instances when healthcare workers would engage in more strenuous activities (e.g., surge of patients in a major catastrophe response).

A single model (non-splash resistant) surgical mask (3M model 1818), rated type II (i.e., breathing resistance < 3.0 mm H_2O pressure at 8 L/min flow [British Standards Institution, 2005]), two models of N95FFR (3M model 1860, AO Safety model N9504C), and a N95FFR/surgical mask (3M model 1870) were selected for testing. In addition, a single N95FFR with exhalation valve (3M model 8511) was tested and is reported separately from the other data. Each N95FFR was glued to the facial portion of the Smartman using an Arrow Electromatic TR550 Hot Melt Glue Gun (Arrow Fastener Co., Saddle Brook, NJ) loaded with ethylene-vinyl acetate polymer/hydrocarbon resin glue. Prior to gluing, a layer of electrical tape was added to the application region in order to prevent leakage and avoid damage to the mannequin's rubber bladder. The glue was applied evenly around the inside edge of the N95FFR and immediately placed on the Smartman. Drying time was less than one minute and, upon completion, the N95FFR/glue interface was visually inspected for any leaks and additional glue applied, if necessary. A TSI Particle Generator, Model 8026 (TSI Inc., Shoreview, MN), utilizing sodium chloride solution, maintained room particle counts at 16,000-30,000/m^3 during testing. Protection factors (PF), the ratio of contaminant concentration outside the respirator to the concentration inside that represents a respirator's efficiency in removing air contaminants from the user's breathing air (American Lung Association, 2007), were then determined using the TSI Portacount Plus® (Shoreview, MN), a device that measures ambient and within-respirator particulate counts by optical density measurement using condensation nucleus counting technology. This method is capable of detecting particles as small as 0.02 µm in a range of 0.1 - 5 x 10^5 particles/cm^3. Three consecutive PF determinations of >100 were documented on three replicates

of each respirator model to ensure reproducibility and accuracy of PF determinations, for a total of nine N95FFR's achieving a PF greater than 100 at 25 L/min.

Mean peak inspiratory and expiratory pressures were measured utilizing a Validyne® Variable Resistance Pressure Transducer Model DP45-24 (Validyne Engineering Corp, Northridge, CA) attached to inhalation and exhalation sampling ports of the Dynamic Breathing Machine. The pressure transducer was calibrated prior to the study, and once again after half the trials had been completed, using a Setra Datum 2000™ electronic manometer (Setra Systems, Inc., Boxborough, MA) with National Institute for Standards and Technology (NIST) traceable calibration. This model of pressure transducer is highly sensitive to low pressures, and has a pressure range of 22.5 cm with an anticipated error of 0.5% (0.1 cm). Three-minute pressure tracings were obtained for each N95FFR at 25 L/min. and 40 L/min., following which the surgical mask was secured over the N95FFR by the two securing ties (Figure 1) and a second series of three-minute pressure tracings obtained at the same two breathing volumes. Testing was performed three times for each N95FFR, with the exception of the N95FFR with an exhalation valve (3M model 1811) that was tested once only (to serve as a reference comparison to the non-exhalation valve-equipped N95FFR). Within each three-minute collection period, the middle minute's data was isolated by Labview® computer software (National Instruments, Austin TX) and the peaks and troughs of the isolated minute were then identified and recorded.(Figure 2).

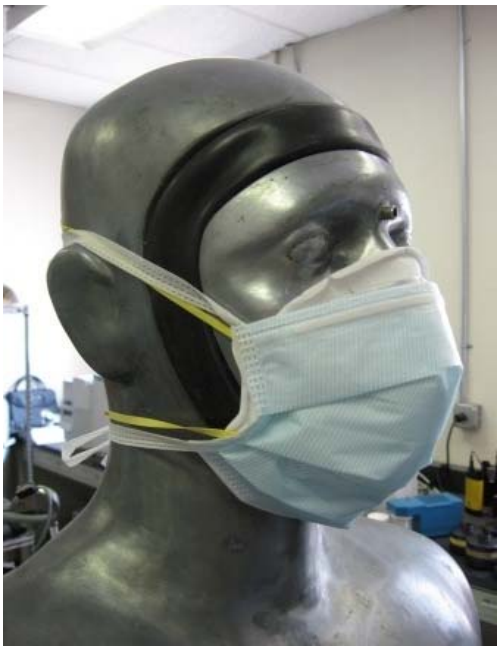

Figure 1. Smartman breathing mannequin with a N95 filtering facepiece respirator and surgical mask affixed.

Statistical Methods

For a given N95FFR model, 19 inhalation and exhalation measurements were recorded at a breathing volume of 25 L/min. and 24 measurements were recorded at the higher 40 L/min. breathing volume, and each such experiment was repeated three times with and without a surgical mask, for a total of 774 inhalation and 774 exhalation measurements. To account for the fact that these measurements were not all independent (since measurements from the same trial and same N95FFR model tend to be less variable than measurements across different models and different trials), a linear mixed effects model was fit with a random effects term for the trial number nested within the given N95FFR model. The

linear mixed effects model is essentially an analysis of variance (ANOVA) model, except that we are correctly accounting for notable correlations within certain runs of the experiment (e.g., enhanced performance of one specific respirator model). The model was fit to assess significance of breathing volume, presence versus absence of a surgical mask, and interaction of those two factors. For the purposes of this study, a p-value < 0.05 was considered significant.

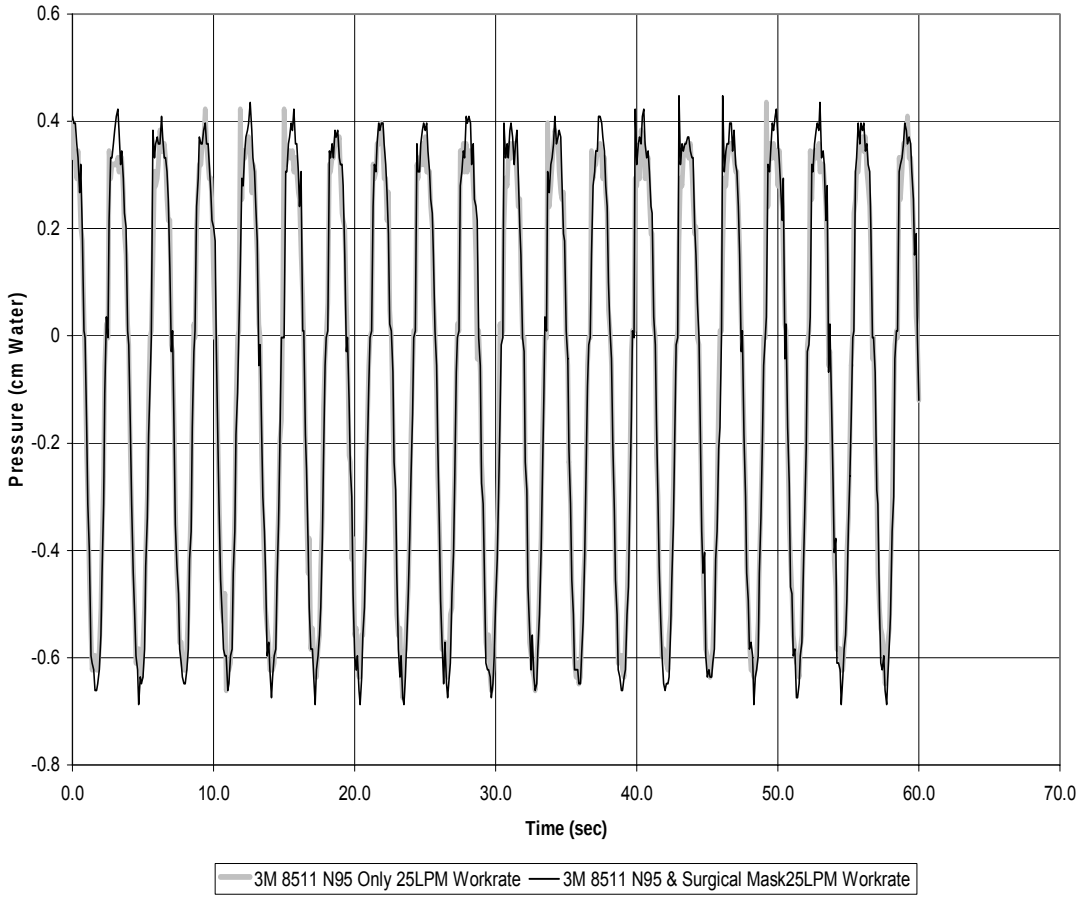

Figure 2. Tracing of pressure waveforms of a N95 filtering facepiece respirator and combination of surgical mask/N95 filtering facepiece respirator during inhalation and exhalation.

RESULTS

Breathing through a N95FFR at 25 L/min. resulted in a peak mean exhalation resistance of 0.709 cm H_2O pressure (SD 0.155 cm; range, 0.609 cm to 0.918 cm) and peak mean inhalation resistance of -0.704 cm H_2O (SD -0.166 cm; range, -0.582 cm to –0.928 cm), and at 40 L/min. produced a mean peak exhalation resistance of 1.086 cm H_2O (SD 0.242 cm; range, 0.917 cm to 1.412 cm) and mean peak inhalation resistance of -1.083 cm H_20 (SD -0.260 cm; range, -0.899 cm to -1.433 cm). Utilizing a surgical mask concurrently with a N95FFR at 25 L/min. resulted in a mean peak exhalation resistance of 0.769 cm H_2O pressure (SD 0.151 cm; range, 0.653 cm to 0.971 cm) and mean peak inhalation resistance of -0.753 cm H_20 pressure (SD -0.163 cm; range, -0.626 cm to -0.971 cm), and at 40 L/min. resulted in a peak mean exhalation resistance of 1.189 cm H_20 pressure (SD 0.240 cm; range, 1.005 cm to 1.461 cm)

and mean peak inhalation resistance of -1.178 cm H_20 pressure (SD -0.255 cm; range, -0.980 cm to –1.520 cm). The mean percentage increases in exhalation and inhalation resistances of a N95FFR/surgical mask combination over that of a N95FFR alone were 8.43% (range 5.79% to 12.29%) and 6.99% (range 4.60% to 10.08%), respectively at 25 L/min., and 9.48% (range 3.44% to 13.22%) and 8.70% (range 6.03% to 12.60%) respectively at 40 L/min (Table I).

Table I. Breathing Resistances of N95 Filtering Facepiece Respirators and Surgical Mask/N95 Filtering Facepiece Respirator Combinations at Two Different Breathing Volumes

			⇐ Pressures (cm H_2O) ⇒					
	Test Description		N95 FFR Only		FFR & Surgical Mask		Percent Difference	
	Work Rate (Lpm)		25	40	25	40	25	40
No Exhalation Valve	3M 1860 (three 1min trials per model)	Peak Mean Exhalation (Std Dev)	0.609 (0.035)	0.929 (0.051)	0.683 (0.053)	1.052 (0.077)	12.3	13.227
		Peak Mean Inhalation (Std Dev)	-0.602 (0.029)	-0.918 (0.044)	-0.663 (0.049)	-1.033 (0.073)	10.09	12.610
	3M 1870 (three 1min trials per model)	Peak Mean Exhalation (Std Dev)	0.601 (0.046)	0.917 (0.065)	0.653 (0.027)	1.005 (0.035)	8.561	9.588
		Peak Mean Inhalation (Std Dev)	-0.582 (0.044)	-0.899 (0.059)	-0.626 (0.024)	-0.980 (0.029)	7.616	8.991
	AO Safety N9504C (three 1min trials per model)	Peak Mean Exhalation (Std Dev)	0.918 (0.057)	1.412 (0.094)	0.971 (0.058)	1.461 (0.067)	5.795	3.442
		Peak Mean Inhalation (Std Dev)	-0.928 (0.062)	-1.433 (0.112)	-0.971 (0.066)	-1.520 (0.110)	4.607	6.034
	All N95 FFR Without Exhalation Valves	Peak Mean Exhalation (Std Dev)	0.709 (0.155)	1.086 (0.242)	0.769 (0.151)	1.189 (0.240)	8.436	9.485
		Peak Mean Inhalation (Std Dev)	-0.704 (0.166)	-1.083 (0.260)	-0.753 (0.163)	-1.178 (0.255)	6.998	8.709
Exhalation Valve	3M 8511 (one 1min trial per model)	Peak Mean Exhalation (Std Dev)	0.380 (0.026)	0.545 (0.025)	0.415 (0.019)	0.601 (0.022)	9.11	10.360
		Peak Mean Inhalation (Std Dev)	-0.644 (0.018)	-0.998 (0.020)	-0.674 (0.015)	-1.046 (0.016)	4.64	4.848

For exhalation measurements, there was a significant increase with the surgical mask at a breathing volume of 25 L/min. (adjusted mean difference of 0.084; $p<0.0001$) and a significant increase with the 40 L/min. breathing volume (adjusted mean difference of 0.199; $p<0.0001$). Adding the interaction of the surgical mask and breathing volume to the model led to a slight but statistically

significant further increase (adjusted difference of 0.022; p<0.0001). For inhalation measurements, there was a very similar pattern of a significant increase using the surgical mask at a breathing volume of 25 L/min. (adjusted mean difference of 0.074; p<0.0001) and a significant increase with the 40 L/min. breathing volume (adjusted mean difference of 0.201; p<0.0001). Adding the interaction to the model again led to a slight but statistically significant further increase (adjusted difference of 0.023; p<0.0001). The separate analysis of the N95FFR equipped with an exhalation valve (3M model 8511) at 25 L/min. exhibited exhalation and inhalation resistance of 0.308 and -0.644 cm H_20 pressure, respectively, and 0.545 and -0.998 cm H_2O, respectively, at 40 L/min. When combined with a surgical mask, this model exhibited exhalation and inhalation resistances of 0.415 and -0.674 cm H_20 pressure respectively at 25 L/min., and 0.601 and -1.046 cm H_20 respectively, at 40 L/min. This amounted to an increase in inhalation and exhalation resistance of 9.10% and 4.64% respectively at 25 L/min., and 10.36% and 4.84%, respectively, at 40 L/min. in this single trial (Table I).

DISCUSSION

Studies evaluating the concurrent use of more than one form of respiratory protection are rare. A previously published study (Derrick and Gomersall, 2005) examined the concurrent use of multiple surgical masks on filtration efficacy, but did not examine the effect on breathing resistance. The purpose of the current study was to determine the effect of wearing a surgical mask concurrently over a N95FFR on breathing resistance at low/moderate (25 L/min.) and moderate/high (40 L/min.) breathing volumes. Our data indicate that resistance differences are small but consistently higher when a surgical mask is worn concurrently with a N95FFR as opposed to a N95FFR alone. Mean resistances consistently increased further when the breathing volume was raised from 25 L/min to 40 L/min., and the 40 L/min breathing volume resulted in a greater percentage increase in resistances of the N95FFR/surgical mask combination in all but one case. Thus, both the breathing volume and the surgical mask had an effect on breathing resistance of the N95FFR, as did the interaction between the two (p<0.0001 for each parameter). Based on our data, on average, the wearer of a N95FFR/surgical mask combination can expect to experience increases of ± 7% and 8.4% in exhalation and inhalation resistances, respectively, at 25 L/min. and ± 8.7% and 9.5%, respectively, at 40 L/min. Although the percentage increases in breathing resistance noted with the exhalation valve-equipped N95FFR were similar to those in N95FFR not so equipped, the exhalation resistance continued to be markedly less than that noted for N95FFR not equipped with an exhalation valve.

How does this data translate to potential real-life effects upon the wearer of a surgical mask/N95FFR combination? Pressure drop (ΔP) across a respirator or surgical mask, measured in mm H_2O pressure/cm^2 is an indicator of ease of breathing and comfort; the higher the ΔP, the more difficult breathing becomes (British Standards Institution, 2005). The 3M model 1818 surgical mask has been rated as having a low ΔP (<2.0 mmH_2O/cm^2) (3M, 2007) ; adding this relatively small ΔP to that of the 3M model 1860 N95FFR (<6.5 mm H_2O/cm^2) (3M, 2007) results in a total potential ΔP of <8.5 mm H_20/cm^2, representing a 30% increase over the N95FFR baseline ΔP. However, our study data indicate that this combination of surgical mask and N95FFR resulted in considerably less ΔP (i.e. 12% - 13% [Table I]), suggesting that the breathing resistances of the surgical mask and N95FFR are only partially additive. This may be due to the fact that, during laboratory testing of surgical masks for ΔP, the surgical mask material is tethered to the testing equipment in a manner that allows less redirection of airflow peripherally as would occur in real life situations when a surgical mask is loosely tied over a respirator (Figure 1). That the addition of a surgical mask to a N95FFR will probably not result in an appreciable increase in the wearer's respiratory effort is supported by the fact that our mean inhalation and exhalation pressures for all N95FFR/surgical mask combinations (Table I) were similar to the reported values of -0.94 cm H_2O inhalation pressure at mild work rates and -1.24 cm H_2O inhalation pressure at moderate work rates reported in a study evaluating the breathing resistance experienced by healthcare workers utilizing a disposable low resistance filtering facepiece respirator (3M model 8715 – no longer in production) (Jones, 1991). This presumed limited effect on respiratory effort is further supported by the fact that the breathing

resistances of the combination N95FFR/surgical masks are well below the NIOSH filtering facepiece respirator certification maximums for inhalation and exhalation resistance (i.e., 35 mm and 25 mm, respectively) (NIOSH, 2004).

Limitations of the current study include the limited number of N95FFR models tested and the relatively small sample size of individual models. Similarly, the testing of only one exhalation valve-equipped N95FFR limits extrapolation of our data relative to similarly-equipped N95FFR, and use of only one model of surgical mask limits generalization of our data to other type II surgical mask models only. Use of a breathing mannequin that supplies uniform respirations at a pre-determined rate, as opposed to the use of human subjects who inherently exhibit variable respiratory excursions, could potentially result in lower peak pressures that underestimate real-life situations (the Warwick Dynamic Breathing Machine used in this study utilizes a sinusoidal pattern of breathing so that the estimated peak flow rates can be determined by the formula, $\pi \cdot$ minute volume = flow rate (Nunn and Ezi-Ashi; 2006), indicating that peak flows of 78.5 L/min and 125.6 L/min were possible, respectively, for the 25 L/min. and 40 L/min. breathing volumes utilized in this study). Also, because NIOSH certification testing of N95FFR utilizes a constant flow rate of 85 L/min (as opposed to the intermittent breathing volumes we utilized in the current study), we are unable to state whether the N95FFR/surgical mask combination would exceed NIOSH inhalation and exhalation pressure limits (i.e., 35 mm inhalation, 25 mm exhalation) (NIOSH, 2004). For some of the trials, the ΔP values obtained were smaller than the anticipated error range of 0.5% (0.1 cm) for the pressure transducer; therefore, some of the measured variability of the respirators could potentially be due to instrument error. However, carrying out three separate trials for each respirator (three minutes each trial) and utilizing the middle minute's data for analysis, as well as repeat calibrations of the pressure transducer to ensure accuracy would have served to minimize any anticipated instrument error. Lastly, the N95FFRs were affixed with glue on both the internal and external regions of the N95FFR which could have resulted in elevated resistances compared with those from a non-glued human face by eliminating bypassing ("venting") of exhaled breath at the respirator/face interface.

Concerns over the possibility of inadequate supplies of N95FFR in the face of a pandemic influenza have led to suggestions that a surgical mask worn as a barrier on a N95FFR could extend the useful life of the respirator (IOM, 2006; CDC, 2006). Although this suggestion has some plausibility, it has not been evaluated for efficacy or its effects on the wearer. Our data suggest that the use of a type II surgical mask concurrently with a N95FFR will result in increases in breathing resistance that will be somewhat more significant during the exhalation phase of respiration. The observed slight increases in breathing resistances resulting from addition of a type II surgical mask as an outer protective barrier over a N95FFR likely will not result in appreciable increases in the wearer's respiratory effort. Human studies will be required to more fully elucidate the physiological effects of this combination respiratory protective equipment upon the wearer.

CONCLUSIONS

The concurrent use of a type II surgical mask as a barrier over a N95FFR will likely result in a slight increase in breathing resistance for the wearer that will be more pronounced in the exhalation phase of respiration and that will not result in an appreciable increase in the respiratory effort of the wearer. Human studies will be needed to clarify more fully the physiological effects of this combination respiratory protective equipment.

Disclaimer: The findings and conclusions in this report 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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