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Urinary Fluoride Levels in Polytetrafluoroethylene Fabricators

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Urinary fluoride levels were investigated as an index of polytetrafluoroethylene (PTFE) exposure, since carbonyl fluoride, a pyrolysis product of PTFE, is metabolized and excreted as inorganic fluoride ion. Spot urine samples and occupational histories relating to polymer fume fever were obtained from 77 workers at a small PTFE fabricating plant. Environmental air sampling for PTFE was also performed. Air levels of PTFE ranging from 0 to 5.48 mg/m³ were found. All urine values fell below the level at which systemic effects are reported to occur. Analyses of the results by the method of analysis of variance demonstrated that the mean urinary fluoride level among workers who had one or more years of exposure to PFTE who also had experienced one or more reported episodes of polymer fume fever was significantly higher ($P < 0.01$) than that among employees with less than one year or more of exposure and no history of polymer fume fever. Additional exposure beyond one year and additional polymer fume fever episodes did not result in the further elevation of urine fluoride levels.

POLYTETRAFLUOROETHYLENE* (PTFE—Teflon, Halon, Fluon), a fluorocarbon, has been utilized for commercial purpose since 1941. Each year the list of uses for this polymer continues to expand. Production figures for total fluorocarbon have increased from 14,000 tons in 1965 to 610,000 tons in 1971 and a predicted 675,000 tons in 1976.[1] An undetermined but significant percentage of these figures is contributed to by PTFE. These increases can be attributed to the many desirable properties that PTFE possesses. These include lubricity, chemical inertness, plasticity, low toxicity, and thermal stability. Pardoxically, it has been PTFE's characteristic of thermal stability that has been the cause of much concern. This property makes PTFE very desirable for many uses at elevated temperatures, but a sizable number of scientific investigations[2-5] have implicated elevated temperatures as the major cause for the adverse toxicological effects associated with PTFE.

Historically, the first account of PTFE's adverse effects on man appeared in the literature ten years after this product's introduction onto the commercial market. In 1951, Harris described situations in which young workers in close proximity to PTFE at sintering temperatures (ca. 350°C) developed temporary influenza-like illness.[6] Since that time other investigators have reported similar episodes.[7-12] Although the nature of the pathophysiological mechanism involved is still not clearly underhtood, it apparently results from the inhalation of some particulate material evolved during the pyrolysis of PTFE.[3] The symptom complex, consisting of chills, body and joint pains, nausea, chest tightness, and febrile response, is self-limited and clears spontaneously within 48 hours. This syndrome is similar to the already well-known "metal fume fever," first described by Thackrah in 1831. "Polymer fume fever" was the name given to the syndrome when caused by PTFE fumes.

The chemical and toxicological nature of

PFTE's pyrolysis products is temperature-related. At temptratures below 275°C there does not appear to be any hazard from the pyrolysis products of PTFE. At 300° to 360°C, tetrafluoroethylene, hydrogen fluoride silicon tetrafluoride, and an incompletely characterized waxy sublimate have been isolated. At temperatures above 380°C, small amounts of the toxic gases hexafluoropropylene and octafluoroisobutylene have been found in the pyrolyzate. As temperatures increase above 400°C, pyrolysis occurs more rapidly and the principle toxic compounds found are perfluoroisobutylene and carbonyl fluoride.[13]

Owing to the above-mentioned complexities, monitored human exposure has been almost unknown. Furthermore, it has been impossible to correlate toxicological research performed on laboratory animals to humans, as the effects found in animals are different from those that occur in man. In animals fatal doses of individual pyrolyzate products have caused pulmonary edema, while in humans there has never been a reported death nor any illness worse than the typical one-day syndrome. As yet, it has not been possible to cause polymer fume fever in animals.

This paper describes an in-plant evaluation of PTFE exposure in a PTFE fabricating establishment.

Method

The investigation concerning human exposure to PTFE took place at a small factory (employing 130 persons). Over the last five years repeated episodes of polymer fume fever were reported by workers in this facility. On six occasions, outside regulatory agencies have investigated this problem. The company is engaged solely in the fabrication of PTFE parts, which are utilized primarily by the automobile and compressor pump industries. Each month 20,000 to 25,000 pounds of PTFE is used (approximately equal amounts of DuPont Teflon 8 and 8A, Teflon 5, and Allied Chemical Company Halon G-80 and G-18). No other resins or chemicals are used in significant amounts in this plant.

The processes in this facility are divided roughly into two major operations: general molding and machining. There are nine sintering ovens (321° to 376°C) in the general molding area which have been implicated by previous investigators as the major cause for the polymer fume fever. The machine shop area occupies a large and separate area of the plant. Lathes, grinders, mills, and automatic screw machines are present. No operation involving the heating of PTFE occurs here. Employees are allowed to smoke cigarettes throughout the plant with no restrictions imposed.

To properly carry out the investigation both a medical and an environmental evaluation was performed.

During the environmental evaluation breathing zone and general area samples for PTFE dust were collected. MSA Model G battery-powered vacuum pumps were used to draw air through Millipore AA filter (pore size 0.8 μm). The filters were 37 mm in size and were weighed before the survey. The filters were placed in open-face holders which were attached to the worker's lapel or collar. General area samples were taken with the same instruments. The sampling rate was maintained at 2.0 liters/min, and the sampling times ranged from 40 to 117 minutes.

The medical evaluation consisted primarily in the administration of a medical questionnaire and the collection of urine samples. The medical questionnaire gathered data pertaining to the following items: period of employment, place of employment within the plant, smoking history, number of episodes of polymer fume fever in the past year, severity of each episode, and brief past medical history.

Each individual who completed the questionnaire provided a spot urine sample to be analyzed for fluoride level. All urine samples were analyzed in accordance with the method of Frant and Ross.[14] Briefly, this procedure involves dilution of the urine sample with an equal volume of commercially avaliable total ionic strength adjustment buffer (TISAB) and measurement with a fluoride-specific ion activity electrode.

Results:

Environmental Evaluation

Twenty-seven filter samples were returned to NIOSH laboratories in Cincinnati, Ohio. The filters were reweighed to obtain the weight of the dust, and the dust was analyzed by a mass spectrometer for PTFE content. The weight of the PTFE dust was divided by the total volume of air sampled to obtain PTFE dust concentrations in miligrams of dust per cubic meter of air (mg/m^3).

Eight breathing zone samples were taken in the glow mold area. The PTFE dust levels ranged from 0.0 to 2.4 mg/m^3. The figure (0.0) was reported but may not be exact. Weighing variation and limits on the analytical method resulted in zero concentration of PTFE dust, when in fact small quantities may have been present. Four general area samples were collected on top of the Michigan ovens in the glow mold area of the plant. The PTFE dust levels ranged from 0.0 to 3.2 $mg/m.^3$ Eight personnel breathing zone samples were collected in the ring room, where gaskets are produced. The PTFE dust concentrations ranged from 0.4 to 5.5 $mg/m.^3$ Three personnel breathing zone samples were obtained from the worker operating the ring-grinding machines. The PTFE dust level ranged from 2.5 to 2.9 $mg/m.^3$ In the machine shop, four personnel breathing zone samples were collected. The PTFE dust levels were between 0.2 and 2.9 $mg/m.^3$

Medical Evaluation

MEDICAL QUESTIONNAIRE

The questionnaire was completed by 77 individuals (about 75% of the total production workers in the plant) including 40 workers from the first shift, 30 from the second, and 7 from the administrative staff. The following information was obtained from these questionnaires. Seventy percent of these individuals had been employed on the job for greater than 5 years. More than 60% of the workers engaged in smoking while on the job.

Eighty-six percent (60/70) of the production workers stated that they had "experienced polymer fume fever" sometime in the past, but of this same group only 50% acknowledged that they had experienced symptoms of polymer fume fever in the past year. Fourteen percent of the workers reported that they had more than three episodes of the malady in the preceding 12 months. A third of the workers had been absent from work because of alleged polymer fume fever. Only 10% of these with a history of polymer fume fever had deemed it necessary to seek the aid of a physician or had consulted a physician.

URINE SAMPLES

Seventy-seven urine samples were obtained with urine fluoride levels ranging in concentration from 0.098 to 2.19 mg/liter. The local water supply was also analyzed for fluoride concentration and had a value of 0.190 mg/liter.

A statistical analysis was performed of urine concentrations with respect to three items of information recorded in the medical questionnaire:

Factor L: Length of employment with PTFE (in years) with levels grouped into four ranges: L_1 (<1), L_2 (1 to <5), L_3 (5 to <10), and L_4 ($\geqq 10$).

Factor E. Number of Teflon fume fever episodes experienced in the last year: Administration (0 episode), E_1 (0), E_2 (1 to 2), E_3 (3 to 5), and E_4 (>5).

Factor S: Smoking habit while working: S_1 (nonsmoker), and S_2 (smoker).

To avoid confusing an effect of any one of the L, S, or E factors with effects of the other two factors, the urine fluoride levels were studied in an L × E × S three-way cross-classification. The raw data table contained 65 observations in 4 × 5 × 2 = 40 cells. The numbers of observations in each cell are given in Table I. Unfortunately, 13 of 40 cells were empty (no data), and sample sizes were very small (⩽5) in 37 of 40 cells. Therefore, to increase sample sizes, it was desirable to eliminate smoking as a factor, and it seemed clear from mere inspection of the raw data that average urine fluoride concentrations for smokers were no higher than for nonsmokers as long as comparison was restricted to the same combination of length of employment and number of episodes experienced in the last year. To support the validity of eliminating S as a factor, a formal *F*-test was performed to test the joint hypothesis of nullity of the collection of eleven differences between true average urine fluoride concentrations of populations of smokers and nonsmokers. Our subjects are considered to be taken as a random sample from these populations. The value of the criterion *F* in the statistical significance test was only 1.18, with 11 and 38 degrees of freedom ($P = 0.33$), indicating that levels for smokers and nonsmokers were nearly identical within L × E cells—that is, within the same combination of length of experience (L) and number of episodes (E). Therefore, data for smokers and nonsmokers were pooled, resulting in 20 L × E cells.

Administrative personnel were then pooled into group E_1 along with plant workers who had experienced no episodes. Urine fluoride levels were obviously in the same range for these two groups; nevertheless, a formal *F*-test for joint nullity of the collection of differences between mean urine fluoride levels of administrative personnel and of plant workers with no episodes was performed. The result was $F = 1.67$, with 3 and 49 degrees of freedom ($P = 0.18$), which shows that observed differences between pairs of means could easily be attributed to mere random variation.

Af er smokers and nonsmokers were pooled and administrative personnel were put into group E_1 of factor E, 4 × 4 = 16 larger cells replaced the 40 smaller cells. Unfortunately, 3 of the 16 larger cells were still empty, and only 6 cells had sample sizes larger than 5. Hence, it was desirable to do additional pooling, and the validity of such pooling over three of four levels of E

TABLE I
Sample Sizes for Combinations of Levels of Length of Employment (Factor L), Number of Episodes (Factor E), and Emoking Habit (Factor S).

Number of Episodes	Smoking	Length of Employment (years) <1	1 to <5	5 to <10	≥10
0	No	4	2	0	1
(administrative)	Yes	2	2	1	1
0	No	0	6	3	1
(plant)	Yes	0	2	7	3
1–2	No	0	1	1	0
(plant)	Yes	1	6	5	4
3–5	No	0	2	1	1
(plant)	Yes	0	2	1	0
5	No	0	0	0	1
(plant)	Yes	0	2	0	1

TABLE II

F-Tests for Homogeneity of Means of Log_{10} (Urine Fluoride Concentrations) for Four Lengths of Work Experience Compared within Control and Episode Groups of Workers

Group	Effect Tested	Degrees of Freedom	Variance	*F*	*P*
Control Control (E_1)	L_2 vs L_3 vs L_4	2	0.1132	1.80	0.157
Episode ($E_2 + E_3 + E_4$)	L_2 vs L_3 vs L_4	2	0.1854	2.95	0.040
	Replicate subjects (error)	57	0.0628	—	—

TABLE III

One-Tailed Student's *t*-Tests of Differences between Pooled Means of Log_{10} (Urine Fluoride Concentrations) and Bartlett's Test for Homogeneity of Cell Variances

Group		Length of Work Experience <1 Year (L_1)	Length of Work Experience ⩾1 Year ($L_2 + L_3 + L_4$)	*t*	*P*
Control (E_1)	*n*	6	30	1.22_{NS}	0.113
	$\bar{x}$	−0.4754	−0.3424		
	s^2	0.0238	0.0617		
Episode	*n*	1	28	2.81**	0.0033
($E_2 + E_3 + E_4$)	$\bar{x}$	−0.8633	−0.1670		
	s^2	—	0.0631		
	t	-1.48_{NS}	2.74**		
	P	0.93	0.0040		

Pooled variance: $s^2 = 0.0592$, 61 degrees of freedom
Bartlett's test: Chi-square = 1.59, 2 degrees of freedom, $P = 0.45$

NS—not statistically significant at the 0.05 probability level.
**—statistically signifcant at the 0.01 probability level.

and over three of four levels of L was tested by means of respective *F*-tests similar to that described above for smokers versus nonsmokers. The result of a joint *F*-test for E_2 versus E_3 versus E_4 (within levels of L) was $F = 0.13$, with 5 and 49 degrees of freedom ($P = 0.98$). This result indicates a high degree of statistical homogeneity among means for E_2, E_3, and E_4 within levels of L. Similar analyses of variance were performed to investigate homogeneity of means at the three highest levels of L. Results shown in Table II indicate that L_2, L_3, and L_4 data may be pooled. All statistical analyses were performed by utilizing a common logarithm transformation of the urine fluoride concentrations. This is a common practice for the purpose of stabilizing the variance over a wide range of concentration levels. The result of these three stages of pooling was a new table with two rows, E_1 and $E_2 + E_3 + E_4$, and two columns, L_1 and $L_2 + L_3 + L_4$, as shown in Table III. The validity of the aforementioned pooling is clear, since the variance of replicate subjects within the 4 cells was nearly equal ($S^2 = 0.0592$ with 61 degrees of freedom) to the variance computed within the original 27 (nonempty) cells ($s^2 = 0.0615$ with 38 degrees of freedom). Another indication that pooling was valid is that the resulting four variances within cells are quite homogeneous as indicated by the results of Bartlett's test (Table III).

The final step in the statistical analysis of urine fluoride concentrations was to perform tests of statistical significance of differences between pairs of logarithmic means within the same row or within the same column of Table III. Since variances are honogeneous, it was appropriate to use the pooled average variance to perform all *t*-tests between pairs of means. Results given in Table III indicate that the mean for the ($E_2 + E_3 + E_4$), ($L_2 + L_3 + L_4$) cell is significantly higher than means above it or to the left of it in the 2 × 2 table.

Table IV is a 2 × 2 summary table which shows the detransformed cell means expressed in concentration units (milligrams per liter). Ratios between pairs of sample means in the same row or same column are give nalong with one-tailed 95% lower confidence limits for the ratio of corresponding true means. When a 95% confidence limit for the ratio of two means exceeds unity (1.0), the mean in the numerator can be said to be significantly larger than the mean in the denominator at the 0.05 probability level.

Discussion

Although PTFE has been thoroughly studied in the past by numerous investigators, it is still the belief of many that there remain unanswered questions. These questions concern the exact chemical composition of the particulate that causes the polymer fume fever, and whether any insidious, detrimental health affects occur from repeated episodes of polymer fume fever. It is hoped that this in-plant environmental–medical evaluation has provided some new knowledge on this particular fluorocarbon.

At the present time a mandatory occupational health standard for PTFE dust does not exist, but current research seems to indicate that the nuisance or inert dust standard of 15.0 mg/m^3, as promulgated by the U. S. Department of Labor, is adequate for protection if the temperature of the dust is kept below 275°C. The American Conference of Governmental Industrial Hygenists (ACGIH) recommended threshold limit value (TLV) for nuisance dust is 10.0 mg/m^3. These levels are based on a total dust sample (time-weighed average for an 8-hour day). None of the samples taken in this plant showed levels that were more than approximately one-third the Federal standard or one-half the TLV. However, exposed individuals can suffer adverse effects at these lower dust concentrations if the dust is heated to a high enough temperature. For example, it takes only a very small amount of the resin on a lit cigarette to cause an episode of polymer fume fever. Therefore, the question arises whether the parameter of nuisance or inert dust is the best factor in monitoring PTFE exposure.

The medical questionnaire revealed that 86% of the workers stated that they had had polymer fume fever in the past. The number of these workers who had polymer fume fever per se is unknown. The company does not keep accurate medical records on this malady, nor do they do any biological monitoring. There is also the question of how many of the workers mistook polymer fume fever for other diseases with similar symptoms, such as influenza. Over the last

TABLE IV
Germetric Mean Urine Fluoride Concentrations and Ratios
(95% one-tailed lower confidence limits in parentheses)

	Little Experience (<1 year)	More Experience (≥1 year)	Ratio
Control (E_1) (no exposure or no episodes)	n = 6 Av = 0.335	n = 30 Av = 0.455	Ratio = 1.36 (>0.90)
Episode (one or more episodes)	n = 1 Av = 0.137	n = 28 Av = 0.681	Ratio = 4.97 (>1.94)
Ratio	Ratio = 0.41 (>0.15)	Ratio = 1.50 >1.18)	

year there has been a 30% decrease in the number of reported cases of polymer fume fever. This may be due to the significant modifications which have been made within this facility. Plant ventilation has been improved. The sintering ovens have been enclosed, and more stringent housekeeping practices have been instituted.

In an attempt to monitor exposure to PTFE biologically, determinations of urinary fluoride levels were performed on a majority of workers. According to Scheel[4,5] and Ranney[5] PTFE's carboxylate end group, when heated to the fabrication temperature, decomposes, carbon dioxide is released, and a vinyl bond is formed in the polymer chain. This vinyl bond, at the elevated temperatures, has the potential to react further, either to attach to an existing polymer chain, or to add oxygen to form an acid fluoride group (COF) which, in turn, can then be hydrolyzed to form the carboxylate end group. This series of reactions can repeat itself, leading to the buildup of the volatile components CO_2, COF_2, and HF. The COF_2 and HF equilibrate with the body fluids and bone and eventually will lead to the excretion of free fluoride ion in the urine.

Recently, Dilly[16] demonstrated that male rats when exposed to atmospheres containing various fluorinated ethylene derivatives or hexafluoroproprene in sublethal concentrations showed an increase in urinary fluoride levels. Sherwood[17] describes a case in which a spot urine was taken from an individual suffering from polymer fume fever and analyzed for fluorine. Its concentration was found to be 5 mg/liter. This individual drank water that had a fluorine level of 0.8 mg/liter.

Where domestic waters were free of fluorine, the fluorine present in urine averages 0.3 to 0.5 ppm. Fluorine in urine specimens is strikingly proportional to the fluorine content of the drinking water through the range of 0.5 to 5.1 ppm fluorine in the domestic water.[18]

In searching the literature, we could find no reports of urinary fluoride levels from individuals who were exposed to PTFE but who were not suffering actively from polymer fume fever, as was the case in this plant. The urinary fluoride levels for the workers in this plant, as mentioned previously, ranged from 0.098 to 2.19 mg/liter. All the workers in this plant drank nonfluorinated water which had a fluoride content of 0.19 mg/liter. According to F. F. Heyroth,[19] a mean daily urinary output of 4 mg/liter of fluorides reflects the maximum permissible fluoride exposures. None of the workers, then, were exposed to toxic levels of soluble fluorides.

Even though markedly elevated urinary fluoride levels were not found, it was possible, through statistical analysis of the limited data available, to make correlations between the urinary fluoride levels and the history regarding symptoms compatible with polymer fume fever and the number of years of PTFE exposure. It was found that the history of one or more PTFE fume fever episodes produced signficantly higher($P < 0.01$) average concentrations of fluoride in the urine of the workers with more than one year of experience. However, no significant increase ($P < 0.05$) above controls was detectable for workers with less than one year of exposure. Longer exposures did not significantly increase ($P > 0.05$) the average urine fluoride concentrations unless one or more episodes had also been experienced. Thus a significant increase in urinary fluoride was found only with a history of symptoms compatible with polymer fume fever and more than one year of exposure to PTFE.

We realize that the higher urine fluorine levels observed in certain categories of workers indicate only a correlation with job tenure and episodes of polymer fume fever. No attempt was made to account for possible group differences in age, previous work experiences, and intrinisic differences in life style. In the future, more carefully controlled investigations with large numbers of subjects will have to be carried out before the true meaning of using urinary fluoride levels as a biological minitor to PTFE exposure is ascertained.

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Laser Safety Short Course and Workshop

The sixth Laser Safety Short Course and Workshop will be offered by the staff of the Laser Laboratory of the University of Cincinnati Medical Center on March 18-22, 1974. This is a five-day comprehensive short course on all aspects of safe laser practices. Lectures will include numerous demonstrations, slides and films. There will be ample opportunity for question and answer sessions as well as special workshops on technical problems. Special emphasis of this year's course will center on the various laser safety standards and codes that have been enacted for compliance with the national and state legislation.

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