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Phase-Out Filter Perforation: Effects on Human Tobacco Smoke Exposure

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STITZER, M. L., J. BRIGHAM AND L. J. FELCH. *Phase-out filter perforation: Effects on human tobacco smoke exposure.* PHARMACOL BIOCHEM BEHAV **41**(4) 749–754, 1992.—Phase-Out® is a mechanical device that dilutes the cigarette smoke stream by mechanically perforating cigarette filters. Machine testing of Phase-Out-treated cigarettes suggested that smoke exposure reductions of 90–95% could be achieved with the device. This study evaluated exposure to carbon monoxide (CO) and nicotine when humans (N = 10) smoked Phase-Out-treated cigarettes under controlled laboratory conditions. Using boost (i.e., change from baseline) measures of constituent exposure, reductions ranging from 30–80% were seen for both nicotine and carbon monoxide. Orderly graded reductions in constituent exposure were observed for both nicotine and carbon monoxide as the number of filter perforations increased from zero to six holes, with no further reduction at the eight-hole condition. Percentage reductions in constituent exposure generally corresponded well to those anticipated from machine testing, indicating that the controlled smoking technology was valid and that the Phase-Out device operated as expected in a human smoking assay. The utility of partial constituent-level reductions is discussed both with regard to lowered health risks of smoking and ease of quitting when partial reduction is used as a gradual weaning preparation for quit attempts.

Cigarette smoking Tobacco smoke exposure reduction Filter perforation Nicotine Carbon monoxide

PHASE Out® is a marketed device that produces cigarette smoke stream dilution by mechanically perforating commercial cigarette filters. Operation of the device involves inserting the front end of a cigarette pack into a slot provided and mechanically squeezing the device to push a spring-loaded array of steel needles through the entire cigarette pack. The additional filter perforations created by the device allow air to enter the smoke stream when the smoker draws from the cigarette, the amount of air entering the stream increasing with the number of holes added to the filter. Dilution of the smoke stream to reduce the amount or concentration of tobacco smoke that reaches the smoker is conceptually similar to the strategies employed by commercial cigarette manufacturers to produce low- and ultralow-yield cigarettes (8) and is also the same strategy utilized in previously marketed ventilated cigarette holders (7,12,15). Use of the Phase-Out filter perforation device may allow smokers to continue smoking their usual preferred brand of cigarettes while reducing their exposure to tobacco smoke constituents. This could have beneficial health effects and could be particularly useful as a weaning method prior to smoking cessation.

Machine testing of Phase-Out-treated cigarettes conducted in 1982 by the United States Testing Company, Inc. (16) suggested that reductions of 80–95% in various smoke constituents could be achieved with the device. The present study provided a controlled laboratory evaluation of biological exposure to the major tobacco smoke constituents carbon monoxide (CO) and nicotine from cigarettes treated with the Phase Out device. The study, which allows for a direct comparison between human and machine smoking results, was designed to determine whether the filter perforation methodology works as expected to reduce tobacco smoke exposure when tested in a human smoking protocol. Different study results might be expected depending on the smoking procedures selected (controlled vs. ad lib smoking) due to the possibility of compensation during ad lib smoking. Nevertheless, controlled smoking was chosen for this study as a first step in determining the potential effectiveness of the new device with the understanding that additional studies using ad lib smoking would be necessary for a complete evaluation of effectiveness.

METHOD

Subjects

Study participants were seven males and three females recruited through community advertising for a paid laboratory

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study of cigarette smoking. Three subjects were black and seven were white. They ranged in age from 27–57 years (mean = 37.5 years). Subjects smoked 20–50 cigarettes per day (mean = 31 cigarettes per day) with a nicotine yield of 1.1 mg and had been smoking regularly for 10–40 years (mean = 20.6 years). Exclusion criteria were self-reported current or previous drug abuse or the detection of illicit drugs in a urine screen. Each subject was paid $100 for study participation.

Procedure

Subjects participated in five laboratory sessions conducted in the morning and were required to abstain from cigarettes before reporting to the laboratory on session days. Overnight abstinence was verified by expired CO readings at or below 20 ppm.

During each laboratory session, subjects smoked two Marlboro cigarettes spaced by a 30-min interval. Both session cigarettes were pretreated with either zero, two, four, six, or eight perforations using the Phase-Out device. Perforation conditions were presented in random order across days and testing was run under double-blind conditions. Treated cigarettes were visually examined prior to the session by a nonblinded technician in an attempt to select for use only those with the specified number of perforations. Cigarettes were smoked using a plastic holder and computer feedback was provided to the subjects to aid in standardizing the number (eight puffs), size (60 ml), and spacing (1 min apart) of puffs. These controlled smoking procedures have been previously described (17,18).

A data collection battery was completed at five time points within the session: prior to smoking, immediately after cigarette 1, 20 min after cigarette 1, immediately after cigarette 2, and 20 min after cigarette 2. The battery consisted of a blood draw (10 ml) for nicotine analysis, an expired air sample for CO analysis, a heart rate measurement taken manually, and subjective ratings. Subjects rated four cigarette characteristics on a 10-point scale: the strength of the cigarette (1 = very weak; 10 = very strong), satisfaction derived from smoking (1 = very unsatisfying; 10 = very satisfying), degree to which the cigarette had taste (1 = no taste; 10 = lot of taste), and amount of smoke vs. air in the smoke stream (1 = mostly air; 10 = mostly smoke). Subjects also rated themselves on 18 tobacco withdrawal symptoms (1 = not experienced; 10 = extreme) based on the checklist previously used by Hughes and Hatsukami (9).

Data Analysis

Nicotine and CO boost or change scores were calculated by subtracting the first presmoking baseline from the values observed immediately after smoking each of the two session cigarettes. All data were analyzed using repeated-measures analysis of variance (ANOVA) with two factors: perforation condition (zero, two, four, six, or eight) and within-session time. Since values obtained after the first vs. second cigarette of the session generally did not differ significantly for any measure, data for all measures are presented as averages for the two session cigarettes. Huynh-Feldt corrected p values were used. Posthoc tests were conducted using Tukey's HSD procedure.

RESULTS

Effects of Untreated Cigarettes

Figure 1 shows plasma nicotine and expired air CO levels from the zero-hole (untreated) condition at each measurement point. Prior to smoking, plasma nicotine levels were below 10 ng/ml (mean = 7.6 ng/ml). These levels rose to 23.4 ng/ml after the first cigarette, fell to 12.6 ng/ml by 20 min postsmoking, and rose again to 22.6 ng/ml after the second cigarette. A similar pattern was seen with expired air CO. Average baseline level prior to smoking was 16.3 ppm. Levels rose to 29.3 ppm after the first cigarette and continued to rise, reaching 35.9 ppm after the second cigarette of the day. Average heart rate during the zero-hole condition (data not shown) rose from a presmoking value of 69.2 bpm to a postsmoking value of 78 bpm ($p < 0.05$) following the first cigarette. Heart rate then stabilized at about 73 bpm for the remaining measurement points.

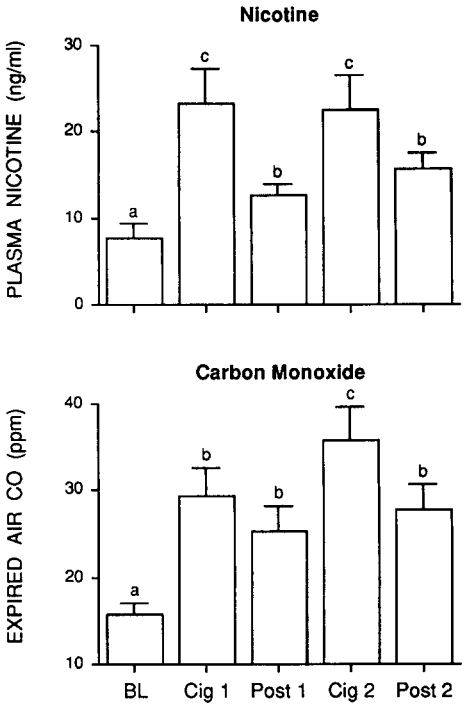

FIG. 1. Nicotine blood levels (top) and expired breath CO levels (bottom) for the zero-hole or untreated condition. Each bar represents one of the five measurement points during an experimental smoking session: prior to any smoking (BL), immediately after smoking the first cigarette (Cig 1), 20 min after the first cigarette (Post 1), immediately after the second cigarette (Cig 2), and 20 min after the second cigarette (Post 2). Data are averages for 10 subjects; brackets are SEM. Lowercase symbols above the error bars represent results of posthoc tests; study conditions that share a common letter are not significantly different from each other, while conditions with no common letter are significantly different.

Filter Perforation Effects: Nicotine Exposure

Figure 2 (top) shows average nicotine blood levels as change from presmoking baseline to immediately after smoking for cigarettes treated with increasing numbers of filter perforations. Blood nicotine levels increased by 15 ng/ml on average after smoking untreated cigarettes. The size of the nicotine boost was systematically reduced by filter perforation conditions providing two to six holes, with no further reduction seen at the eight-hole condition. Average nicotine boosts observed were 9.44, 6.25, 3.15, and 3.60 ng/ml as the number of perforations increased; the smallest average nicotine boost was seen in the six-hole condition.

Filter Perforation Effects: CO Exposure

Figure 2 (bottom) shows average expired air CO as change from presmoking baseline to immediately after smoking for cigarettes treated with increasing numbers of filter perforations. Expired air CO level increased by 17 ppm on average after smoking untreated cigarettes. As with nicotine, the size of the CO boost was systematically reduced by filter perforation conditions providing two to six holes, with no further reduction seen at the eight-hole condition. Average CO boosts observed were 12.2, 8.4, 3.7, and 6.5 ppm as the number of perforations increased; the smallest average CO boost was seen in the six-hole condition.

Filter Perforation Effects: Heart Rate

Average postsmoking heart rate after the first cigarette was 78 bpm in the zero-perforation condition. These first cigarette postsmoking heart rate values declined systematically to 76.4, 71.6, 70.0, and 70.4 bpm as the number of filter perforations increased. Postsmoking heart rates in the six- and eight-hole conditions were significantly lower than those obtained in the zero-hole condition.

Comparison to Smoking Machine Results

Figure 3 presents a comparison between human and machine smoking results for tobacco constituent delivery shown in both cases as percent reduction from delivery observed in the unperforated control condition. Data obtained from machine smoking tests conducted with Marlboro cigarettes by

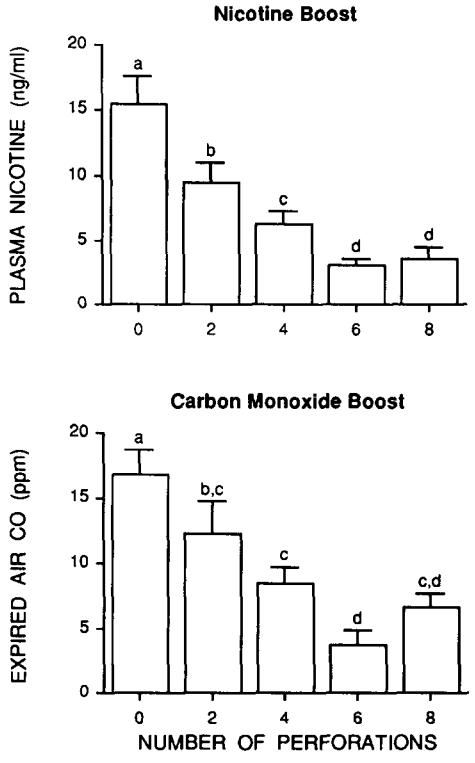

FIG. 2. Nicotine blood levels (top) and expired breath CO levels (bottom) as a function of five filter perforation conditions. Data are averages of the two cigarettes smoked by each of 10 subjects; brackets are SEM. Lowercase symbols above the error bars are as in Fig. 1.

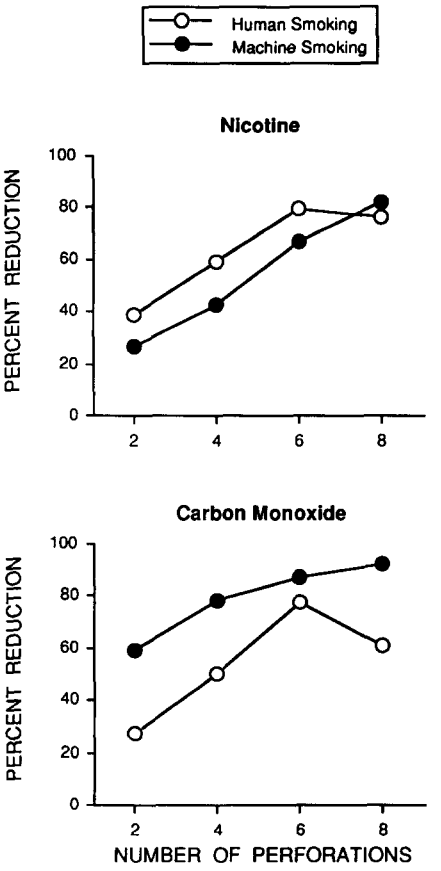

FIG. 3. Percentage reductions in nicotine (top) and CO (bottom) for five filter perforation conditions. (●), data from machine testing conducted by United States Testing Company, Inc.; (○), data from human testing (averaged across two cigarettes smoked during the test session).

the United States Testing Company, Inc. in 1982 indicated nicotine reductions from 27.0% in the two-hole condition to 82.4% in the eight-hole condition. Human data obtained for nicotine boost were quite comparable to machine smoking predictions, with reductions from 39% in the two-hole condition to 80% in the six- and eight-hole conditions. Machine test reductions in CO delivery ranged from 59.0% in the two-hole to 92.3% in the eight-hole conditions. Reductions in human CO exposure, as measured by CO boost, started at 28% in the two-hole condition, increased to a peak of 78% in the six-hole condition, and declined again to 61% in the eight-hole condition.

Cigarette Ratings

Figure 4 shows subjects' assessment of cigarette characteristics for the five filter perforation conditions. As the number of perforation holes increased, there were reliable decreases in reported cigarette strength, satisfaction derived from smoking, degree to which the cigarette had taste, and amount of smoke vs. air in a puff. The pattern of posthoc test results was similar across measures. Ratings in the two- and four-perforation conditions were similar to each other; for strength and smoke vs. air, these were significantly lower than ratings in the unperforated control condition. Ratings in the six- and

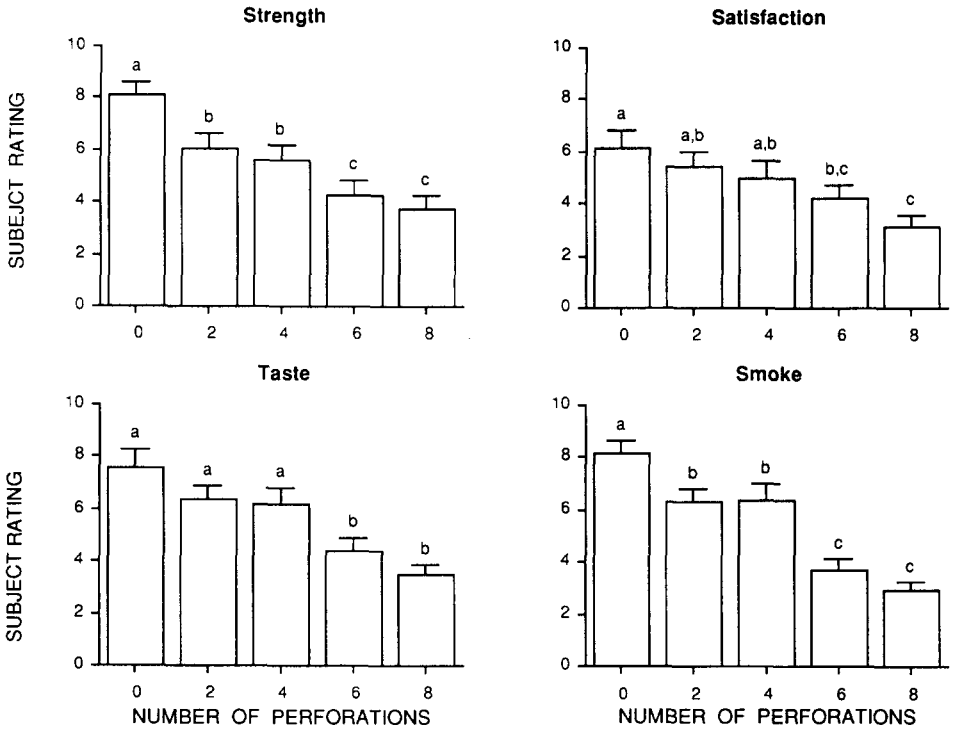

FIG. 4. Subjects' assessments of cigarette characteristics for five filter perforation conditions. Subjects rated four attributes on a 10-point scale: strength of the cigarette (1 = very weak; 10 = very strong), satisfaction derived from smoking (1 = very unsatisfying; 10 = very satisfying), degree to which the cigarette has taste (1 = no taste; 10 = lot of taste), and amount of smoke vs. air in the smoke stream (1 = mostly air; 10 = mostly smoke). Data are averages obtained after two cigarettes smoked by each of 10 subjects; brackets are SEM. Lowercase symbols above the error bars represent results of posthoc tests as in Fig. 1.

eight-perforation conditions were also similar to each other; in general, these ratings were significantly lower than those observed in the two- and four-perforation conditions, as well as in the unperforated control condition.

Tobacco Withdrawal Ratings

Withdrawal symptom scores tended to decline from presmoking baseline values at postsmoking measurement points. There were no significant condition effects on the total withdrawal symptom score, but two individual items (urge to smoke, cigarette craving) did show significant condition effects. Figure 5 presents filter perforation effects on urge and craving ratings obtained prior to smoking and after each of the two cigarettes smoked during the session. Prior to smoking, subjects consistently rated urges and cravings at a mild intensity level (2–3 on a 10-point scale). After smoking untreated cigarettes, these ratings declined substantially. However, postsmoking ratings of urge and craving were progressively less suppressed as the number of filter perforations increased.

DISCUSSION

Plasma nicotine and expired air CO levels increased substantially after subjects smoked the first two untreated cigarettes of the day (Fig. 1). The patterns and levels observed were generally consistent with those previously reported in the literature (3,4), although peak nicotine levels achieved were somewhat lower than those reported in these previous studies. The main procedural difference between this and previous studies was that subjects in the present study were required to control the size, spacing, and number of their puffs instead of smoking ad lib. This would be expected to influence the size of the constituent boosts observed. Nevertheless, data from untreated cigarettes indicate that our controlled smoking protocol produced the expected rise in human tobacco constituent levels as a function of smoking the first two cigarettes of the day.

Treatment of cigarettes with the Phase-Out device to produce an increasing number of filter perforations resulted in reduced nicotine and CO exposure as compared to exposure from unperforated control cigarettes. Using boost (i.e., change from baseline) measures of constituent deliveries, reductions ranging from 40–80% were seen in nicotine delivery, with CO delivery reductions similarly ranging from 30–80% (Fig. 2). A linear reduction in exposure levels was predicted as the number of filter perforations increased. Linear reductions were observed in both nicotine and CO levels as the number of perforations increased from zero to six holes (Fig. 2), with no further reduction at the eight-hole condition. The data suggest that orderly progressive amounts of smoke dilution can be accomplished with the filter perforation/smoke dilution technology. The fact that no further gains in exposure reduction were observed at the eight-hole condition may be due to mechanical deficiencies of the Phase-Out device since informal observations of treated cigarettes suggested that the

eight-hole setting in particular did not always create the full expected number of perforations.

Percentage decrements in nicotine delivery observed in humans were strikingly similar to reductions observed in smoking machine testing (Fig. 3). The concordance between human and machine testing data supports the conclusion that the Phase-Out device works as expected to dilute the smoke stream and reduce constituent exposure. The concordance with machine testing results also substantiates the validity of the controlled smoking technology used in the present study, designed to circumvent any tendency of smokers to compensate with altered smoking behavior in the face of smoke dilution. Data from human testing revealed similar percentage reductions in nicotine and CO across the filter perforation conditions, while machine testing detected a greater reduction in CO than in nicotine levels, especially in the two- and four-hole conditions (Fig. 3). Thus, for example, machine testing detected a 60% reduction in CO under the same filter perforation condition (two holes) that produced only a 30% reduction in nicotine. It seems that the human data showing similar percentage reductions in both CO and nicotine levels are more in keeping with what would be expected from simple air dilution of the smoke stream.

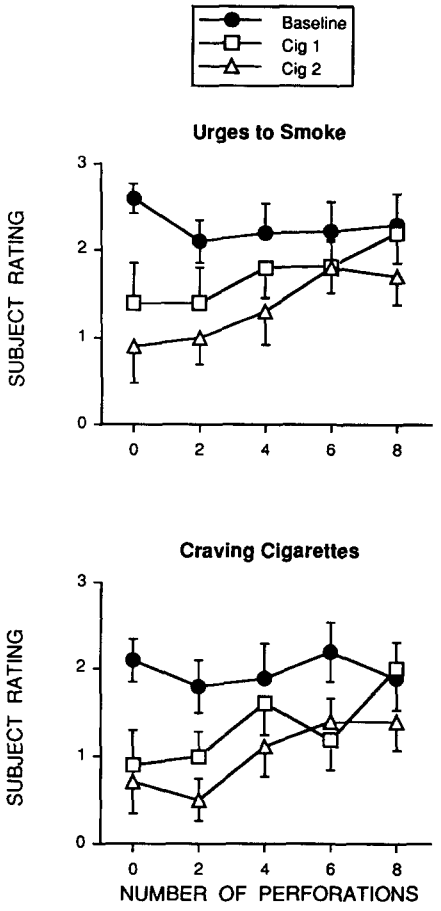

FIG. 5. Data from two items of the tobacco withdrawal questionnaire as a function of five filter perforation conditions. Shown separately in each graph are data obtained during the presmoking baseline measurement (filled symbols) and data obtained immediately after smoking each of two consecutive cigarettes spaced 30 min apart. Subjects rated their urges and cravings on a 10-point scale from 1 = none experienced to 10 = extreme. Data points are averages for 10 subjects; brackets are SEM.

Human subjects could detect the dilution of smoke produced by filter perforation. Changes in the smoke-to-air mixture were reported with a good degree of accuracy and were accompanied by reliable decreases in ratings of cigarette strength, amount of taste, and satisfaction derived from smoking (Fig. 4). These findings are consistent with previous reports obtained from subjects smoking cigarettes that varied in yield characteristics (18,19).

Withdrawal symptom scores were elevated in the morning prior to smoking sessions and reduced by smoking untreated cigarettes. Filter perforation prevented this reduction in symptoms, particularly ratings of cigarette cravings and urges, but did not result in further elevation of withdrawal scores. Other studies of partial tobacco exposure reduction using low-yield commercial cigarettes have reported increased withdrawal symptoms during partial smoke exposure reduction (6,18). In these studies, however, symptoms were measured after prolonged periods of smoking in the natural environment, whereas the present study examined partial exposure reduction effects during a brief smoking period in a laboratory setting and thus may not have been as sensitive to withdrawal effects.

There may be potential health benefits of using smoke dilution devices such as Phase-Out if exposure to tobacco constituents is reduced substantially when the devices are used chronically in the natural environment. However, it is a mistake for smokers to think that they can eliminate their health risks by continuing to smoke with the use of filtration devices. Previous studies have amply demonstrated that smokers compensate by smoking more cigarettes and by smoking each cigarette more intensively when they switch to lower-yield cigarettes (5,18), use devices that mechanically dilute the smoke stream (7,12,15), or reduce the number of cigarettes smoked per day (2). In the case of low-yield cigarettes, which achieve their delivery reductions in part by perforated filters, smokers can substantially increase their smoke exposure by mechanically blocking filter holes with fingers or lips (11,19), and indeed previous research has shown that biological levels of smoke exposure are at best only weakly correlated with the package yield of cigarettes (1,14). Clearly, there is a similar danger of hole blocking and compensatory increases in smoking intensity with the Phase-Out device. Additional studies will be needed to determine exposure reduction levels achieved when smokers use Phase-Out during prolonged periods of natural environment smoking. Another related issue requiring evaluation is the effectiveness of the device when used with commercial cigarettes that already employ smoke dilution as a means of reducing their tar and nicotine ratings.

Although not an issue directly addressed in the present study, gradual exposure reduction could provide a benefit to smokers who are trying to quit. If smokers can be gradually weaned from exposure to tobacco products prior to a quit attempt, then levels of uncomfortable withdrawal symptoms may be reduced and the chances of successful abstinence enhanced. The Phase-Out device may be more acceptable to smokers for this purpose than previously marketed smoke dilution devices such as graduated filters because the Phase-Out filter perforation technique is unobtrusive and convenient to use. However, additional studies will be needed to determine whether gradual precessation smoking reductions do in fact confer any benefits to smokers attempting to quit (10,13).

In conclusion, this study showed that filter perforation achieved with the Phase-Out device significantly reduced human exposure to tobacco smoke constituents when tested in an acute smoking protocol under controlled laboratory smoking conditions. Exposure reductions of 30–80% were observed for both nicotine and CO. Percentage reductions in constituent exposure generally corresponded well to those anticipated from machine testing, indicating that the controlled smoking technology was valid and that the Phase-Out device operates as expected in a human smoking assay. The implications of partial constituent level reductions need to be further studied both with regard to lowered health risks of smoking and with regard to ease of quitting when partial reduction is used as a gradual weaning preparation for quit attempts.

ACKNOWLEDGEMENTS

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