The Effects of Progressive Cigarette Smoke Dilution Upon Smoking Pattern and Stress Responses in Humans

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THE EFFECTS OF PROGRESSIVE CIGARETTE SMOKE DILUTION
UPON SMOKING PATTERN AND STRESS
RESPONSES IN HUMANS

by

David M. Keenan

A Dissertation
Submitted to the
Faculty of The Graduate College
in partial fulfillment of the
requirements for the
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Department of Psychology

Western Michigan University
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David M. Keenan

11

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# TABLE OF CONTENTS

ACKNOWLEDGEMENTS ................................................................. ii

Chapter

I. INTRODUCTION ....................................................................................... 1

II. METHOD ........................................................................................................ 12
   Subjects and Setting ...................................................................................... 12
   Apparatus and Materials ............................................................................. 13
   Procedure ....................................................................................................... 17
   Design ........................................................................................................... 19
   Responses of Interest .................................................................................. 21

III. RESULTS ..................................................................................................... 24

IV. DISCUSSION ................................................................................................ 44

REFERENCE NOTES ......................................................................................... 50

APPENDICES .................................................................................................. 51

BIBLIOGRAPHY ............................................................................................. 75
CHAPTER I

INTRODUCTION

Nicotine, the most active pharmacological agent in tobacco, is generally recognized as the primary factor involved in the maintenance of cigarette smoking (Gritz and Jarvik, 1978; Jarvik, 1970, 1973, 1977, 1979). Two aspects which are frequently cited as demonstrating the role of nicotine in smoking are dependency and withdrawal. These factors are directly related to understanding cigarette smoking as a "dependence process", and to elucidating the behavioral variables associated with maintenance and cessation. (Krasnegor, 1979).

With respect to dependency, various researchers have attempted to demonstrate "regulation" or "titration" of nicotine intake by cigarette smokers (Gritz and Jarvik, 1978; Russell, 1978; Schacter, 1979). The basic assumption is that,

... each smoker will, in any one situation smoke to obtain a fairly constant individually characteristic nicotine level which is sufficient to produce a particular pattern of pharmacological effects that (the smoker) desires or requires in that particular situation... (Russell, 1978, p. 109).

Thus, individuals have been observed to alter their smoking patterns, including smoking rate (consumption) and inhalation (puff frequency, puff duration and puff volume), as a function of I.V. oral ingestion and smoke delivery levels of nicotine (Russell, 1978; Schacter, 1979). These compensatory changes in smoking patterns presumably occur without the apparent awareness of the individual. However, regula-
tion does not appear to be precise, since consistent observations of compensatory changes have not been always reported (Schacter, 1979).

Several factors may be related to the reported inconsistencies among studies. The specific aspects of the smoking pattern which were monitored may have been insensitive to the compensatory changes that could have occurred during regulation. To accurately identify these changes, simultaneous monitoring of multiple responses would be required (Fredericksen, Martin and Webster, 1979). To achieve regulation a cigarette smoker can alter both the rate of consumption and the topography of inhalation. Topography is the inhalation pattern of puff frequency, duration and volume. The inhalation pattern, rather than smoking rate has been shown to be the most critical feature related to peak plasma nicotine levels (Russell, 1978). A further consideration concerns the assessment of abrupt changes in nicotine values (Prue, Martin and Krapfl, Note 3). Thus, compensatory changes in the smoking pattern may have been the result of abrupt changes in nicotine delivery. Unfortunately though, whether regulation is due to the positive effects associated with nicotine intake, or due to the avoidance of subtle withdrawal reactions is not known (Jaffe and Jarvik, 1978).

A variety of symptoms have been reported to occur concurrent with smoking withdrawal. These have included physiological changes associated with cardiovascular, metabolic and CNS functions; and behavioral and subjectively reported symptoms related to psychomotor performance, physical illness, negative affective states and craving (Shiffman, 1979). Although, a dose-dependent relationship
between smoking and severity of symptoms would be expected, this has not been consistently reported. In addition, the range of symptom severity appears to be quite diverse (Shiffman, 1979).

Failure to identify a specific smoking withdrawal syndrome is perhaps related to two aspects, the assessment of drug dependency and the objective measurement of withdrawal symptoms. Studies frequently utilize rate of smoking as an indicator of dependency and dose related effects. Yet, as previously stated, rate has been shown to be minimally related to peak plasma levels of nicotine (Russell, 1978). Additionally, measurement of behavioral and psychological withdrawal symptoms typically utilize self-report assessments, which are not standardized. Thus, meaningful comparison of results reported by various researchers are difficult to determine (Shiffman, 1979).

Studies investigating the effects of smoking abstinence have typically assessed abrupt changes in smoking behavior. Additionally, it has been reported that partial abstinence and gradual rate of reduction results in more prolonged and disruptive withdrawal symptoms than immediate total abstinence (Jarvik, 1979; Shiffman, 1979). Jarvik (1979) commented that this finding is incongruent with "sound behavioral principles" and discrepant from "the usefulness of gradual withdrawal in other dependency disorders (p. 32)." He suggested that further research is needed to determine if there exists a specific rate of reduction that would not precipitate withdrawal, and thus allow a smoker to be "weaned" from tobacco. However, an important distinction between gradual smoking rate reduction and
gradual reduction by smoke dilution should be made.

Several studies have investigated the effects of gradual reductions in the dilution of cigarette smoke (Foxx and Brown, 1979; Turner, Sillett and Ball, 1974; Sutton, Feyerabend, Cole and Russell, 1978; Hutchinson and Keenan, Note 1; Prue, Martin and Krapfl, Note 3; Schindler, West, Gordon and Fantino, Note 4). Dilution corresponds to the tar/nicotine (T/N) delivery values based on standardized machine smoked cigarettes. Three procedures have been utilized by these studies to achieve smoke dilution: "brand fading", in which a smoker switches to cigarette brands delivering progressively lower T/N values; ventilated cigarette holders which progressively increase the degree of air filtration; and by varying the number of pinholes inserted into the cigarette filter which also increases the amount of filtration. The distinguishing feature of these studies is the progressive dilution of the smoke delivery in contrast to abrupt and dramatic changes. Statistical studies have suggested that lower T/N cigarettes may pose a reduced health hazard for individuals continuing to smoke (Gori, 1976). Furthermore, progressive reduction of T/N smoke delivery has been advocated as a smoking abstinent and/or "controlled smoking" treatment procedure (Foxx and Brown, 1979; Turner, et. al., 1974; Prue, et. al., Note 3).

Three studies have assessed the effects of "brand fading" upon smoking behavior and health related changes. Although each study required individuals to switch to progressively lower T/N cigarette brands, the rate and degree of each successive reduction varied. Turner et. al. (1974) utilized a two week schedule of approximately
a 40% reduction each week from baseline T/N values (20/1.4 mg, 12/0.8 mg, and 4.0/0.3 mg). Foxx and Brown (1979) required a 30% reduction in T/N delivery for each of three weeks, but did not report the actual values of T/N. Prue, et al. (Note 3) employed the most gradual reduction (approximately 15 to 30% bi-weekly) for the longest time period (8 to 16 weeks). All subjects in this study eventually switched to "very low" T/N cigarettes (4.0/0.3 mg to 1.0/0.1 mg).

With respect to smoking pattern (rate and inhalation) Turner et al. (1974) reported that subjects exhibited a slight increase in smoking rate and altered their inhalation pattern as evidenced by shorter cigarette butt lengths and changes in the calculated observed to expected filter nicotine ratios. Presumably, these changes reflected partial compensation for reduced cigarette smoke delivery, i.e., regulation of nicotine. Foxx and Brown (1979) reported that the subjects in the brand fading condition demonstrated the largest percentage reductions in rate and T/N intake over successive weeks of follow-up (6 months). Unfortunately, they did not report data for consumption patterns occurring during the reduction schedule; nor monitor changes in inhalation. Prue et al. (Note 3) did not observe any mean overall rate changes, but did find individuals who exhibited smoking rate increases. They did not directly monitor inhalation patterns, but reported that subjects decreased their "biochemical exposure" (alveolar carbon monoxide and saliva thiocyanate levels) when switching to very low T/N cigarettes. They suggested that the lack of regulation effects may have been due to the small discrete reductions in T/N delivery over an extended time period.
The effects of "ventilated holders" upon smoking behavior has been reported in two studies. Schindler, et. al. (Note 3) utilized holders which progressively increased filtration in four successive stages of 10 days each. They reported that the maximum stage reduced T/N values by 85%/65% respectively. They did not observe changes in rate, which suggested that there was no regulatory compensation. However, they did not monitor inhalation patterns. Sutton, et. al. (1978) required two groups of subjects to use one of two holders in a counterbalanced design. The holders were reported to reduce nicotine delivery values by 22.6% for holder 1 and 58.5% for holder 2. Compensation was not observed with respect to changes in rate. However, inhalation patterns differentially changed for each holder as determined by plasma nicotine and COHb levels with respect to the observed/expected ratios.

Inserting pinholes in the cigarette filter also has been described. Wynder and Hoffman (1979) reported that a hole-punching device produced reductions up to 90%/80% respectively for T/N values, and carbon monoxide reductions up to 95%, for machine-smoked cigarettes. They did not report any data for smokers, but commented that individuals could "compensate for the change in draw resistance by inhaling puffs of greater volume and velocity than those taken from an unperforated filter cigarette (p. 295)."

Hutchinson and Keenan (Note 1) examined the effects of progressively increasing the number of pinholes inserted in the cigarette filter upon smoking rate changes. In this study smokers increased
the number of pinholes at a rate of two per week up to 14 holes, at which time they switched to a "very low" T/N (2.0/0.2 mg) cigarette. This was followed by additional insertions of pinholes. During the first phase half of the subjects either increased or decreased their overall rate. Switching to the very low T/N cigarette immediately resulted in a substantial increase in smoking rate, with subsequent declines until smoking cessation or termination of the participant in the study occurred. Unfortunately, observations of inhalation patterns were not completed.

In these studies the time schedule for reduction of smoke dilution was associated with observed changes in smoking behavior. Compensatory changes were reported for more "abrupt" reduction schedules (Sutton, et. al., 1978; Turner, et. al., 1974), but not for those which utilized more "gradual" reductions (Foxx and Brown, 1979; Hutchinson and Keenan, Note 1; Prue, et. al., Note 3; Schindler, et. al., Note 4). However, the more gradual reduction schedule studies did not monitor inhalation patterns. Additionally, only one study (Sutton, et. al., 1978) reported observations regarding withdrawal symptoms. These symptoms, though, were based on subjective self-reports.

The "optimal" schedule for smoke dilution is not known with respect to minimizing regulatory smoking pattern changes and withdrawal symptoms. Objective measurement of inhalation changes and irritability reactions to dilution of cigarette smoke delivery values are needed. Current research has suggested specific procedures for objectively monitoring inhalation patterns (filter weight increment).
and emotional responses related to withdrawal symptoms (nonfunctional teeth clenching and grinding).

A recent study has indicated that the "filter weight increment" provides a valid measurement of inhalation patterns (Keenan, Hutchinson and Proni, Note 2). This measurement was the difference between the pre- and post- smoking weights of the cigarette filter. The obtained increase in filter weight following smoking corresponded to the total amount of smoke which was drawn through the filter, and provided an indirect estimate of "inhaled" smoke. These researchers determined the average percent reduction in machine-smoked filter weights which corresponded to specific increases in a smoke dilution schedule. Lower filter weight values were obtained as the dilution increased. The obtained or "expected" values of filter weights were compared with the "observed" filter weights of individual smokers. Discrepancies between the observed and expected filter weights were then attributed to the changes in the inhalation pattern of the smokers over the dilution schedule.

Specific procedures also have been described for objectively assessing negative affective states associated with "irritability" and "hostility". These emotional responses are frequently reported by individuals upon abstinence from smoking (Shiffman, 1979). Hutchinson, Pierce, Emley, Proni and Sauer (1977) have described a laboratory procedure for objectively measuring emotional behavior with respect to stressful environmental events. In this method, EMG activity of the masseter muscle is recorded with bio-potential electrodes. Non-functional teeth clenching and grinding (i.e., not
associated with mastication or talking), measured by EMG masseter activity, have been shown to occur in response to stress producing stimulus conditions. Increases in the frequency of masseter contractions have been related to both the presentation of aversive stimuli, such as loud noises; and the removal of positive stimuli, including money and cigarettes. These results suggest that non-functional jaw contractions are indicative of noxious environmental situations and reflect emotional states of irritability and hostility. Of particular interest was the observation that abrupt smoking cessation resulted in an increased frequency of jaw contractions as compared to prior smoking conditions. Subsequent decreases were recorded over successive weeks of abstinence or after resumption of smoking (Hutchinson and Emley, 1973; Hutchinson, et. al. 1977).

These data correspond to the numerous observations reported in dental literature describing bruxism which has been defined as non-functional teeth grinding and clenching. The specific etiology of bruxism has not been fully determined, but emotional factors such as fear, anxiety, frustration and anger are assumed to have a significant influence on its occurrence (Rugh and Solberg, 1976).

Portable EMG biofeedback units have been utilized to monitor both diurnal and nocturnal bruxing episodes. Increases in bruxism have been reported to occur concurrent with emotionally arousing situations and stressful life events, such as marital discord and loss of employment. Subsequent decreases have been recorded during vacation and holiday periods and while taking tranquilizing medication (Rugh, 1978; Solberg and Rugh, 1972). Furthermore, episodes
of nocturnal bruxism have been reported to occur following "moderate to heavy alcohol intake", defined as two or more cocktails in an evening (Hartmann, 1979). Preliminary observations suggest then that bruxism is associated with emotionally stressful environmental situations, and possibly to the intake of "mood-altering" psychoactive agents.

An alternative bruxism monitoring procedure has been described by Forgione (1974). This procedure utilizes a laminated plastic mouthguard device which is worn during sleeping. The mouthguard material is constructed of four colored layers of plastic with microscopic dots printed on the top surface. Bruxing by the individual wearing this mouthguard causes the destruction of the dots and underlying layers of plastic. A "bruxscore" is determined by examining the mouthguard for areas of missing dots and exposed layers of plastic. Forgione (1974) has reported a direct relationship between the duration of teeth grinding and the total score which is obtained. Additionally, the "bruxscore monitor" has been shown to be a reliable measure of nocturnal bruxing (Heller and Forgione, 1975). Since bruxing involves both teeth clenching and grinding episodes, a direct relationship between EMG and bruxscore monitoring procedures should exist. Furthermore, the bruxscore monitor should provide a reliable and objective assessment of nocturnal bruxing concurrent with stressful life situations.

The present study investigated the effects of three schedules of progressive cigarette smoke dilution upon smoking behavior and stress responses in chronic cigarette smokers. Changes in smoking
behavior were assessed by self-recorded reports of smoking rate and objectively measured filter weight increments. Both diurnal EMG masseter contractions and nocturnal bruxing (bruxscore monitor) were evaluated to determine negative emotional states (stress responses) associated with reductions in smoke delivery content.
CHAPTER II

METHOD

Subjects and Setting

Nine adult volunteers (5 females and 4 males) ranging in age from 27 to 41 years ($\bar{X} = 32$ years) participated in the study. All subjects were chronic cigarette smokers who reported smoking more than 10 cigarettes per day (range, 10–30 cigarettes) for at least one year prior to the study (range, 5–20 years). The cigarettes currently smoked by the subjects had an average FTC rating of $12/0.9$ mg T/N (tar/nicotine) respectively (range, $1.0/0.2$ mg to $19/1.3$ mg). (See Appendix A for a description of individual characteristics of subjects and applicants to the study).

Subjects were recruited from two local midwestern cities with populations under 250,000. Subjects responded to either a newspaper or radio announcement request for volunteers to participate in a research study investigating the effects of cigarette smoking on physiological responses. No subject was compensated for their involvement in the study. However, one of the subjects (S-9) was informed prior to the study that he would be able to participate in a "smoking cessation clinic" following the completion of the research. This service was announced to the other subjects after the study was completed. Subjects S-1, S-2, S-6 and S-9 chose to participate in the clinic. One subject (S-7) was unable to complete the study, due
to work re-location.

All procedures and possible risks and discomforts were reviewed individually with each subject. Each was informed that s/he was free to withdraw at any time, that her/his identity would remain anonymous, and that the results would be explained in detail following the study. All experimental procedures were reviewed and approved by relevant human research ethics committees.

Experimental sessions were conducted at a private research facility located midway between both communities. One building housed the waiting and testing areas and an adjacent control room station.

Apparatus and Materials

Recording sessions were conducted in an acoustically shielded, ventilated test chamber (Industrial Acoustics, Type VI50). Ambient temperature ranged from $20^\circ - 26^\circ$ C with a mean of $24^\circ$ C. Continuous white noise, 55db, was delivered during recording sessions through speakers mounted within the chamber. The subject sat in a padded highback chair facing a wooden table which was secured to the walls and floor of the chamber. Throughout each recording session continuous visual and auditory observations of the subject were maintained via a closed circuit T.V. and intercom system.

Mounted on the table was a plexiglass stand, measuring 16mm x 7mm x 8mm, which held an aluminum cigarette holder (7mm long, 10mm diameter) and rubber tubing (60mm long, 6mm inside and 10mm outside diameters) with a mouthpiece. (See Figure 1) A 5mm diameter tubing
Figure 1. Schematic drawing of the cigarette holder utilized during each recording session (Scale = 0.75).
was attached to the aluminum cigarette holder, midway between the cigarette and filter placements. This tubing was connected to a Stathem pressure transducer (model #P23) which permitted continuous recording of pressure changes concurrent with puffing while smoking. The cigarette holder was utilized for all cigarettes smoked during the recording sessions. Periodically, the holder and tubing were cleaned of residual particulate matter from the tobacco smoke.

All physiological responses (EMG of the masseter and forearm muscle and heart rate), pressure changes from puffing, and elapsed time for smoking were recorded on an Offner Type 146 polygraph. Special high gain differential preamplifier circuits provided electrical isolation of the subject. Polygraph speed was maintained at 5mm/sec. Calibration of the input signal was determined at the beginning and end of each session. All recording equipment, T. V. and polygraph, were located in an adjacent room to the testing area.

Cigarette filters were individually weighed on a Sartorius electronic balance scale. Filter weights were measured to one thousandth of a gram. The filters of each cigarette were precisely separated from the tobacco by cutting the cigarette with a razor knife.

Subjects were provided with a set of cigarette smoking recording cards and a bruxscore monitor (Forgione, 1974) at each session. Each smoking recording card corresponded to one day of the week and was divided into 24 hour time intervals by quarter hour divisions. Subjects were instructed to mark the appropriate time interval in which a cigarette was smoked. Cards (7.5mm by 5mm) could be con-
veniently carried in the celophane wrapper of the cigarette pack. In addition, each subject was requested to collect at least three cigarette butts from each pack smoked. At the onset of the study, each subject had an impression of the upper dentition completed. This impression provided the model for forming each bruxscore monitor (the material was obtained directly from Dr. Forgione, Tufts University, Boston, MA). Subjects were instructed to wear the monitor each night during sleep and to record the time it was worn. Subjects returned the completed recording cards, collected cigarette butts and worn monitors at each subsequent session. (See Appendix B for samples of all forms and recording cards).

**Procedure**

Throughout the study subjects were scheduled for weekly recording sessions at the same time and day. Exceptions occurred during the experimental conditions when sessions were scheduled more frequently. Upon arrival at the research facility, all subjects were greeted and escorted to a waiting area. Subjects presented the completed recording cards, collected cigarette butts, used monitor, and one unsmoked cigarette to the experimenter. Several single page forms which surveyed sleeping, eating and drug intake patterns for the past 24 hours, subjectively experienced physical and emotional symptoms occurring since the last session, and immediate affective state ("moods"), were then completed by the subject. These forms were used to monitor unusual changes in the subjects' general routine. None were recorded. Subjects were allowed to smoke while answering these
forms. Typically, five of the nine subjects did smoke. While sub-
jects were responding to the survey questions, the filter was cut off
the cigarette and weighed. Then the cigarette and filter were
secured in place in the holder and tubing. Each subject was provided
with an individual mouthpiece which was inserted into the subject's
end of the tubing.

Following the completion of the forms, body weight, hand tremor
and blood pressure were recorded before preparation with electrodes.
These data were not analyzed further. All skin areas for electrode
placement were gently scrubbed with a gauze pad moistened with iso-
propyl alcohol. Beckman 15mm diameter surface electrodes were utilized
for the bi-polar recording of the EMG masseter and right forearm
muscles, and heart rate responses. Reference electrodes were
attached to the nose and ears. In general, electrode preparation
procedures were similar to those described by Hutchinson, et. al.

Subjects were then escorted to the test chamber and seated
facing the table with the cigarette stand. Subjects were informed
that several minutes were required to adjust and calibrate the rec-
cording equipment before and after smoking. This allowed for a 5
minute observation interval pre- and post- smoking. All subjects
were requested to sit quietly and that they would be instructed via
the intercom when to begin smoking. Subjects were instructed how to
use the cigarette holder, to smoke as normally as possible, and to
remove the cigarette butt from the holder when finished smoking.
The five minute post-smoking interval began when the cigarette butt
was removed from the holder and extinguished in the ash tray. The recording session lasted between 15 and 20 minutes.

Upon completion of the session, subjects were escorted from the chamber to the preparation area. The electrodes were removed and blood pressure was measured. Subjects were provided with a new set of recording cards, a bag for saving cigarette butts, and a new bruxscore monitor with a card for recording the date and time worn. The fit of the monitor was checked and trimmed accordingly at each session. During the dilution conditions, subjects were also given a straight pin and instructed in the number of holes to be inserted in the filter. The next recording session was then scheduled. Overall, each session was approximately 45 minutes in duration. The filter of the cigarette smoked during the session was again weighed immediately after the subject departed.

Design

Baseline. During baseline and subsequent conditions subjects recorded their weekly cigarette smoking rate and collected the cigarette butts. Recording sessions were scheduled at the end of each weekly period. Beginning in the third week and until the end of the study, the bruxscore monitors were worn. No instructions regarding smoking were presented. This condition lasted 7-8 weeks.

Dilution. Subjects were assigned to one of three experimental conditions based on their time availability. An attempt to balance each condition with respect to baseline smoking rate was made. During the dilution phases, subjects were instructed to increase the
degree of smoke dilution by inserting pinholes in the cigarette filter. A 0.8mm diameter straight pin was utilized and was to be inserted approximately 5mm into the filter. A four step reduction in smoke delivery content of 5 pinholes per step was followed. All subjects were instructed to follow the same sequence of reductions, but each condition varied with respect to the time schedule for achieving maximum dilution (20 pinholes). In the first condition (Daily) subjects increased the number of pinholes in units of five on a daily basis. Full dilution was achieved within one week. Subjects in the second condition (Twice Weekly) increased the number of pinholes each 3-4 days, with maximum dilution occurring in a two week period. For the third condition (Weekly) subjects were instructed to increase the number of pinholes once each week and reached maximum dilution in four weeks. Recording sessions for each condition were scheduled at the end of each dilution phase, prior to the introduction of the next dilution step.

Post-dilution. Following the maximum dilution phase, all subjects were instructed to begin smoking their cigarettes without pinholes. Weekly recording sessions were again scheduled for each subject. No other instructions were provided. This condition lasted from 1 to 3 weeks.

Reversal. Three subjects (S-2, S-5, S-6) were exposed to the maximum dilution condition for one week following 1 to 2 weeks of post-dilution recordings. These subjects were requested to smoke cigarettes with 20 pinholes. No progressive reduction was utilized. This period was again followed by 1 to 2 weeks of further post-
dilution conditions.

Responses of Interest

Smoking rate. Each subject was instructed to record on the data cards every time a cigarette was smoked. One subject (S-6) would smoke ½ of a cigarette, extinguish it, and later re-light it to finish smoking. In this case each re-light was counted as a "new" cigarette. Total smoking rates were obtained by tallying the number of cigarettes marked for each week. When there were less than seven days between recording sessions, the total weekly smoking rate was extrapolated from the daily averages. This occurred during the experimental conditions for the "Daily" and "Twice Weekly" groups, and aperiodically if sessions had to be re-scheduled.

Filter weight increment. Each cigarette filter from the session was weighed pre- and post- smoking. The difference between the unsmoked and smoked weights was designated as the increment weight. Filters were again weighed following a minimum of 48 hours drying time to control for moisture retention. The filters from the cigarette butts saved by the subjects were also weighed. Since a pre-smoking weight was not obtained for these, the average weight of the unsmoked filters was utilized as the pre-smoked value. The expected filter weight values for the dilution condition were also calculated for each subject. The expected filter weight was based upon the percent reductions in weight obtained for the machine-smoked cigarettes. The expected filter weight was determined as a percent reduction of the average obtained baseline weight for each dilution.
step. (See Appendix C for the machine-smoked data for each subject).

**EMG masseter contractions.** A procedure similar to that employed by Hutchinson, et al. (1977) was followed for the scoring of the jaw contraction responses. EMG tracings which exceeded a 50 mv p/p criterion for 0.2 second duration following a slow wave period of 0.5 seconds were scored as masseter contraction responses. Visual observation of the subject, via the closed circuit T.V., permitted detection of functional activity such as swallowing, coughing and facial movements. These responses were excluded from the scoring analysis. Masseter contractions were monitored for a 5 minute period preceding and following smoking of the cigarette.

**Bruxscore.** Each bruxscrore monitor was scored analogous to the procedures outlined by Forgione (1974). A Gaertner single lens microscope was utilized to detect the number of dots ground away. Three subjects stated that they disliked wearing the monitor. However, only one subject (S-9) failed to wear it less than four nights per week. A weekly total score was extrapolated based upon the daily average whenever a subject wore the mouthguard less than seven nights. This allowed appropriate comparisons between subjects to be completed. (See Appendix D for bruxscores of three non-smokers).

**Reliability**

An "Independent Observer" was designated by each subject at the onset of the study. This individual was someone who had frequent contacts (more than three times per week) with the subject and was willing to make periodic observations of the subject's smoking.
behavior. Each observer was requested to periodically monitor the subject for the brand smoked, the use of pinholes in the filter during the dilution phases, the number of cigarettes smoked, and for accurate recording of each cigarette smoked. These observations occurred on an average of once every two weeks.

Reliability checks were also completed for a random sample of the bruxscore monitors by an independent recorder. This sample included approximately 15% of the used monitors, but was 25% of those monitors exhibiting wear in excess of 100 points.
CHAPTER III

RESULTS

All figures present the data obtained for each individual subject. Each figure is arranged such that the "row" corresponds to the high, medium or low smoking rate recorded in baseline condition. Each "column" corresponds to the scheduled rate of reduction in smoke delivery to which the subject was exposed, "Daily", "Twice Weekly" or "Weekly".

Filter Weight Increment and Smoking Rate

The obtained values for the filter weight increment immediately after smoking and following drying directly corresponded. The dried filter averaged 48% of the immediate post-smoked weight (range 36% to 65%). The dried filter weight was subsequently utilized in all further analysis.

The relationship between the weight of filters smoked during the recording session and those collected each week by the subject was not consistent. The obtained values of the subject-collected filters varied from 40% to 230% of the session filter weights. For this reason the data for these filters were not analyzed with respect to the other variables. The lack of consistency may have been due to a measurement error. It was observed that the unsmoked filter weights varied by more than 20 mg. This variability frequently exceeded the obtained session smoked filter weight increment. Thus, the average
pre-smoked filter weight may have been an inappropriate value to have utilized. A second factor may also have been operating. The recording session was a controlled environment for smoking. In contrast, the collected butts were from cigarettes smoked in uncontrolled situations. The inhalation pattern would be expected to vary during the week, thus the sample size may have been too small to control for this variability.

Figure 2 displays the total smoking rate and the filter weight increments for each week during baseline. Although there was initial variability in both measures, stability was evident during the last four weeks prior to the dilution phases. For six of the nine subjects less than a 15% change from the four week average was observed. Trends were noted for individual subjects, but infrequent disruptions were recorded. An examination of the data revealed an inverse relationship between the weekly smoking rate and the obtained filter weight of the session smoked cigarette for six subjects (S-1, S-2, S-3, S-4, S-7, S-9). For these subjects when their smoking rate increased, the filter weight decreased; and when the rate decreased the weights increased.

The effects of the progressive smoke dilution phases upon smoking patterns are presented in Figure 3. Weekly smoking rates for each specific phase of dilution were extrapolated from the daily averages for subjects in the "Daily" and "Twice Weekly" schedules. Six of the subjects exhibited a decreasing trend in the rate of smoking over
Figure 2. Display of the Baseline weekly smoking rates and the dried weights of the filters smoked during the recording sessions.
Figure 3. Recorded changes in each subjects' smoking rate and filter weight are presented for successive phases of the smoke dilution condition, and for the average post-dilution values. The solid line represents the average baseline smoking rate; the dashed line the average baseline filter weight increment.
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successive phases of smoke dilution. Two subjects (S-1 and S-9) recorded higher than baseline averages, while S-6 evidenced an increasing trend toward the initial smoking rate. The obtained filter weight increments were less than baseline averages for most subjects. One subject (S-4) though, did record an elevated filter weight at the maximum dilution. Three subjects (S-2, S-5 and S-6) were re-exposed to the maximum dilution condition. Both filter weight and smoking rate for these subjects approached baseline averages. For these subjects the obtained filter weight was more than twice the value recorded during the first presentation of the maximum dilution. Finally, for all subjects the obtained values for smoking rate and filter weight during the post-dilution weeks again approached baseline averages.

A comparison of the obtained and expected filter weight is displayed in Figure 4. The expected weight was calculated from standardized machine-smoked cigarettes as a function of obtained reductions from baseline averages. Three subjects (S-1, S-4 and S-9) exhibited filter weights in excess of the expected value, whereas, S-2 consistently obtained lower than expected filter weights. The remaining five subjects did not demonstrate consistent differences from expected values across the dilution schedule.

Regulation of the Smoking Dose

Since regulation can involve both changes in smoking rate and inhalation patterns (as measured by the filter weight increment), the "smoking dose" appeared to be an appropriate summary of these changes.
Figure 4. The "observed" and "expected" filter weight increments are presented for each successive phase of the smoke dilution schedule and for the post-dilution averages. The dashed line represents the baseline averages for the filter weight increments.
The dose was calculated as a multiple of the smoking rate and the filter weight increment.

Figure 5 presents the calculated dose for successive weeks of the baseline condition. Several subjects (S-3, S-6 and S-10) exhibited increasing or decreasing trends. However, major disruptions were infrequently observed. Again, the majority of subjects (six out of nine) demonstrated stability (±15% of the average) during the four week period immediately prior to the dilution condition.

A comparison of the calculated and expected dose for each subject over smoke dilution phases is displayed in Figure 6. The baseline represents the average values obtained during the last four weeks prior to the dilution. The expected dose was estimated as a multiple of the mean smoking rate in baseline and the expected filter weight. This calculation controlled for changes that could occur in both rate and inhalation patterns. During the dilution schedule, three subjects (S-1, S-4 and S-9) clearly evidenced a dose exceeding the expected values. For these three subjects, the actual dose was less than 20% of the baseline average as compared to an expected reduction of 50-60%. Only S-2 consistently demonstrated an actual dose less than expected values for all dilution points. The remaining subjects' actual dose reduction corresponded to the expected reductions. Following the reversal to baseline conditions, the average dose again returned to levels corresponding to the pre-dilution values.
Figure 5. The baseline smoking dose for each subject is displayed. The smoking dose was calculated as the total weekly smoking rate times the filter weight increment obtained for each session smoked cigarette.
Figure 6. A comparison of the observed and expected dose for each successive condition. Baseline (B) and post-dilution (P-D) conditions are both averages for the smoking rate and filter weight which were obtained over several weeks.
**Stress Responses**

Figure 7 depicts the total number of EMG masseter contractions recorded during each dilution phase and the average number of responses per session for baseline conditions. A consistent pattern emerged. Subjects (S-1, S-5 and S-6) in the daily dilution condition consistently exhibited a greater number of masseter contractions during successive dilution phases than during the baseline condition. Reductions in the frequency of jaw contractions were recorded in the post-dilution sessions. On the average, subjects in the other two schedules of reduction (Twice Weekly and Weekly) did not exhibit this pattern. Four of these subjects though, did demonstrate a decreasing trend in the frequency of EMG contractions over successive conditions.

The effects of the dilution schedule on nocturnal bruxing are displayed in Figure 8. Subjects in the "Weekly" condition exhibited more overall bruxing than all other subjects. The bruxscore data do suggest two contrasting trends. Subjects in the "Daily" dilution schedule tended to show a pattern of increased bruxing or no change during dilution, followed by a subsequent reduction in the post-dilution phase. Subjects in the other two conditions (Twice Weekly and Weekly) exhibited a pattern of decreasing bruxing during dilution phase with a subsequent increase in post-dilution condition. For three subjects (S-3, S-4, S-10) there appeared to be a direct relationship between bruxscore and dose. S-6 and S-9 are the exceptions with S-6 demonstrating increasing trend over all conditions and S-9 a decreasing trend.
Figure 7. The total EMG masseter contractions per session are depicted for each successive condition. The baseline and post-dilution conditions were averaged across 1-4 sessions.
Figure 8. The bruxscores for each subject are displayed across successive conditions. For subjects in the Daily and Twice Weekly schedule data were not available for all phases of dilution.
Reliability

The reliability observations completed by the Independent Observers for the subject's smoking behavior did not correspond to outlined procedures. Thus, specific reliability figures could not be determined. In general, reliability checks did indicate that there were no discrepancies between subject and observer reports, suggesting that the subject reports were accurate.

Reliability was calculated for a random sample of bruxscore monitors. Total reliability (smallest score divided by largest score) ranged from 94% to 99% with an average of 97%.
CHAPTER IV

DISCUSSION

The baseline data supported a smoking regulation model. Stable regulation of the smoke dose delivery was evident for the majority of subjects during the extended baseline observations. Additionally, the observation of an inverse relationship between smoking rate and filter weight increment provided further support that regulation was a function of changes in both rate and inhalation patterns. Thus, when smoking rate increased the filter weight decreased and subsequent decreases in rate corresponded to increases in the filter weight.

The accuracy of the self-reported data was reasonably certain. Although the reliability checks were imprecise, no discrepancies were reported between the observer and subject reports. At the onset of the study each subject was cautioned to report honestly all information and any deviations from instructions. Subsequently, several subjects did report their difficulties in complying with the instructions for the dilution schedule. Additionally, data cards were designed for optimal ease in recording. All subjects were observed to keep the cards either along with the cigarette pack or in a purse. Throughout the study only one set of recording cards was lost. No subjects failed to record their smoking rate.

The observed changes in dose delivery recorded during the dilution schedule corresponded to observations by other researchers (Schacter, 1977, 1979). These studies reported that "heavy" smokers
will tend to compensate for reduced smoke delivery values more than "light" smokers. In the present study, subjects who generally exhibited the higher baseline smoking dose values maintained the highest dose intake during the dilution conditions. These three subjects (S-1, S-4, S-9) demonstrated either no change, or less than a 20% average decrease across all dilution conditions. Additionally, the actual dose obtained for these subjects exceeded the calculated expected values in all instances. In contrast the "moderate" and "light" smoking dose subjects showed an average decrease of 50% from baseline values (which ranged from 30% to 65%). Their dose pattern throughout dilution conditions tended to be less than the expected values.

The failure of all subjects to demonstrate a regulation effect during dilution is not entirely consistent with a titration hypothesis, but has been observed by other researchers (Foxx and Brown, 1979; Sutton et. al., 1978; Hutchinson and Keenan, Note 1; Prue et. al., Note 3; and Schindler, et. al., Note 4). The simultaneous monitoring of both rate and inhalation changes allowed for an accurate determination of compensatory regulation. Thus, the dilution schedule appeared to have an initial inhibitory effect upon smoking behavior, corresponding to the recorded reductions in both smoking rate and filter weight for six of the nine subjects. This inhibitory effect has also been reported by Sutton, et. al. (1978). They observed that plasma nicotine and COHb levels while using a 23% dilution cigarette holder were lower at 2 days than at 7 days. Since these researchers did not observe changes in smoking rate, they at-
tributed the inhibitory effect to a reduction in inhalation. In the present study there appeared to be a more complex interaction of changes in rate and inhalation patterns which would account for the inhibitory effect. Examination of Figure 4 suggests that a consistent reduction in inhalation occurred only for one subject (S-2). For the other subjects the actual filter weights were comparable to or higher than the expected values, suggesting that these subjects maintained consistent or increased inhalation patterns. Interestingly, three subjects (S-2, S-5, S-6) who were exposed to the maximum dilution condition a second time, exhibited filter weights more than twice the obtained value of the first exposure, suggesting that this initial inhibitory effect may be a transitory factor in a dilution schedule. Thus, the Sutton et. al. (1978) comment that "adjustment in smoking pattern that occurs in response to smoke dilution is made immediately and does not change in the short term (p. 402)...", may not be correct for all smokers.

Finally, the relative greater importance of inhalation as compared to rate in regulating smoking dose was confirmed for the three subjects when the actual filter weight increment exceeded the expected values. This change in inhalation patterns concurrent with reduced T/N smoke delivery also has been reported by Ashton, Watson, Marsh, R. and Sadlers, J., (1970) and Frith (1971). Additionally, Russell (1979) has stated that plasma nicotine levels are more closely associated with inhalation patterns than with rate changes. The need to monitor multiple parameters of smoking behavior in order to ascertain regulatory effects is evident.
Overall, the range of regulation observed for the subjects in this study directly corresponds to other research reports (Friedman and Fletcher, 1976; Forbes, Robineson, Hanley and Colburn, 1976; Russell, Wilson, Patel, Feyerabend and Cole, 1975; Schacter, 1979; Sutton et. al., 1978). Sutton et. al., (1978) has suggested that the failure to observe compensatory responses for all smokers is not necessarily inconsistent with the nicotine regulation aspects of smoking. Rather, this indicates that compensatory regulation may occur when there is a percentage decrease in nicotine plasma levels, but is not associated with decreases below an absolute minimum plasma level or a given delivery amount.

With respect to the effects of the three smoke dilution schedules upon stress responses the daily reduction produced the greatest increases in masseter contractions, reflecting the occurrence of withdrawal symptoms associated with a rapid reduction in smoke delivery values. This finding is in accordance with other studies assessing the abrupt withdrawal of nicotine delivery (Hutchinson and Emley, 1973; Shiffman, 1979). The overall decreasing trend in recorded masseter contractions for most other subjects may have been due to the gradual adaptation to reduced smoke delivery values. Hutchinson and Emley (1973) recorded a similar effect, in that EMG masseter contractions decreased over successive weeks of smoking abstinence. This is in general agreement with the studies reported by Shiffman (1979), in which the frequency and severity of self-reported withdrawal symptoms decreased over successive days of abstinence.

A comparison of Figures 6 and 7 provides for a descriptive
analysis of the recorded changes in masseter responses. Jaw contrac-
tions tended to be inversely related to the calculated dose for each
subject. Thus, during the dilution schedule masseter contractions
increased when the overall dose decreased. This accounts for the un-
expected decreases in masseter contractions at various phases of
the dilution steps. The subjects were maintaining and in some in-
stances increasing the smoking dose.

The obtained results for nocturnal bruxing are unclear. The
results obtained for the subjects exposed to the daily changes in
smoke dilution correspond to the recorded increase in EMG contrac-
tions. For these subjects overall increases in bruxing tended to be
associated with a decrease in smoking dose. However, this trend was
not observed for the other subjects. For these subjects there
appeared to be a direct correspondence between bruxing and smoking
dose. Perhaps these subjects maintained greater regulation and were
less affected by the dilution schedule. Three of these subjects did
exhibit a 30% or less decrease in smoking dose during dilution
(S-4, 20%; S-9, no change; S-10, 30%).

In conclusion the overall results of this study support the
"titration hypothesis" regarding regulation of nicotine intake. The
observation of compensatory changes in smoking behavior for several
subjects, but not all, corresponds to other research reports. The
calculated "smoking dose" values provided an appropriate summary of
changes in smoking behavior concurrent with a smoke dilution schedule.
Furthermore, the comparison of actual and expected filter weight
increments validly indicated changes in inhalation patterns exhibited

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by the subjects. These results also lend further support to the
sensitivity of EMG masseter contractions as an objective measure of
withdrawal symptoms. Further research is needed to clarify the
relationship between nocturnal bruxing and smoke withdrawal reactions.
REFERENCE NOTES


APPENDIX A

Descriptive characteristics of individuals selected/not selected for participation in the study. The following table presents individual and average data for each applicant.
<table>
<thead>
<tr>
<th>Selection criterion</th>
<th>Sex</th>
<th>Age</th>
<th>T/N mg.</th>
<th>Rate</th>
<th>Smoked</th>
<th>Occupation</th>
</tr>
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<tbody>
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<td>1</td>
<td>M</td>
<td>36</td>
<td>17.0/1.0</td>
<td>30</td>
<td>18</td>
<td>Business Exec.</td>
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<tr>
<td>2</td>
<td>F</td>
<td>34</td>
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<td>40</td>
<td>14</td>
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</tr>
<tr>
<td>3</td>
<td>F</td>
<td>27</td>
<td>11.0/0.8</td>
<td>30</td>
<td>7</td>
<td>Housewife</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>27</td>
<td>17.0/1.0</td>
<td>30</td>
<td>11</td>
<td>Computer Tech.</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>31</td>
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<td>30</td>
<td>12</td>
<td>Social Worker</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>32</td>
<td>17.0/1.3</td>
<td>20</td>
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</tr>
<tr>
<td>7</td>
<td>M</td>
<td>31</td>
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<td>15</td>
<td>Para-medic</td>
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<td>10</td>
<td>F</td>
<td>41</td>
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<td>30</td>
<td>14</td>
<td></td>
</tr>
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</table>

**Applicants not selected:**

Age 45

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<th>Rate</th>
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<td>16.0/1.1</td>
<td>30</td>
<td>Factory worker</td>
</tr>
<tr>
<td>F</td>
<td>52</td>
<td>5.0/0.4</td>
<td>40</td>
<td>Housewife</td>
</tr>
<tr>
<td>F</td>
<td>53</td>
<td>3.0/0.4</td>
<td>40</td>
<td>Nurse Sup.</td>
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<tr>
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<td>19.0/1.3</td>
<td>60</td>
<td>Retired</td>
</tr>
<tr>
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<td>13.0/1.0</td>
<td>40</td>
<td>Serv. Man.</td>
</tr>
<tr>
<td>F</td>
<td>63</td>
<td>1.0/0.2</td>
<td>30</td>
<td>Housewife</td>
</tr>
<tr>
<td>M</td>
<td>68</td>
<td>17.0/1.0</td>
<td>20</td>
<td>Retired</td>
</tr>
<tr>
<td>M</td>
<td>70</td>
<td>8.0/0.6</td>
<td>20</td>
<td>Retired</td>
</tr>
</tbody>
</table>

**N/A**

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<th>T/N mg.</th>
<th>Rate</th>
<th>Occupation</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
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<td>19.0/1.3</td>
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</tr>
<tr>
<td>F</td>
<td>42</td>
<td>16.0/1.0</td>
<td>20</td>
<td>Med. Tech.</td>
</tr>
<tr>
<td>M</td>
<td>37</td>
<td></td>
<td></td>
<td>Grad. student</td>
</tr>
</tbody>
</table>

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APPENDIX B

Examples of all forms and instructions presented to the subjects and the smoking and bruxscore monitor recording cards.
Research Application Form

Briefly explain why you are interested in the study and what you think the study will be about.

The Foundation is a nonprofit organization and will not be able to compensate you for your time involved in the study. Are you willing to volunteer your time, 5-10 hours, for the duration of the study, which will be 5-10 weeks?

All information which is obtained will be kept in strict confidence. Only the results of the study will be used and each participants' anonymity will be maintained. The results of the study will be explained in full to each participant at the completion of the study.
## Personal Data Sheet

| Name ____________________________________________ | Sex __________________________ |
| Address __________________________________________ | Birth Date ____________________ |
| Marital Status __________________________ | Dependents ____________________ |

**Home Phone** __________________________

**Occupation** __________________________

**Employer** __________________________

**Address** __________________________

**Family Physician** __________________________

**Family Dentist** __________________________

May we contact them regarding your present health? __________

Insurance Company __________________________

Policy # __________________________

### Medical/General Information:

1. Do you consider yourself to be in good health at the present time?  
   - yes____ no____

2. Have you ever been refused employment, insurance, or rejected from the armed forces because of your health? yes____ no____

3. Do you now have or have you ever had any of the following illnesses?

<table>
<thead>
<tr>
<th>Illness</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
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<td>asthma</td>
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<td></td>
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<tr>
<td>bronchitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>hay fever</td>
<td></td>
<td></td>
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<tr>
<td>rheumatic fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>epilepsy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>tuberculosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>diabetes</td>
<td></td>
<td></td>
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<tr>
<td>increased blood pressure</td>
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<tr>
<td>stomach trouble</td>
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<td></td>
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<td>serious infections</td>
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<td></td>
</tr>
<tr>
<td>tooth ache</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bleeding gums</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bladder or kidney trouble</td>
<td></td>
<td></td>
</tr>
<tr>
<td>nervous or mental disorder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>infectious mononucleosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>heart trouble</td>
<td></td>
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</tr>
</tbody>
</table>
4. Do you have any allergies to drugs, foods, animals, plants, insects, dust, etc? yes____ no____ If yes, please explain _____________________________________________________________________

5. Have you ever been treated for excessive or chronic drug or alcohol use? yes____ no____

6. Do you suffer from headaches? yes____ no____
   If so, how frequently? daily____ weekly____ monthly____

7. Are you currently experiencing any other chronic physical pain? yes____ no____
   Describe _________________________________________________________________________________

8. Are you a tooth grinder? yes____ no____

9. Are you presently under the care of a physician, psychiatrist, therapist, or dentist? yes____ no____
   Describe _________________________________________________________________________________

10. Are you presently taking any prescription medication for any reason (including insulin, diet pills, tranquilizers, birth control pills, pain control)?
    yes____ no____ Type (drug name) __________________________________________________________

11. Are you on any special diet? yes____ no____
    Describe ________________________________________________________________________________

12. Has anyone in your family had any of the following illnesses? (grandparents, parents, brothers, sisters, children)
    
    | Illness                | Yes | No | Relationship |
    |------------------------|-----|----|--------------|
    | asthma                 |     |    |              |
    | hay fever              |     |    |              |
    | epilepsy               |     |    |              |
    | nervous or mental disorder | |    |              |
    | cancer                 |     |    |              |
    | heart disease          |     |    |              |
    | severe headaches       |     |    |              |
    | high blood pressure    |     |    |              |

13. Date of your last physical exam?__________________________________________________________

14. Date of your last dental check up?________________________________________________________

15. Are you right____ or left____ handed?

16. Do you wear any of the following:
    False teeth or bridge yes____ no____
    Hearing aid
    Glasses
    Braces for teeth
Research Application Forms (Continued)

17. How many hours do you sleep per night? ________ hrs/night
   Do you take naps? yes no
   Do you have trouble falling asleep? yes no
   Do you awake at night and cannot go back to sleep? yes no

18. How many hours do you exercise per day _______ or week _________?
   Describe how you exercise

19. Is your diet well balanced? yes no
   Please indicate your consumption of the following:
   - salt: light moderate heavy
   - sugar: light moderate heavy
   - coffee cups/day decaffeinated? yes no
   - tea cups/day soft drinks (coke/pepsi) /day
   - milk glasses/day water glasses/day
   - candy amount/day

20. Do you use tobacco? If yes, please indicate:
   - cigarettes packs/day pipe bowls/day cigar /day
   - chewing oz/day snuff oz/day

21. Do you use alcohol? never seldom frequently
   If yes, please indicate the type: (beer, wine, cocktails):

22. Do you use non-prescription medications? yes no
   If yes, please indicate:
   - vitamins never monthly weekly daily
   - aspirin
   - laxatives
   - pep pills
   - sleeping pills
   - diet pills
   (other)

23. Recreational Activities:
   Do you actively participate in sports? yes no
   Do you have any hobbies? yes no
   If so, what?

How many hours do you spend each week:
   - watching T.V. _______ reading _______ music

How often do you take a vacation?
   What do you do on vacation?

_____________________________ Signature  ______________________ Date

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Research Application Forms (Continued)

E: SPECIFIC QUESTIONNAIRE

Name

1. How many cigarettes do you smoke per day? __________________

2. What brand of cigarette do you smoke?
   A. Regular, King, or 100's __________________
   B. Filter tip or Plain? __________________
   C. Regular or Menthol? __________________

3. Please mark how far from the lighted end you usually smoke your cigarette.

   ________________  ________________  ________________

4. When do you typically smoke during the course of an average day? For
   example: after meals, in the evening, just at work (9-5), constantly
   all day, a couple in the morning and the rest at night, etc.

   ________________  ________________  ________________

5. How many years have you smoked? __________________

6. When you smoke, how deeply do you usually draw in the smoke?
   A. As deeply into the chest as possible. ______________
   B. Partly into the chest. __________________
   C. As far back as the throat. ______________
   D. 'Well back into the mouth. ______________
   E. Don't know depth. __________________
   F. Just puff - don't really draw at all. ______________

7. Do you usually:
   A. Inhale every puff of each cigarette? ______________
   B. A few puffs of each cigarette? ______________
   C. A few puffs of some cigarettes? ______________
   D. Don't know frequency. ______________
   E. Do not inhale. ______________
Subject Instructions; Statement of Risks

Instructions to Subjects:

The purpose of this study is to determine if your cigarette smoking patterns are related to any specific physiological and psychological responses. Your participation in the study will be required for at least ten one-hour sessions during the next six to ten weeks. Depending upon your availability, these sessions will be scheduled weekly, twice weekly, or daily. You are free to withdraw from this study at any time. Furthermore, your identity will remain anonymous, and every precaution will be taken to ensure the confidentiality of all information which is obtained. The results of the study will be explained to you in detail upon its completion.

At each session you will be prepped with surface electrodes for recording physiological responses. These will be attached to your arms and face. (Display the electrodes to the subject; explain the preparation method; and point out where the electrodes will be placed.) Additionally, your weight, muscle tremor, and blood pressure will be recorded. Following this, you will be seated in a ventilated chamber for approximately 45 minutes (show the testing chamber to the subject). During each recording session you will be required to smoke at least one of your cigarettes, utilizing this specially designed cigarette holder. (Display the holder to the subject and explain how it is to be used.) You may experience a minimum of skin irritation from the electrode placement and some discomfort from sitting for the recordings.

During the study you will be requested to wear a specially designed mouthguard. This will be made from your dental impression which will be completed by a consulting dentist. (Exhibit and demonstrate the wearing of the mouthguard.) You may be temporarily inconvenienced in wearing the mouthguard, but should not experience any discomfort in their use. New mouthguards will be provided to you as needed.

You are requested to maintain an accurate record of your cigarette smoking throughout the study. Data recording cards will be provided to you at each session. (Display recording cards and explain their use.) Additionally it will be necessary for you to specify two individuals who have contact with you each week at times when you are likely to smoke. These individuals must be willing to complete brief, independent observations of your cigarette smoking. Periodically, during the study these individuals will be contacted to provide specific information about your smoking patterns. You will be informed of all observation dates and times that were completed at the end of the study.
Finally, during the study you will be given instructions regarding your cigarette smoking. In complying with these instructions you may perceive some dissatisfaction in smoking your cigarettes. It is very important that you always provide honest information about your smoking patterns, data recording, and ability to comply with instructions. The results of the study will be valid only to the extent that you relate honest and accurate information.

Do you have any questions?
Subject Consent Form

Consent To Experimental Procedure

I, ____________________________ hereby consent to serve as a volunteer experimental subject for the Foundation for Behavioral Research. I have been informed of the experimental procedure. I understand that I may withdraw at anytime from participation in this research.

Signed ____________________________

Witness ____________________________

Date ____________________________
Recording Session Survey Form

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>How many hours did you sleep last night?</td>
<td>hrs.</td>
</tr>
<tr>
<td>2.</td>
<td>When did you get up this morning?</td>
<td>AM</td>
</tr>
<tr>
<td>3.</td>
<td>Did you sleep well last night?</td>
<td>YES</td>
</tr>
<tr>
<td>4.</td>
<td>Did you drink alcohol (beer, wine, etc.) last night?</td>
<td>YES</td>
</tr>
<tr>
<td>5.</td>
<td>Did you smoke tobacco last night?</td>
<td>YES</td>
</tr>
<tr>
<td>6.</td>
<td>Did you smoke grass last night?</td>
<td>YES</td>
</tr>
<tr>
<td>7.</td>
<td>Did you have any trouble getting to sleep last night?</td>
<td>YES</td>
</tr>
<tr>
<td>8.</td>
<td>Did you have intercourse last night?</td>
<td>YES</td>
</tr>
<tr>
<td>9.</td>
<td>Did you have breakfast today?</td>
<td>YES</td>
</tr>
<tr>
<td>10.</td>
<td>Did you drink tea today?</td>
<td>YES</td>
</tr>
<tr>
<td>11.</td>
<td>Did you drink coffee today?</td>
<td>YES</td>
</tr>
<tr>
<td>12.</td>
<td>Did you smoke tobacco today?</td>
<td>YES</td>
</tr>
<tr>
<td>13.</td>
<td>Did you smoke grass today?</td>
<td>YES</td>
</tr>
<tr>
<td>14.</td>
<td>Did you eat lunch today?</td>
<td>YES</td>
</tr>
<tr>
<td>15.</td>
<td>Do you feel awake now?</td>
<td>YES</td>
</tr>
<tr>
<td>16.</td>
<td>Do you feel nervous now?</td>
<td>YES</td>
</tr>
<tr>
<td>17.</td>
<td>Have you taken any drugs during the last 24 hours?</td>
<td>YES</td>
</tr>
<tr>
<td>18.</td>
<td>If the answer to the last question was yes please explain what drugs were involved and what the doses were.</td>
<td></td>
</tr>
</tbody>
</table>
During the past ______ have you ever noticed any changes in:

<table>
<thead>
<tr>
<th></th>
<th>INCREASE</th>
<th>DECREASE</th>
<th>NO CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. alertness and energy?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. anger and irritation with others?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. appetite and eating?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. consumption of alcohol?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. consumption of chewing gum or candy?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. consumption of coffee, tea, or cocoa?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. disagreements and disappointments in friends or associates?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. diarrhea or constipation?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. enthusiasm and cheerfulness?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. fatigue?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. frequency of headaches?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. heart palpitations?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. nervousness?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. perspiration of body, hands, etc.?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. pleasant personal encounters?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. pressure or problems in family or work?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. resourcefulness and productivity?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. restlessness and insomnia?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. severity of headaches?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. sexual feelings?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. stomach irritability (nervous stomach)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. use of tranquilizers?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Any other changes in you or your world?
Recording Session Survey Form

MCGILL MOOD SCALE QUESTIONNAIRE

Each of the following adjectives in the list describes feelings of mood. Please read the following instructions and then use the word list to describe your feelings at the moment you read each word.

If the word definitely describes how you feel at the moment you read it, circle the double \( \checkmark \) to the right of the word. For example, if the word is relaxed, and you definitely are feeling relaxed at the moment, circle the \( \checkmark \) as follows:

- relaxed \( \checkmark \) v ? no

If the word only slightly applies to your feelings at the moment, circle the single v as follows:

- relaxed \( \checkmark \) v ? no

If the word is not clear to you, or you cannot decide whether or not it applies to your feelings at the moment, circle the ? as follows:

- relaxed \( \checkmark \) v ? no

If you definitely decide the word does not apply to your feelings at that moment, circle the no as follows:

- relaxed \( \checkmark \) v ? no

Work rapidly, your first reaction is best. Work down the first column, then go on to the next. Please mark all words. This should take only a few minutes. Please begin.

<table>
<thead>
<tr>
<th>Affectionate</th>
<th>( \checkmark ) v ? no</th>
<th>Fearful</th>
<th>( \checkmark ) v ? no</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angry</td>
<td>( \checkmark ) v ? no</td>
<td>Engaged in thought</td>
<td>( \checkmark ) v ? no</td>
</tr>
<tr>
<td>Beastful</td>
<td>( \checkmark ) v ? no</td>
<td>Sluggish</td>
<td>( \checkmark ) v ? no</td>
</tr>
<tr>
<td>Carefree</td>
<td>( \checkmark ) v ? no</td>
<td>Sad</td>
<td>( \checkmark ) v ? no</td>
</tr>
<tr>
<td>Clutched up</td>
<td>( \checkmark ) v ? no</td>
<td>Warm-hearted</td>
<td>( \checkmark ) v ? no</td>
</tr>
<tr>
<td>Concentrating</td>
<td>( \checkmark ) v ? no</td>
<td>Rebellious</td>
<td>( \checkmark ) v ? no</td>
</tr>
<tr>
<td>Drowsy</td>
<td>( \checkmark ) v ? no</td>
<td>Self-centered</td>
<td>( \checkmark ) v ? no</td>
</tr>
<tr>
<td>Regretful</td>
<td>( \checkmark ) v ? no</td>
<td>Witty</td>
<td>( \checkmark ) v ? no</td>
</tr>
<tr>
<td>Kindly</td>
<td>( \checkmark ) v ? no</td>
<td>Jittery</td>
<td>( \checkmark ) v ? no</td>
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<tr>
<td>Defiant</td>
<td>( \checkmark ) v ? no</td>
<td>Serious</td>
<td>( \checkmark ) v ? no</td>
</tr>
<tr>
<td>Ecstatic</td>
<td>( \checkmark ) v ? no</td>
<td>Tired</td>
<td>( \checkmark ) v ? no</td>
</tr>
<tr>
<td>Playful</td>
<td>( \checkmark ) v ? no</td>
<td>Sorry</td>
<td>( \checkmark ) v ? no</td>
</tr>
</tbody>
</table>

Subject Name ___________________________ Number 1 2

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Subject Consent Form

Release From Experimental Procedure

I, __________________________ have served as a volunteer experimental subject for the Foundation for Behavioral Research.

I felt _____, did not feel _____, unpleasant side effects. If so they were __________________________

______________________________

______________________________

______________________________

Signed _________________________

Witness ________________________

Date ___________________________
## Smoking and Bruxscore Recording Forms

<table>
<thead>
<tr>
<th></th>
<th>2:00</th>
<th>3:00</th>
<th>4:00</th>
<th>5:00</th>
<th>6:00</th>
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<tr>
<td>SUN</td>
<td></td>
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<td>7:00</td>
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<td></td>
<td>NOON</td>
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<td>1:00</td>
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<tr>
<td>7:00</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>DATE</th>
<th>DAY</th>
<th>TIME IN</th>
<th>TIME OUT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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Independent Observer's Questions

Independent Observations of Smoking Behavior

__________________________
Client

Observer: __________________________
Relationship __________________________
Observation Date __________________________
Observation Time: ______________ to ____________ Total Time: ____________

Information:
1) Did the individual smoke during the observation time? yes____ no____
2) If so, what did the individual smoke?
   # of cigarettes____   # cigars____   pipe____   other____
3) For cigarette smoking only:
   brand smoked_________________________ # of pin holes________
4) Did the individual record the smoke on data cards? yes____ no____
5) In the past week have you observed the individual:
   a) Smoke different brands of cigarettes? ____ yes ____ no
      If so, what brand? ____________________________________________
   b) Smoke cigarettes without pin holes in them? ____ yes ____ no
      If so, about how many? __________________________
   c) Smoke cigarettes but not record in the data cards? ____ yes ____ no
      If so, how often? __________________________
Subject De-briefing Questions

DE-BRIEFING QUESTIONS FOR SUBJECT:

1. What was the purpose of this study?

2. What responses were being recorded by the electrodes?
   - From the arms:
   - From the face:
   - From the chest strap:
   Did you try to "act" or behave in a particular way during the session?

3. What responses were of importance on the forms you completed at each session?

4. What was the purpose of having you wear the mouthguard?
   Did you have any problems wearing it at night? If so, describe:

   If you experienced problems, how did you correct them?

   Did you accurately report the actual amount of time the mouthguard was worn?

5. Why were cigarette butts collected during the week?

6. Did you try to accurately record every time when you smoked each cigarette?

7. What was the purpose of the cigarette holder for smoking during the session?

   Did you smoke your cigarette differently because of the holder? If so, describe:
Subject De-briefing Questions (continued)

6. What was the purpose of having pin holes put in your cigarette filter?

Were you "satisfied" smoking cigarettes with pin holes?

Did the cigarettes "taste" different? If so, describe:

Did the cigarettes smoke differently? If so, describe:

Did you notice any changes in your smoking pattern while you used the cigarettes with pin holes? If so, describe:

Did you notice any emotional and/or physical changes while you smoked cigarettes with pin holes? If so, describe:

Did you ever try to "cover-up" the pin holes when smoking?

Did you mark all cigarettes which you smoked that did not have pin holes in them?

9. Can you think of any discrepancies between the data you reported and what actually happened? If so, describe:
APPENDIX C

Filter weight increments of machine smoked cigarettes for each brand smoked by the subjects.

The smoking machine apparatus utilized a constant draw vacuum pump for simulating puffing. Standardized conditions were maintained for all cigarettes with respect to: puff duration - 2 seconds; puff volume - 60 ml; and inter-puff-interval - 60 seconds. Puff frequency was constant for each brand, but ranged from 8 to 12 puffs depending upon the cigarette brand length. This corresponded to FTC standards for total amount smoked. The following table presents the percent reductions for each cigarette brand over successive numbers of pinholes. These percent reductions were employed in the calculation of "expected" filter weights for each subject. The figure displays the changes in average filter weight as a function of the number of pinholes. Data are presented for each cigarette brand smoked by the subjects.
<table>
<thead>
<tr>
<th>Subject</th>
<th>Brand *</th>
<th>T/N</th>
<th>% Reduction from 0 Holes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>S-1</td>
<td>&quot;Marlboro&quot;</td>
<td>17.0/1.0</td>
<td>Post-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>48 hrs</td>
</tr>
<tr>
<td>S-2</td>
<td>&quot;Winston Lights&quot;</td>
<td>13.0/1.0</td>
<td>Post-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>48 hrs</td>
</tr>
<tr>
<td>S-3</td>
<td>&quot;Doral&quot; (Menthol)</td>
<td>11.0/0.8</td>
<td>Post-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>48 hrs</td>
</tr>
<tr>
<td>S-4</td>
<td>&quot;Marlboro&quot;</td>
<td>17.0/1.0</td>
<td>Post-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>48 hrs</td>
</tr>
<tr>
<td>S-5</td>
<td>&quot;Winston 100's&quot;</td>
<td>19.0/1.3</td>
<td>Post-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>48 hrs</td>
</tr>
<tr>
<td>S-6</td>
<td>&quot;Max-120&quot; (Menthol)</td>
<td>17.0/1.3</td>
<td>Post</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>48 hrs</td>
</tr>
<tr>
<td>S-7</td>
<td>&quot;Carlton&quot;</td>
<td>1.0/0.2</td>
<td>Post</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>48 hrs</td>
</tr>
<tr>
<td>S-9</td>
<td>&quot;Triumph&quot;</td>
<td>3.0/0.4</td>
<td>Post</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>48 hrs</td>
</tr>
<tr>
<td>S-10</td>
<td>&quot;Max-120&quot; (Menthol)</td>
<td>17.0/1.3</td>
<td>Post</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>48 hrs</td>
</tr>
</tbody>
</table>

* Registered Trade Marks.
APPENDIX D

As a control for the interaction of smoking and bruxism, three nonsmokers (Controls) were requested to wear the bruxscore monitor. Each subject wore the monitor for seven days per week for 4 consecutive weeks. One subject had been a cigarette smoker, but had been abstinent for two years (C-1). The other two subjects had never been smokers. All scoring was similar to Forgione (1974). The following figure displays each subject's data for 4 weeks.
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Schacter, S. Regulation, withdrawal and nicotine addiction. In N. A. Krasnegor (Ed.), Cigarette smoking as a dependence process


