Human smoking behaviour, cigarette testing protocols, and constituent yields

by

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A thesis
presented to the University of Waterloo
in fulfilment of the
thesis requirement for the degree of
Doctor of Philosophy
in
Psychology

Waterloo, Ontario, Canada, 2005

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ABSTRACT

The issue of how to test and ultimately regulate tobacco products represents a critical challenge for the public health community. Although the current international testing regime for conventional cigarettes is widely acknowledged to be seriously flawed, there is a lack of data to guide potential alternatives, particularly in the area of human puffing behaviour. The current study sought to: 1) collect naturalistic measures of smoking behaviour, 2) examine the extent to which levels of tar, nicotine, and carbon monoxide from each of five testing protocols were associated with measures of nicotine uptake among smokers, and 3) examine the validity of self-report measures of smoking behaviour. These questions were examined through two different studies. First, a field study of smoking behaviour was conducted with 59 adult smokers, who used a portable device to measure smoking topography over the course of 3 one-week trials. Participants were asked to smoke their usual "regular-yield" brand through the device for Trial 1 and again, 6 weeks later, at Trial 2. Half the subjects were then randomly assigned to smoke a "low-yield" brand for Trial 3. The smoke intake and constituent yield of each brand was then tested under five testing protocols: ISO, Massachusetts, Canadian, a Compensatory protocol, and a Human Mimic regime. Participants also completed self-report measures of puffing behaviour at recruitment and immediately following each of the three one-week smoking trials. Several of these self-report measures were subsequently included in the Waves 2 and 3 of the International Tobacco Control Policy Evaluation (ITC) Survey—an international cohort survey of adult smokers from Canada, Australia, the US, and the UK.

The results of the field study indicate a high degree of stability in puffing behaviour within the same smoker over time, but considerable variability between smokers, including those smoking the same brand. Puffing behaviour was strongly associated with cotinine levels, particularly when included in an interaction term with cigarettes per day (*Part r* = .50, p<.001). Smokers who were switched to a "low-yield" cigarette increased their total smoke intake per cigarette by 40% (p=.007), with no significant change in their in salivary cotinine levels.

The results indicate systematic differences between human puffing behaviour and the puffing regimes used by machine testing protocols. The puffing behaviour observed among participants during the one-week smoking trials was significantly more intense than the puffing parameters of the ISO and Compensatory testing regimes. When cigarette brands were machine tested using participants' actual puffing behaviour, the results suggest that participants ingested two to four times the level of tar, nicotine, and carbon monoxide indicated by the ISO regime, and twice the amounts generated by the Compensatory regime for "regular-yield" brands. The Canadian and Massachusetts regimes produced yields much closer to the "Human Mimic" yields, although nowhere near a maximum or intense standard, as they were designed to do. Only the nicotine yields from the Human Mimic regime were correlated with measures of nicotine uptake among smokers, and only moderately so (*Part r* = .31, p=.02).

Self-report measures of puffing behaviour collected during the field study were moderately correlated with physiological measures of puffing and exposure. Self-report measures of puff depth and puff number showed some promise as predictors of salivary cotinine, although the results are characterized by inconsistencies across models. The self-report measures included in the ITC survey were only weakly associated with age and cigarettes per day, with modest between-country differences.

Overall, this research highlights the importance of puffing behaviour as a determinant of smoke exposure, and provides strong evidence of compensatory smoking for "low-yield" brands. The findings also highlight the variability in human smoking behaviour and the limitations associated with machine testing protocols. Perhaps most important, the findings underscore the immediate need to revise the ISO protocol, which systematically underestimates smoking behaviour among humans and exaggerates differences between cigarette brands.

ACKNOWLEDGEMENTS

I would like to thank my committee members, Mark Zanna and Roy Cameron, for their contributions, as well as the co-investigators of this research: Mike Cummings, Murray Kaiserman, Andy Hyland, Gary Giovino, and Rich O'Connor. I would also like to acknowledge Jean Costello, Tara Elton, and Taryn Sendzik for their help in conducting this research.

In particular, I would like to thank my supervisor, Geoff Fong. Geoff has taught me much about integrity and creativity in research, as well as how little one needs to sleep. It has been a privilege to learn from such a generous mentor and someone with such passion for their work.

I would like to thank my family, who have served as proof readers for various pieces of this thesis. Most of all, thank you Jennifer for your patience and your willingness to trade-in the temperate climes of the West Coast for Waterloo.

This research was supported by funds from the American Cancer Society and Health Canada. I would like to acknowledge the support of a Canadian Institutes for Health Research (CIHR) Canada Graduate Award, as well as the CIHR Strategic Training Program in Tobacco Control program.

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1.0 INTRODUCTION

Tobacco use has been recognized by the World Health Organization as the leading cause of death and disability in the world.[1] To date, more than two dozen different smoking-related diseases have been identified and the list of known health effects continues to grow.[2] Worldwide, more than 5 million people die from tobacco use each year. Based upon current rates of smoking, the health and economic burden of tobacco use will increase dramatically in the coming decades: of all the people alive today, more than 500 million are projected to die from smoking-related disease.[3]

In Canada, the prevalence of smoking has decreased from a high of more than 50% in 1965, to less than 20% today.[4] Although this decline represents a major public health achievement, over 5 million Canadians continue to smoke, and tobacco use remains the primary cause of preventable death among Canadians.[5] Thus, whatever policies have already been implemented, there is a need for even stronger policy alternatives.

Reducing the prevalence of smoking remains the primary goal of tobacco control policy. At the same time, there is an implicit understanding within the tobacco control community that not even the best regulatory framework will succeed in completely eradicating smoking. Moreover, in countries such as Canada, further declines in prevalence are likely to be more gradual and progressively more difficult to achieve as the number of "hardcore" smokers increases as a proportion of all tobacco users.

These realities have sparked growing discussion of so-called "harm-reduction" measures that promote the use of less toxic tobacco products as an alternative to abstinence. In other words, if hardcore smokers cannot be convinced to abandon tobacco use, there may be considerable public health benefit to having them switch to less hazardous tobacco products, such as smokeless tobacco or the next generation of potentially-reduced harm products (PREP's) that heat, rather than combusted tobacco.

The merits of such an approach remain the source of much controversy and debate within the tobacco control community. [6,7] Yet, regardless of whether or not regulators pursue harm reduction policies that promote less toxic tobacco products or more traditional policies that restrict the toxicity of conventional cigarettes, there is an immediate need for valid testing protocols capable of assessing toxicity.

To date, regulators and tobacco control advocates lack an effective means with which to measure the toxicity of cigarettes. The issue is not simply one of legal jurisdiction or regulatory authority, but one of science. In Canada, for example, the government already has complete authority to regulate how cigarettes are designed.[8] Nevertheless, Canada has yet to implement any restrictions on how tobacco products are manufactured, largely because the government lacks appropriate testing standards to ensure that any such restrictions would succeed in reducing health risks, and would not be circumvented by tobacco manufacturers in some unforeseen fashion. As a consequence, tobacco products remain among the least regulated consumer products and are subject to fewer restrictions than pharmaceutical products, prepared foods, and virtually every other household product available to Canadians. In fact, there are only a handful of jurisdictions in the world that have set any restrictions on the constituents, emissions, or design of tobacco products.

The issue of how to test and ultimately regulate tobacco products represents a critical challenge for the public health community. A poor regulatory testing protocol would confer little or no benefit to consumers, insulate the tobacco industry from culpability, and provide false assurances to consumers and regulators. Maintaining the status quo, however, is equally unacceptable. A failure to establish new testing standards and to pursue meaningful reductions in cigarette toxicity is not only a missed opportunity, but perpetuates the untenable situation, whereby the most lethal consumer product in history is virtually unregulated.

The proposed research seeks to improve the evidence base for evaluating the toxicity of tobacco products. In particular, this research will: 1) review both independent and tobacco industry studies of testing protocols and smoking behaviour, 2) measure puffing behaviour among smokers in their "natural" environment, and 3) evaluate the extent to which existing cigarette testing protocols are valid reflections of human smoking.

1.1 Cigarette Testing Protocols

Cigarette smoke is a complex mixture of over 4,000 chemicals.[9] Since its inception, the tobacco industry has recognized the need for a standardized means of measuring these chemicals, not only to assess their health risks, but also to understand the reinforcing properties of different tobacco blends and product designs. In 1934, J.A. Bradford from the American Tobacco Company reviewed the different approaches that were being used at the time and proposed a smoking apparatus and a standard puffing regime to test smoke constituents.[10] By 1930, this technique was widely adopted and formed the basis for the *Cambridge Filter Method*, which would become the official testing protocol for CORESTA, the international association of tobacco industry researchers.[11]

Until 1966, cigarette testing and the reporting of smoke constituents was the responsibility of tobacco manufacturers. However, the release of the first U.S. Surgeon General's report on smoking, published in 1964, increased public pressure on regulatory authorities to establish independent testing standards for all products. In response, the U.S. Federal Trade Commission (FTC) made only minor changes to the *Cambridge Filter Method* before adopting the industry standard as its official testing protocol in 1967. The same protocol was adopted soon after by the International Standards Organization (ISO) for use in countries outside the United States, such as Canada.[12]

The "standard" FTC / ISO protocol tests cigarettes using a smoking machine that "puffs" on the filtered end of cigarettes through the suction of a pump. The cigarettes are smoked according to a standardized puffing regime: the pump draws 35ml puffs for two seconds, once per minute, until the lit end reaches a fixed distance from the cigarette filter. (Note that the FTC/ISO protocols use the same puffing regime that was "arbitrarily" selected by Bradford, in 1936.) With each puff, the mainstream smoke –the smoke drawn through the filtered end of the cigarette— passes through the smoking port and through filter pads. These filter pads collect the particulate matter (the solid and liquid matter from tobacco smoke), while gases pass through the filter pad into collection bags. Various chemical and physical separation techniques are then used to isolate and quantify the individual chemical constituents in the smoke.[13]

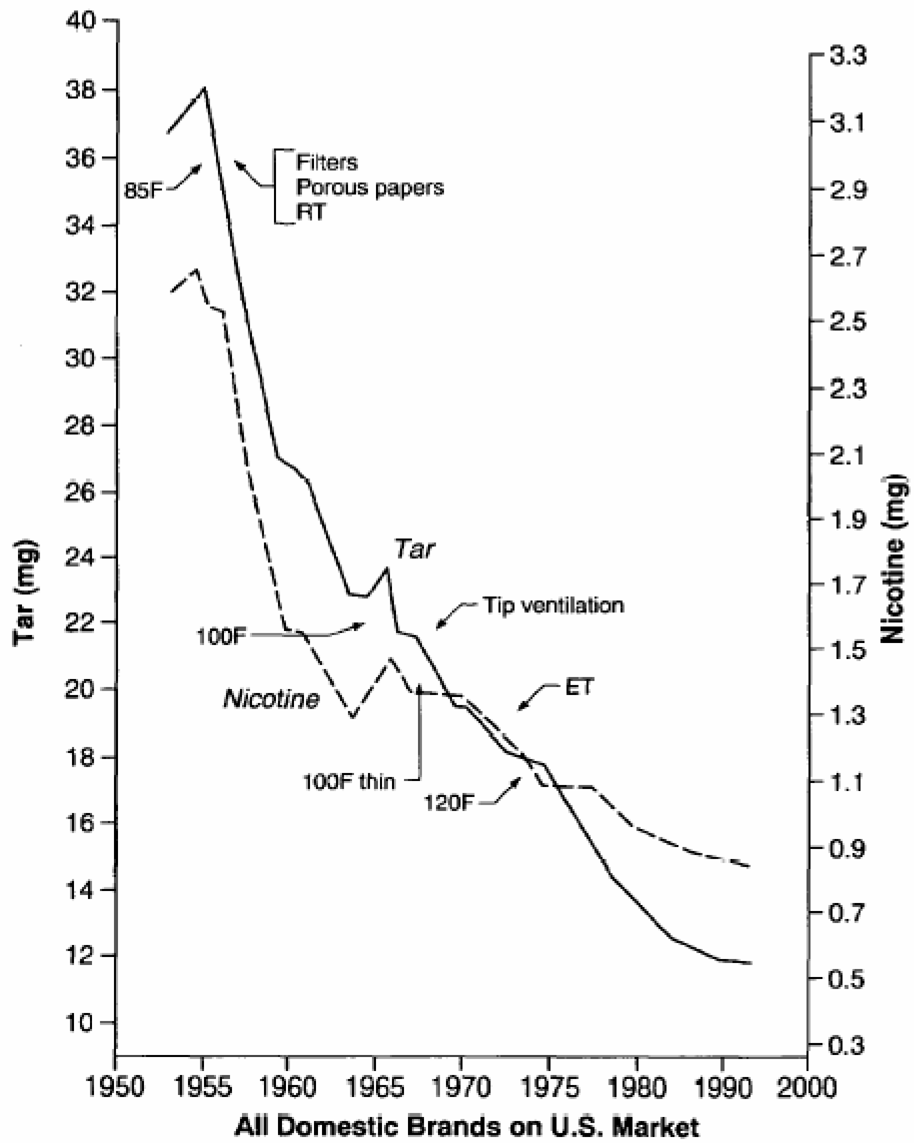
Figure 1. Filtrona smoking machine

At present, these testing protocols are mandatory for cigarettes sold in most jurisdictions, including Canada, the U.S., and the European Union. In most of these jurisdictions, tobacco manufacturers are required to report three main constituents, or smoke "yields": nicotine, carbon monoxide (CO), and tar –a "summary" measure of the total particulate matter after nicotine and water are removed. In many countries, tar and nicotine yields are reported directly to consumers either via cigarette packs or as part of warning labels that accompany print advertisements. Several jurisdictions also require tobacco manufacturers to report a more comprehensive list of chemicals. In Canada, for example, tobacco manufacturers must report emission data for more than 40 different chemicals.[8]

1.2 Factors that Influence Smoke Constituents

The constituents in cigarette smoke are determined by a complex set of product characteristics, including the tobacco blend, additives, and design features such as filter ventilation and paper porosity.[14] Tobacco manufacturers developed many of these design changes in the 1950's in response to growing pressure from public health authorities to reduce the machine-determined tar yields of cigarettes. The impact of these design features on nicotine and tar yields is illustrated in Figure 2.

Figure 2. Sales-weighted tar and nicotine values for U.S. cigarettes as measured using the FTC method 1954-1998[15]



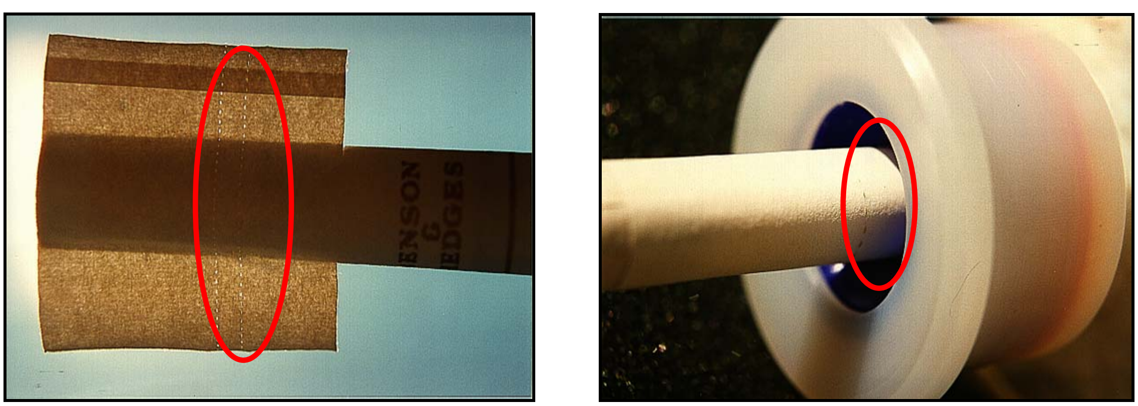
Key: RT = reconstituted tobacco; F = filter; ET = expanded tobacco.

Source: Hoffmann and Hoffmann, 1994a.

Prior to 1950, the vast majority of cigarettes were unfiltered. The introduction of filters represents the most significant design change during this period and had a substantial impact on cigarette yields. As the proportion of filtered cigarettes increased over the following decade, there was a sharp decline in the average tar yield of cigarettes, as depicted in Figure 2.

The introduction of filter ventilation and expanded tobacco in the 1960's and 70's was responsible for further declines in cigarette yields. Filter ventilation is achieved by cutting small perforations into the paper wrapping the filter. These perforations are designed to sit outside the smoking port when cigarette yields are tested (as depicted in Figure 3), but in locations where the lips or fingers of the smoker can easily cover the holes. When the holes are uncovered and the low draw rates specified by the ISO protocol are used, air is drawn into the filter through the vent holes, diluting the smoke coming through the rod of tobacco and lowering the machine-measured tar values. When the vent holes are covered or when the smoker draws more rapidly on the cigarette, much more of the puff volume is composed of smoke drawn through the rod of tobacco and much less is composed of air drawn from the ventilation holes. The result is a dramatic rise in the tar and nicotine delivered to the smoker by the cigarette. As Figure 3 illustrates, the vent holes are largely imperceptible to the naked eye.

Figure 3. Filter ventilation



A. Filter "vent-hole" perforations

B. Position of vent-holes outside the port of the FTC smoking machine.

1.3 Puffing Behaviour and Behavioural "Compensation"

Filter ventilation and other design changes had a substantial effect on the machine-smoked yields; however, they also changed how cigarettes were smoked. Indeed, the changes in cigarette design over the past 50 years highlight the critical difference between human smoking and the "standard" puffing behaviour of the smoking machine. This phenomenon is best illustrated by examining the role of nicotine in smoking behaviour.

Nicotine is the principal addictive ingredient in cigarettes and the driving force behind smoking behaviour.[16] Smokers attempt to maintain a relatively constant level of nicotine in their bodies and alter their smoking behaviour in order to regulate this level throughout the day.[17,18,19] Smokers do so by varying the number and the timing of cigarettes they smoke, as well as by varying their intake from each cigarette. Indeed, given that the average smoker consumes only 30% of the tobacco available in each cigarette, there is considerable opportunity for smokers to regulate their intake by changing the number, size, and velocity of puffs.[20] In fact, smokers typically alter their puffing behaviour even during the course of a single cigarette in response to the sensory cues of smoking and the immediate pharmacological effects of nicotine.[21]

One important implication is that individuals will adjust their smoking behaviour to compensate for different nicotine levels between products.[17,22] Independent research has demonstrated that smokers of low yield cigarettes take larger puffs, more puffs per cigarette, and puffs with greater flow rates than smokers of "medium" or "high" nicotine-yield cigarettes.[16,23,24,25,26] Indeed, changes in puffing behaviour, rather than vent-hole blocking, are the primary form of behavioural compensation for "low yield" cigarettes.[27] Industry research, described in their internal documents, comes to the same conclusions. One study conducted by British American Tobacco (BAT) on smokers who were switched to a lower nicotine cigarette reported that: "Changes in the number, duration and volume of puffs were noted, as well as butt length and pressure drop differences. In each case, the smoker adjusted his smoking habits in order to duplicate his normal cigarette intake."[28] Although the tobacco industry has yet to publicly acknowledge the extent to which smokers compensate for nicotine, Colin Grieg, a senior BAT researcher, summarized industry research on compensation as follows: "Many people will tell you authoritatively that, on sound statistical analysis of well designed experiments, low tar smokers do not compensate. Rubbish."[29]

Smokers' tendency to compensate means that the low tar and nicotine yields obtained from machine testing protocols may not be valid for human smokers. Yet, the limitations of the testing protocols are not confined to "low-yield" products. Rather, widespread design changes such as filter ventilation have implications for understanding puffing behaviour at the population-level of smokers. Indeed, such design changes appear to have shifted the "normal" parameters of puffing behaviour toward more intensive smoking. For example, one BAT researcher noted: "We have found a trend within the department for smokers to increase the volume of smoke drawn from cigarettes as the standard deliveries have been reduced by manufacturers."[30] Although it is not apparent whether puffing behaviour among human smokers was ever similar to the "standard" ISO and FTC machine puffing regimes, the discrepancy between the two continues to grow. The size of this discrepancy and the actual parameters of human puffing behaviour are important not only to understand compensation, but also to determine the validity of the ISO puffing regime and the validity of the constituent yields that are reported to regulators and consumers.

1.4 Parameters of Human Puffing Behaviour

Human puffing behaviour will inevitably be more variable than any machine-based testing protocol; yet the issue is not simply whether human smoking is more variable, but whether it is systematically different than the testing protocols. A recent review of BAT research found six studies that compared measures of puffing behaviour among humans with the ISO puffing regime for the same cigarette brands. In each of the six studies, every parameter observed among human smokers –including puff volume, puff frequency, puff number, and flow rate— was greater than the ISO puffing regime.[31,32,33,34,35,36] Indeed, BAT research suggests that human smokers typically draw puff volumes almost twice as large as the ISO smoking machine (50-70ml vs. 35 ml, respectively), and at twice the rate as the ISO regime (every 30 seconds vs. every 60 seconds). Overall, human smokers typically inhale twice the total volume of cigarette smoke as the ISO smoking machine.[34, 37] David Creighton, a senior BAT researcher, commented on the systematic differences between human puffing behaviour and the ISO protocol in 1977: "Of the 165 R&D smokers screened with profile recording units, there are fewer than 20% who take puffs of an average volume less than 35ml. Fifty percent take puffs that average 35-55ml and the remaining smokers take even larger puff volumes on their regular brands."[38]

Even taking into account the natural variations in puffing behaviour across smokers and different brands, the evidence is clear, as indicated in this BAT document: "Smoking pattern data have been recorded from several hundreds of smokers in Southampton [England]. No smoker yet has been observed who smokes with the same pattern as a smoking machine."[17,33] Therefore, the flaws of the current testing regimes are not limited only to smokers compensating for low yield products, but are present for virtually every smoker. These industry findings are consistent with those of independent researchers, which has found standard puffing regimes to underestimate the volume, frequency and velocity of puffs for virtually all smokers, including those who smoke "regular yield" brands.[39,40,41]

1.5 Implications of Puffing Behaviour on Cigarette Deliveries and Health Risks

Puffing behaviour has important implications for understanding the health risks of tobacco products. As Dr. Roe, a senior medical consultant to BAT noted: "Perhaps the most important determinant of the risk to health or to a particular aspect of health is the extent to which smoke is inhaled by smokers. If so, then deeply inhaled smoke from low tar delivery cigarettes might be more harmful than uninhaled smoke from high tar cigarettes."[42] Indeed, even modest differences in puffing behaviour can have a significant impact upon the tar and nicotine delivered to smokers.

Variations in puff volume and puff frequency—the two components of the total smoke intake— have the greatest impact on cigarette yields.[31] The velocity of a puff, or "flow rate" also has implications for nicotine and tar yields.[43] For example, greater flow rates increase cigarette yields by reducing the proportion of diluted air entering via the filter vent-holes and increasing the concentration of the smoke in each puff.[43,44] Greater flow rates may also increase the "free" versus "bound" nicotine ratio[45], which increases the bioavailability of nicotine and, ultimately, the addictiveness of a product.[46] Puffing behaviour may also affect the relative amounts of tar and nicotine in mainstream tobacco smoke: "Clearly, the absolute deliveries will be different….Perhaps more importantly, though, the ratio of components within the smoke may be different."[21] For example, the tar/nicotine ratio may decrease under greater puff volumes, as the available nicotine is diluted by a greater production of tar.[21] Finally, nicotine and tar deliveries increase with each subsequent puff due to reduced filtration by the shortening tobacco rod and because there is less diluting air coming through the cigarette paper and more air coming through the coal.[47]

Given the differences between human puffing behaviour and the ISO puffing regime, described in the previous section, what are the implications for cigarette deliveries? The tobacco industry has conducted numerous studies that compare the machine-smoked yields generated under the ISO puffing regime (i.e. 35ml puffs, once per minute), with machine-smoked yields generated from actual puffs recorded from humans smoking the same brand. (In other words, the smoking machine is programmed to mimic the average puffing behaviour of a group of smokers.) A recent review of these studies found that the ISO protocol systematically underestimated the yields obtained by human smokers in every case.[48] The systematic differences between human puffing and the ISO regime were large enough that BAT researchers began to question the utility of the ISO protocol for testing its own products. As a BAT position paper on smoking behaviour recently noted, "If a smoker forms a sensoric evaluation on a product after taking 70ml puffs every 30 seconds, then it may not be appropriate to compare this with the chemistry of smoke generated by machine through puffing 35ml every 60 seconds."[21] C. McBride, an Imperial Tobacco scientist, summarized this data by noting that, one can "reasonably conclude that virtually all smokers are receiving substantially higher deliveries."[44]

Overall, the ISO tar and nicotine levels currently bear little or no relation to the actual levels of tar and nicotine delivered to smokers.[49,50,51] In fact, many of the changes in cigarette design that reduced machine-measured tar yields are responsible for this dissociation. Most important, the dramatic reduction in yields depicted in Figure 2 have failed to yield any significant public health benefit. Indeed, mortality rates from smoking "low tar" cigarettes are not significantly different than either "medium" or "high tar" brands.[52,53]

1.6 Product Strategy and Testing Protocols

The discrepancy between the ISO yields and the actual nicotine and tar delivered to human smokers is not simply an historical accident, but exists by careful design. Early efforts to develop genuinely low-tar cigarettes resulted in a product that few smokers were interested in using and led many to quit.[54] It became clear to tobacco manufacturers that there was a trade-off between reducing the harmfulness of their products and maximizing their market-share. The solution lay in smokers' tendency to compensate and the limitations of the standard testing protocol.

Industry scientists were not only aware of behavioural compensation, but developed strategies to facilitate and reward it.[55,56,57] As Colin Grieg explained in a presentation to his BAT colleagues, the objective was, "…to produce a cigarette which can be machine smoked at a certain tar band, but which, in human hands, can exceed this tar banding."[29] This product strategy was articulated in more detail at an international conference of BAT researchers and marketers the following year: "The challenge would be to reduce the mainstream nicotine determined by standard smoking machine measurement while increasing the amount that would actually be absorbed by the smoker."[58] G. Brookes, another senior researcher speaking at the same conference, noted: "we should strive to achieve this effect without appearing to have a cigarette that cheats the league table [of ISO tar yields]. Ideally it should appear to be no different from a normal cigarette…It should also be capable of delivering up to 100% more than its machine delivery."[59]

This strategy spawned a new design concept whereby cigarettes would provide greater "reward" to smokers for a given puff volume: "Whatever the outcome of the various public debates on compensation and test procedures, we must aim to use our knowledge to develop products that respond to human smoker needs. The concept of 'smoke elasticity' can be expected to play an important role."[60] Elasticity refers to a phenomenon where the concentration of tar and nicotine in cigarette smoke increases as puff volume increases.[61] In other words, elastic cigarettes not only facilitate more intensive puffing in human hands, but also produce greater concentrations of tar and nicotine for a fixed volume of smoke at puffing levels typical of human smokers, relative to the standard ISO machine puffing regime. For example, a 50% increase in smoke volume above the ISO puffing regime might produce a 65% increase in nicotine yield.

The practice of designing ostensibly "low-yield" brands that actually delivered more tar and nicotine to smokers raised ethical concerns among some of the industry's senior scientists. For example, in 1984, David Creighton from BAT questioned the way elastic cigarettes were being marketed: "Is this an ethical thing to do? People who buy an 8 mg product expect to get 8 mg. … If a declaration that this product is elastic is made (which is the honest thing to do) then it could upset the apple cart." [62] Not wanting to upset the apple cart, the industry decided to keep elastic cigarettes secret, and—whatever design changes were introduced to increase elasticity— it was agreed that they should be subtle: "The consensus is that small improvements in elasticity which are less obvious, visually or otherwise is likely to be an acceptable route."[17] Furthermore, "large changes in delivery are not credible (i.e. 1 mg machine delivery giving 10 mg through the consumer compensation). Better to have a 9 mg product giving 15 mg." [17]

Despite the ethical concerns of its scientists and the health risks to consumers, elastic cigarette design soon became an important part of the industry's overall product strategy. In a presentation entitled *BAT stance on compensation*, C.I. Ayres communicated this policy to an international audience of industry researchers and executives: "From a research and product development viewpoint the proposition of designing a cigarette, of high taste to tar ratio, which responds positively to human smoking behaviour has been agreed to be acceptable."[17] In other words, tobacco manufacturers intentionally designed a class of cigarettes which delivered significantly more toxicants to smokers than the numbers on their packs and advertisements indicated, and kept this product strategy secret from consumers and regulators.

1.7 Standard Deliveries and Brand Rankings

Although the tobacco industry has acknowledged some of the limitations of the ISO machine testing protocol, they continue to argue that "Mainstream smoke yields determined by the standard smoking methods are appropriate for the ranking of cigarettes with respect to their yield." [63] In other words, the tar and nicotine values printed on cigarette packs and reported to regulators can be used to compare brands, even if they aren't precise enough to predict the nicotine and tar delivered to individual smokers.

However, elastic cigarette brands have important implications for so-called brand rankings. More "compensatible" and elastic brands that provide relatively low yields under the ISO machine testing may "leapfrog" non-elastic brands when smoked by humans. Table 1 provides an example drawn from BAT research.[64] Table 1 indicates brand with the lowest tar yields under the ISO machine protocols actually delivers the most tar to smokers. Senior BAT scientists remarked upon this phenomenon and concluded that the ISO brand rankings can, "mislead individual smokers. In particular, small differences in simple tables are meaningless and suggestions that single indices covering several factors have any scientific foundation at present must be totally rejected." [65]

Table 1. Machine versus "human" tar rankings

Brand	ISO Machine Tar Level (mg)	ISO Machine Tar ranking	Human Tar Level (mg)	Human Tar ranking
Players Filter Regular	25.3	1	17.0	2
DuMaurier King Size	23.2	2	16.7	3
Matinée King Size	13.6	3	20.7	1

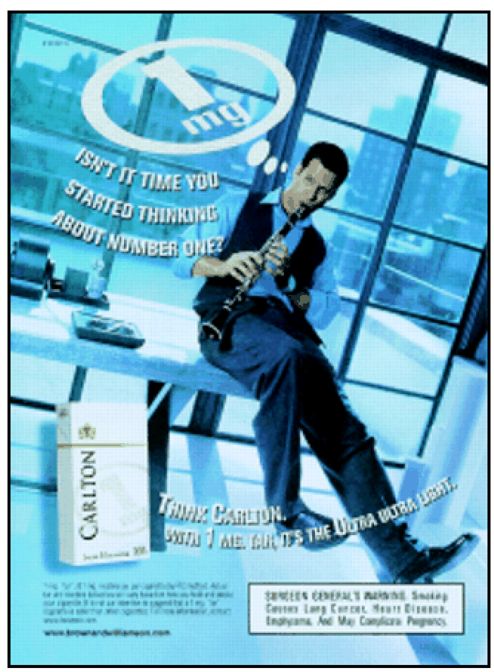
The example in Table 1 demonstrates that even large differences in ISO machine yields can be meaningless when brands are smoked by humans—in fact, the ISO tar rankings are completely reversed when the brands are smoked by humans. R.S. Wade, a senior BAT researcher, came to the same conclusion: "The ITG report on 'Project Jigsaw' was indeed extremely interesting particularly in pointing out the irrelevance of tar levels to smokers..."[19] One of BAT's leading researchers, David Creighton, agreed: "It is impractical to use…standard machine smoked deliveries to predict the deliveries or the ratios of the deliveries of cigarettes smoke components."[43] In other words, consumers who use the standard tar numbers to choose a "lower tar" and presumably less harmful brand—as many do— are being deceived.

1.8 Cigarette Yields and Marketing Strategy

In public, the tobacco industry has insisted that the ISO testing protocol is "not meant to predict actual smoker intake." [66] In other words, the ISO method is only designed to rank machine yields and not the "delivery" of constituents to smokers.[67] The flaws, therefore, lie not with the testing method, but how smokers have been interpreting its results.

In practice, however, the tobacco industry has carefully cultivated the misperception that the machine yields that appear on packages are, in fact, measures of actual human delivery and indicative of a safer product. Beginning in the 1960's, tobacco manufacturers began to promote the ISO tar yields of brands directly to consumers, even though these tar yields bore little or no relation to the levels consumers could expect (see Figure 4). Tobacco manufacturers also used "light" and "mild" brand descriptors and brand imagery to promote "low-tar" brands as healthier alternatives.[68] This duplicity is captured in documents from BAT: "Low tar [brands] that smoke like middle tar is most appropriate for middle tar smokers switching down due to concern of 'health'." In hindsight, "low-tar" cigarettes represented more of a marketing strategy than a product revolution, and there is ample evidence to suggest that this marketing strategy has succeeded. To date, a majority of smokers continue to believe that "low-tar" cigarettes are healthier, an erroneous belief that may reduce the likelihood of quitting among a substantial proportion of smokers.[69,70]

Figure 4. Examples of "low-tar" advertising



1.9 Policy Implications

At present, the regulatory mechanism for testing cigarette toxicity provides constituent information that is at best misleading and, in many cases, deceptive. Highly elastic cigarettes, when tested under the standard protocols with unrealistically low puffing regimes, also have the potential to subvert progressive policies intended to reduce cigarette toxicity. For example, the European Union (EU) recently introduced its "10-1-10" directive, in which all brands must not surpass 10mg of tar, 1mg of nicotine, or 10ppm of carbon monoxide.[71] Because the EU directive uses the ISO machine method as its testing standard, all brands give the appearance of meeting these regulatory standards, but actually deliver levels of tar and nicotine that are far higher than the 10-1-10 limits.

Any policy that seeks to limit smoke constituents will be meaningless unless it is based upon valid testing protocols that are relevant to human smokers. There are growing calls for change in the testing standards among independent research and even from within the FTC itself.[72,73] In response, the World Health Organization (WHO) is currently holding discussions with scientists, regulatory agencies, and the International Standards Organization with the aim of revising the ISO testing protocols.

There is growing support either to supplement or replace the existing ISO standard with a more intensive smoking regime. In fact, the Canadian and Massachusetts governments have already mandated more intensive testing protocols (see Table 2).

The extent to which these alternative protocols succeed where the ISO protocol fails is unclear. The tobacco industry has recently argued that these more intensive protocols will overestimate smoke intake and, therefore, should not be adopted more widely.[74] In particular, they have argued that the 100% vent-blocking condition in the ISO Intense/Canadian protocol is rarely seen among human smokers and will therefore generate unrealistically high yields. In contrast, internal industry documents suggest that, in many cases, human smoking behaviour may actually exceed the parameters used in the

ISO Intense/Canadian and Massachusetts protocols. There is, however, no consensus outside of the industry as to the validity of these alternative protocols.

Table 2. Comparison of international cigarette testing standards

Testing Protocols	Vent Hole Blockage (%)	Puff Volume (ml)	Puff Frequency (secs)	Puff Duration (secs)	Flow Rate (ml/sec)	Butt Length (mm)
FTC	0	35	60	2.0	17.5	Filter + 8mm
ISO	0	35	60	2.0	17.5	Tipping+3mm or 23mm
Massachusetts	50%	45	30	2.0	22.5	Tipping+3mm or 23mm
Canadian	100%	55	30	2.0	27.5	Tipping+3mm or 23mm

The principal obstacle to developing and evaluating alternative testing regimes remains the lack of data on human puffing behaviour. [75] As a BAT researcher noted in 1984, “Governments and their associated laboratories are aware of compensation but are reluctant to change since they can offer no viable alternative to the present smoking regime.”[76] Also, “the high and low end points of ‘likely’ intake of ‘most smokers’ for each of the hundreds of cigarette brand styles on the market have *not* been established,” largely due to the difficulties of measuring smoking behaviour outside of the laboratory setting.[67] In other words, even the basic parameters of human puffing behaviour that could serve as valid benchmarks for testing protocols are lacking.

The lack of data is, in part, due to the challenges inherent in measuring puffing behaviour. Laboratory studies have typically required participants to smoke one or two cigarettes through a mouthpiece attached to a desktop machine.[16] There are inherent limitations to this design. Even in *ad libitum* trials, where participants are asked to smoke as they normally do, smoking topography has been shown to change based upon the number and timing of cigarettes smoked, as well as reactivity to the topography machine.[77 78 79] Although biochemical values from conventional and "machine" smoking in a laboratory environment appear to be similar, this does not imply that laboratory smoking is the same as conventional smoking in a naturalistic setting. Considering that the total time spent puffing on a cigarette is, on average, less than 20 seconds, even small deviations from normal cigarette smoking behaviour can have a substantial impact upon estimates of smoke intake.[16] Indeed, one of the first published studies of smoking behaviour that helped to shape the protocols for the FTC method over 60 years ago noted that subjects "under examination" are apt to be nervous and smoke somewhat more vigorously than normal.[80] The few studies that have measured smoking topography outside of the laboratory also suggest that conventional puffing behaviour may well differ from measures observed in the laboratory.[81,82] Unfortunately, studies outside of the laboratory have rarely been able to measure puff volumes, the critical measure necessary to calculate total smoke intake.[78,81,83,84] In addition, with few exceptions,[85] measurements of smoking topography have been limited to 1 or 2 cigarettes. As a result, the studies that have estimated the effects of brand switching on puffing behaviour have had to rely on transient reactions to brand switching, which may not relate well to longer-term changes in smoking topography. In summary, current estimates of smoking topography lack an important degree of external validity; indeed, knowledge of *in vivo* smoking topography is practically non-existent outside tobacco industry documents.[27]

1.10 Summary

The issue of how to test and ultimately regulate tobacco products represents a critical challenge for the public health community. Although the current international testing regime for cigarettes is widely acknowledged to be seriously flawed, there is a lack of data to guide potential alternatives. There is a particular need for non-industry research on naturalistic puffing behaviour that can serve as a benchmark to evaluate existing testing protocols and to develop a replacement for the ISO standard. There is also a need to examine how smoke constituents change in response to different smoking conditions and brand designs. This interaction between the smoker and the cigarette is critical to our understanding of the toxicity of tobacco products.

2.0 RESEARCH OBJECTIVES

The current study sought to address the following questions:

1. What are the normal puffing parameters of human smoking behaviour, and to what extent does puffing behaviour differ between individuals?

2. How does puffing behaviour and nicotine uptake change following a switch to a "low-yield" cigarette brand?

3. To what extent does puffing behaviour predict nicotine uptake?

4. Are the puffing regimes used by machine testing regimes representative of mean human puffing behaviour?

5. To what extent do cigarette yields change across different machine testing regimes?

6. How do cigarette yields determined under "standard" machine testing regimes (e.g., the ISO regime) relate to machine-yields generated from human smoking behaviour?

7. To what extent is self-reported puffing behaviour associated with demographic variables and key measures of smoking behaviour?

8. To what extent are changes in cigarette brands associated with self-report puffing behaviour?

These research questions were examined through two related studies: 1) a field study of smoking behaviour, and 2) the International Tobacco Control Policy Evaluation Survey (ITCPES), a cohort survey of over 2,000 adult smokers randomly selected in each of four countries—Canada, United States, United Kingdom, and Australia—which included self-report measures of smoking behaviour derived from the field study. The following section provides a description of each.

3.0 METHODS

3.1 Field Study of Smoking Behaviour

3.1.1 Participants

Participants were recruited through a random-digit dial (RDD) telephone survey conducted between March and April 2003 in the Waterloo Region (See Appendix A). Respondents who smoked a minimum of 5 cigarettes per day, had no intention to quit smoking in the next 3 months (the duration of the study period), and who smoked brands with ISO tar yields between 10 and 14mg were invited to take part in a "field" study on smoking behaviour. A list of eligible brands was created from brand data provided by Health Canada.

3.1.2 Procedures

At the conclusion of the telephone survey, eligible respondents were asked to take part in a field study of smoking behaviour. Eligible respondents who expressed interest in the study were re-contacted approximately one-week later to confirm eligibility and to make an appointment for the first visit (see Recruitment Script in Appendix B). Participants were given the option of visiting the laboratory in the Department of Psychology at the University of Waterloo, or arranging for a home visit. All visits were conducted by a team of two trained research assistants.

The field study consisted of 3 one-week trials. For each trial, participants smoked at least 5 cigarettes a day through the smoking topography device for 5 consecutive days, between Monday and Friday. For Trial 1, participants smoked their usual brand of cigarettes. Approximately 6-weeks later, participants completed a second 5-day trial (Trial 2), smoking their usual cigarette brand through the device, as before. Trial 3 occurred during the week immediately following Trial 2. For Trial 3, half of the participants (n=24) were randomly selected to smoke a "lower-yield" cigarette brand (*Matinee Extra Mild*, 4mg tar/0.8mg nicotine ISO yield), whereas half continued to smoke their usual brand (n=27). These lower-yield cigarettes were matched for length and diameter with the participant's usual cigarette brand. All participants were provided with cigarettes for Trial 3 –either their regular brand or the lower-yield brand— free of charge. Table 3 provides an outline of the study protocol.

Table 3. Overview of study protocol

Week	Description
1	Baseline Phone Survey
2	Recruitment
3	Trial 1
8	Follow-up Phone Survey
9	Booking
10	Trial 2
11	Trial 3

Prior to each trial, participants were provided with an overview of how to use the smoking topography device. Participants were instructed to use the device whenever they smoked a cigarette. Participants were also asked to model how they normally held their cigarette. The Research Assistant then demonstrated how to use the device using a similar grip on their cigarette.

Participants completed daily diaries to record their daily consumption and any difficulty with using the devices (see Appendix C). Following each trial, participants responded to a 5-minute "post-use" questionnaire, and provided a saliva sample. Saliva samples were collected using Salivette™ containers according to a standardized protocol and frozen immediately after collection. This study received ethics clearance from the University of Waterloo's Office of Research Ethics Review Committee (ORE #10759).

3.1.3 Measures

Phone Survey

A 20-minute random digit-dial (RDD) telephone survey was conducted within the Waterloo Region. This survey included standardized measures of smoking behaviour, demographic variables, and key psychosocial variables, such as intentions to quit (see Appendix A). The survey also included seven questions on puffing behaviour (see Table 4). Given that we were unable to identify any pre-existing self-report measures of puffing behaviour, these questions were created specifically for the current study. The survey included questions that were intended to mimic each of the individual puffing parameters of smoking behaviour (e.g., puff number). Given the exploratory nature of these items, in some cases, multiple self-report measures were intended to assess the same puffing parameter.

Table 4. Self-report measures of puffing behaviour

Butt length	When you smoke, how much of the cigarette do you usually smoke? **READ** 01 – About half of the cigarette or less 02 – Most of the cigarette 03 – Nearly to the butt 04 – Right to the butt
Inhale Strength	Which of the following best describes how strongly you usually inhale when you smoke? **READ** 01 – You just puff, you don't really inhale 02 – You inhale well back into your mouth 03 – You inhale as far back as your throat 04 – You inhale only partly into your chest 05 – You inhale as deeply into your chest as possible
Puff Number (Scale)	Which of the following statements best describes how many puffs you usually take when you smoke a cigarette? **READ** 01 – You only take a few puffs on each cigarette 02 – You take more than a few puffs, but not as many as you could 03 – You take as many puffs as you can on each cigarette
Puff Number (open)	On average, how many puffs do you take on each cigarette? [enter Number]

Puff Depth	When you smoke, how deeply do you inhale? **READ** 01 – Not at all deeply 02 – Somewhat deeply 03 – Very deeply 04 – As deeply as possibly
Puff Frequency	On average, how long do you let the cigarette burn in between puffs? [enter: 01—seconds or 02 –minutes]
Put Cigarette Down	After you light a cigarette, how often do you usually put your cigarette down or hold it away from your mouth when you smoke? 01 – Never 02 – Not at all often 03 – Often 04 – Very often

<u>Smoking Topography Device</u>

The CReSSmicro device (Plowshare Technologies, Inc.; Baltimore, Maryland) is a battery-operated portable device that measures the full complement of puffing parameters (puff volume, puff number, puff duration, average flow, inter-puff interval, time, and date). The device is small (2.5” x 2.2” x 1.2”, 3.1oz), allowing for independent use in the participant's natural environment. The CReSSmicro uses an orifice flow meter mouthpiece that produces a pressure drop related to the flow rate of smoke through the mouthpiece. This pressure drop is measured in real-time by the CReSSmicro device using an onboard pressure transducer and is converted into the corresponding flow rate. All of the puffing variables are derived from the basic measurements of flow and time.

Figure 5. CReSSmicro device

On the day before each one-week smoking trial, each CReSSmicro device was calibrated at "low," "medium," and "intense" puffing conditions (see Appendix D). Each device was also tested under the same puffing conditions immediately following pick-up of the devices, in order to ensure the accuracy of the device during the study period. Any changes in sensitivity between pre- and post-use testing were noted. Data were downloaded from the device immediately following each one-week trial.

<u>Cotinine Samples</u>

Cotinine is the major metabolite of nicotine with a half-life of approximately 18-hours, and is a reliable indicator of nicotine uptake.[86,87] In addition, there is good correspondence between salivary measures of cotinine and both urinary and serum cotinine levels.[88] Immediately following each smoking trial, participants were asked to provide a saliva sample, which was then frozen for storage. The saliva samples were analysed for cotinine by Labstat International Inc. (Kitchener, Ontario) using a rapid gas-liquid chromatographic method.[89]

<u>Brand Elasticity</u>

Elasticity refers to brands that deliver greater tar and nicotine under more intense puffing than would be expected from the "standard" tar and nicotine yields determined under ISO testing conditions. We calculated a measure of elasticity for each of the brands included in the field study using testing data obtained from Health Canada. This measure was included in our analyses to examine whether brand elasticity would help to account for any discrepancy between the listed ISO nicotine yield of a brand and nicotine uptake among the participants, measured through salivary cotinine.

Brand elasticity was calculated using the Brown and Williamson formula[90], which tests the increase in nicotine delivery relative to increases in puff volume, as follows:

$$\text{Elasticity} = (D_{56mL} / P_{56mL}) \times (P_{44mL} / D_{44mL}) \times (V_{44mL} / V_{56mL})$$

Where D = nicotine delivery, P=the number of puffs, and V=puff volume for cigarettes smoked at 44mL and 56mL puffing regimes. Values greater than 1 indicate an "elastic" brand, with proportionally greater increases in delivery than puff volume. Elasticity values for the current study were drawn from tests conducted by Labstat International Inc. in 1997 on behalf of Health Canada. Twenty replicates* of 115 Canadian brands were tested through a Filtrona smoking machine at 44mL and 56mL puff volumes under otherwise normal ISO smoking conditions (i.e., 2-second puffs, once per minute, with unobstructed vent holes). The number of puffs, nicotine, tar, and CO yields were determined under the 44mL and 56mL puffing regimes for each brand.

<u>Daily Diary</u>

Participants recorded the time of their first cigarette of the day and the total number of cigarettes smoked, including both cigarettes smoked using the CReSSmicro device and those smoked without the device. The daily diary was also used to record any problems with the device or the study protocol (see Appendix E).

3.2 Cigarette Testing Protocols

3.2.1 Measures

Samples of each of the 21 cigarette brands smoked by participants in the field study were purchased and sent to Arista Laboratories (Richmond, VA) to test the tar, nicotine, and carbon monoxide yields. Two replicates (5 cigarettes per replicate) of each brand were smoked through a Filtrona smoking machine according to each of five protocols: the ISO, Canadian, Massachusetts, Compensatory, and Human Mimic protocols (see below for a description of each). The same standard methodology was used to measure the nicotine, tar, and carbon monoxide yields for each protocol.[12] Briefly, particulate matter from the mainstream smoke was collected on a 44-mm Cambridge filter pad from each smoking port, which was then removed and weighed to measure total particulate matter. Extract from the filter pad was injected into a gas chromatograph to determine the moisture content and nicotine yield. Gases that passed through the filter pad were collected and

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* A replicate refers to each "set" of five cigarettes tested at the same time through the *Filtrona* machine.

then tested to determine carbon monoxide levels.[91] Tar level was determined by subtracting the water and nicotine levels from the total particulate matter.[92,93] Puff count was recorded to the first decimal point.

3.2.2 Testing Protocols

A full discussion of the ISO protocol is provided in the Introduction. The Canadian (CAN) and the Massachusetts (MASS) protocols are variants of the standard ISO testing regime; both increase the frequency and size of puff volumes relative to the ISO regime, and both block a percentage of filter vent-holes prior to testing. The main difference between the two is the increase in puff volume (CAN=55ml/puff, MASS=45ml/puf) and the proportion of vent-hole blockage (CAN=100%, MASS=50%).

Table 5. Smoking parameters for cigarette testing protocols

Testing Protocols	Vent Hole Blockage (%)	Puff Volume (ml)	Puff Frequency (secs)	Puff Duration (secs)	Flow Rate (ml/sec)	Butt Length (mm)
ISO	0	35	60	2.0	17.5	Tipping + 3mm
Massachusetts	50%	45	30	2.0	22.5	Tipping + 3mm
Canadian	100%	55	30	2.0	27.5	Tipping + 3mm
Compensatory*	50%	Variable	Variable	2.0	Variable	Tipping + 3mm
Human Mimic*	50%	Variable	Variable	Variable	Variable	Tipping + 3mm

* Note that the puffing parameters from the Compensatory and Human Mimic protocols varies across cigarette brands.

Compensatory Protocol

This protocol has been proposed by Kozlowski and O'Connor in an effort to incorporate behavioural compensation into the testing regime.[73] They advocate varying the puff volume and frequency according to the nicotine yield determined in the ISO method. In other words, each brand is tested using the ISO method and the ISO nicotine yield is used to determine the puffing parameters for a second round of testing—the compensatory testing. Brands with high ISO nicotine yields are smoked less intensely, while brands with low ISO nicotine yields are smoked more intensely under this compensatory regime. Brands with 1mg of nicotine are tested using a 40mL puff taken every 60 seconds. With every 0.1mg decrease in ISO nicotine, the puff volume increases by 4ml and puff frequency decreases by 4 seconds. For example, a cigarette with .5mg of nicotine under the ISO method would be smoked at 60ml puffs every 40 seconds under the Compensatory test, while a 0.1mg cigarette would be smoked at 76mL puffs every 24 seconds. In contrast, with every 0.1mg increase in nicotine above 1.0 mg, puff volume decreases by 4ml and puff frequency increases by 4 seconds. Table 6 illustrates the compensatory regime. Appendix F also provides the actual compensatory testing parameters for each brand included in the current study.

Table 6. Compensatory testing parameters

ISO Nicotine Yield (mg)	Puff Volume (mL)	Puff Interval (secs)
0.7	52	48
0.8	48	52
0.9	44	56
1.0	40	60
1.1	36	64
1.2	32	68
1.3	28	72

Human Mimic Protocol

Human Mimic protocols use puffing behaviour recorded from actual smokers to set the testing parameters for the Filtrona machine. In the current study, we used the puffing behaviour recorded from the subjects in the field study to determine the Human Mimic testing parameters for each brand. In cases where a particular brand was smoked by more than one subject, the average puffing level was used. The Filtrona smoking machine was then programmed to smoke cigarettes using these "mimic" puffing levels. The testing parameters for each brand are listed in Appendix G. Note that this type of testing protocol has been used extensively by tobacco manufacturers to test their products, as described in the Introduction.

3.3 International Tobacco Control Policy Evaluation Survey

The ITC Survey is an international cohort survey of adult smokers designed to evaluate the effectiveness of national-level tobacco control policies**,** including taxation and public smoking restrictions. One important aspect of the ITC survey is to examine the different ways in which smokers may respond to such policies. For example, although many smokers respond to an increase in cigarette taxation by purchasing fewer cigarettes and reducing their consumption, they may compensate for this reduction by smoking more of each cigarette, taking larger puffs, and inhaling the smoke more deeply. In this way, it is possible to increase the nicotine uptake per cigarette and maintain nicotine levels at a lower cost. Thus, before one can infer a public health benefit from policies that prompt reductions in daily consumption, compensatory behaviours, such as changes to puffing behaviour, need to be taken into account.

One of the main objectives of the field study was to validate self-report measures of puffing behaviour that could be administered through the ITC survey. Three measures were introduced in Wave 2 of the ITC survey, conducted between June and August 2003. The following section describes the methodology of the ITC survey.

3.3.1 Sample

Participants in the ITC Survey were 18 years or older, had smoked more than 100 cigarettes in their life, and smoked at least once in the past 30 days. The cohort was constructed using probability sampling methods with telephone numbers selected at random from the population of each country, within strata defined by geographic region and community size. Eligible households were identified by asking a household informant the number of adult smokers living in the household. The Next Birthday

Method[94] was used to select the respondent in households with more than one eligible adult smoker. Representative samples of adult smokers were recruited from each of four countries: Canada, the US, the UK, and Australia. Note that the ITC measures of puffing behaviour were only asked of current smokers. As a result, ITC respondents who reported being abstinent for 24 hours or more were excluded from the present analysis.

3.3.2 Procedure

The survey was conducted using Computer Assisted Telephone Interviewing (CATI) software and was completed in 2 calls: a 10-minute recruitment call was followed one-week later by a 40-minute main phone survey. In order to increase recruitment rates[95], participants were mailed compensation equivalent to $10 USD prior to completing the main survey. Interviews were conducted by two survey firms: Roy Morgan Research (Melbourne, Australia) surveyed Australian and UK respondents, and Environics Research Group (Toronto, Canada) surveyed Canadian and US respondents. All aspects of the interviewer training and calling protocol were standardized across the two survey firms and closely supervised by the ITC team. Wave 1 of the ITC survey was conducted between October-December 2002. Wave 2 was conducted approximately 8 months later, and Wave 3 was completed between June and September 2004. A full description of the ITC methodology, sample profile, and survey rates is available at http://www.itcproject.org.

3.3.3 Measures

The ITC survey was standardized across the four countries: respondents in each country were asked the same questions, with only minor variations for colloquial speech. A copy of the Wave 2 ITC survey is available (http://www.itcproject.org); the following section provides a description of the measures used in the current study.

Demographics and Smoking Behaviour

The survey included validated measures of smoking behaviour and quit history. Intention to quit was assessed by asking: "Are you planning to quit in the next month, 6 months, beyond 6 months, or not at all?" Level of education consisted of three categories: high school diploma or lower; technical, trade school, community college, or some university; and university degree. Annual income was categorized into "under $30,000," "$30,000-59,999,"and "$60,000 and over" for the US, Canadian, and Australian samples. For the UK sample, we used the following categories: "£15,000 or under," "£15,001-30,000," and "£30,001 and over." Ethnicity was measured using the relevant census question for each country and then analyzed as a dichotomous variable to allow for comparisons across countries ("white" vs. "non-white and mixed race"), except Australia. Language was used as a proxy for Australian ethnicity ("English-speaking"=White, "Non-English speaking"=Non-White), as is consistent with the Australian census.

Measures of Puffing Behaviour

The following three self-report questions from the field study of smoking behaviour were included in Wave 2 of the ITC study: 1) *Puff strength* ("Which of the following best describes how strongly you usually inhale when you smoke?"); 2) *Puff number* ("Which of the following statements best describes how many puffs you usually take when you smoke a cigarette?"; and 3) *Butt length* ("When you smoke, how much of the cigarette do you usually smoke?" The *Puff strength* question was re-administered during Wave 3 of the ITC survey, and a measure of Puff frequency ("On average, how long do you let the cigarette burn in between puffs?") was added.

The study protocol was cleared for ethics by research institutional review boards at each of the following institutions: the University of Waterloo (ORE #10556), Roswell Park Cancer Institute (US), the University of Strathclyde (UK), and the Cancer Council of Victoria (Australia).

4.0 ANALYSIS

4.1 Data Cleaning

All of the physiological data collected through the CReSSmicro devices was checked prior to analysis. Several device malfunctions were detected. Most of these consisted of "catastrophic" malfunctions, where either the machine stopped working altogether or the data that was recorded was obviously erroneous. In order to ensure the accuracy of the remaining data, every data point was reviewed by 3 independent raters. Each rater identified invalid data due to device misuse, device inaccuracies, or generally unrealistic values. The 3 raters agreed on 90% of all data points; all other data points were dropped from the analyses to ensure conservative standards for data quality.

4.2 Smoke Intake

A measure of total smoke intake was generated by multiplying the puff number by the mean puff volume recorded through the CReSSmicro device. A measure of total smoke intake for the machine testing protocols (e.g., ISO) was also calculated. For each protocol, the puff volume (e.g., 35ml) was multiplied by the mean number of puffs taken by the machine when testing each brand.

4.3 Puff Frequency

In both the Field Study and ITC surveys, the Puff Frequency measure asked respondents about "how long they wait in between puffs." Responses to this item were reverse coded, so that increasing scores correspond to increasing frequency of puffing. Also note that the Butt Length item was also coded so that higher scores reflect shorter butt length and more intensive smoking.

4.4 ITC Data

Weights were constructed for each of the national samples included in the ITC data. The data was weighted to reflect the appropriate age-sex prevalence estimates within geographical strata (e.g., provinces), as well as to account for non-response and the survey design. All point estimates (e.g., mean cigarettes per day) are derived from weighted data. For multivariate analyses, there were no significant differences between weighted and unweighted data; unless otherwise noted, weighted multivariate results are presented.

All analyses were conducted using SPSS (Version 13.0). For linear regression models, standardized betas are reported, as well as "part" (semi-partial) correlations. In linear regression, the squared part correlation is the proportion of "unique" variance in the dependent variable accounted for by a given independent variable. In other words, it removes any "overlapping" variance in the dependent variable that may be accounted for by other independent variables in the model.

5.0 RESULTS

5.1. Smoking Topography Field Study

5.1.1 Sample

A total of 520 respondents completed the baseline telephone survey. Seventy-six out of the 91 participants who met the eligibility criteria participated in Trial 1. Twelve of the 76 were excluded after Trial 1 for failing to keep appointments or for violating study protocol, such as smoking other cigarette brands. Data from five additional participants were excluded during data cleaning, leaving a final sample of 59 participants. Of these, 52 participants had valid CReSSmicro data for at least two one-week trials, with an additional 7 participants providing data for one trial only.

Of the 59 participants, 30 were male (51%). Participants reported a mean age of 37.1 (SD=11.1), 81% had finished high school, and 38% had completed some form of post-secondary education. Participants smoked an average of 19.3 (SD=8.0) cigarettes per day (CPD) and 81% had previously tried to quit smoking. Although no participant intended to quit within 3 months (as per inclusion criteria), 73% planned to quit at some point beyond 3 months. There was no difference between experimental conditions and on any of these measures.

5.1.2 Use of the Smoking Topography Device

Participants smoked a total of 6,493 cigarettes through the CReSSmicro device. An average of 67 cigarettes per participant was smoked through the device during the first two trials (54% of all cigarettes smoked during this period), and an average of 40 cigarettes through the device at Trial 3 (52% of all cigarettes smoked), with no differences between the control and brand-switching groups. Only 2% of participants reported that the CReSSmicro device was "hard" to use, and only 35% reported that using the machine did not feel "natural." Approximately 42% reported that using the device did not change their smoking behaviour "at all," 50% reported it changed their smoking behaviour "a little," and 8% said it changed their behaviour "a lot." These measures were unrelated to measures of puffing behaviour or experimental condition.

5.1.3 Parameters of Human Smoking Behaviour

The primary objective of this research was to characterize measures of puffing behaviour among smokers using their usual cigarette brand. Table 7 provides measures of puffing behaviour for Trials 1 and 2. As the correlations between Trials 1 and 2 indicate, puffing behaviour was relatively stable within participants, across the two trials separated by 6 weeks. In other words, there were few if any "spontaneous" changes in smoking behaviour observed among participants over the course of the 6 weeks.

Table 7. Smoking topography for "regular-yield" brands (n=58)

	Puff Number	**Puff Duration** (secs)	**Puff Frequency** (secs)	**Mean Flow Rate** (ml/sec)	**Puff Volume** (ml)	**Smoke Intake** (ml)
Trial 1 (SD)	11.3 (3.4)	1.5 (0.2)	33.5 (17.6)	38.1 (5.6)	54.2 (10.3)	612.0 (195.7)
Trial 2 (SD)	11.1 (3.3)	1.4 (0.3)	35.6 (18.4)	37.9 (6.1)	52.3 (12.4)	580.5 (206.9)
Trial 1 -2 Correlation (*p* level)	.91 (<.001)	.82 (<.001)	.96 (<.001)	.85 (<.001)	.86 (<.001)	.87 (<.001)

5.1.4 Individual Differences in Puffing Behaviour

Although puffing behaviour was consistent within smokers, there were large differences in puffing observed between smokers. To illustrate these differences, smokers were separated into quartiles based upon their total smoke intake. Smoke intake was 2.4 times greater for smokers in the highest (863.2 mL, SD=111.0) versus those in the lowest quartile (359.4 mL, SD=67.5; t=14.5 p<.001). In other words, some smokers were inhaling the same amount of smoke from a single cigarette as other smokers were inhaling from two or three cigarettes.

This variability in intake was observed even with smokers of the same cigarette brands. Table 8 includes mean puffing parameters for smokers within each of the three most popular brands smoked in the study. There were no significant differences among brands along any of the individual puffing parameters. Also note that the variability in total smoke intake within each of the two most popular brands –*Players Light* and *DuMaurier Light*— was equal to the variability in smoke intake observed among all 59 participants, across all brands. In other words, the variability in puffing behaviour and smoke inhalation would appear to be driven as much by the individual characteristics of smokers, as by differences between cigarette brands.

Table 8. Puffing behaviour within selected brands

	Puff Number	**Puff Duration** (secs)	**Puff Frequency** (secs)	**Mean Flow Rate** (ml/sec)	**Puff Volume** (ml)	**Smoke Intake** (ml)
Players Light (n=10)	11.7 (3.2)	1.6 (0.3)	29.1 (2.3)	38.1 (7.1)	58.8 (16.7)	673.0 (195.1)
DuMaurier Light (n=8)	11.8 (3.3)	1.5 (0.2)	28.7 (15.2)	37.9 (3.9)	54.9 (7.6)	651.0 (198.0)
DuMaurier (n=5)	10.2 (2.3)	1.6 (0.3)	33.0 (15.1)	35.3 (2.5)	53.2 (7.8)	536.5 (109.9)

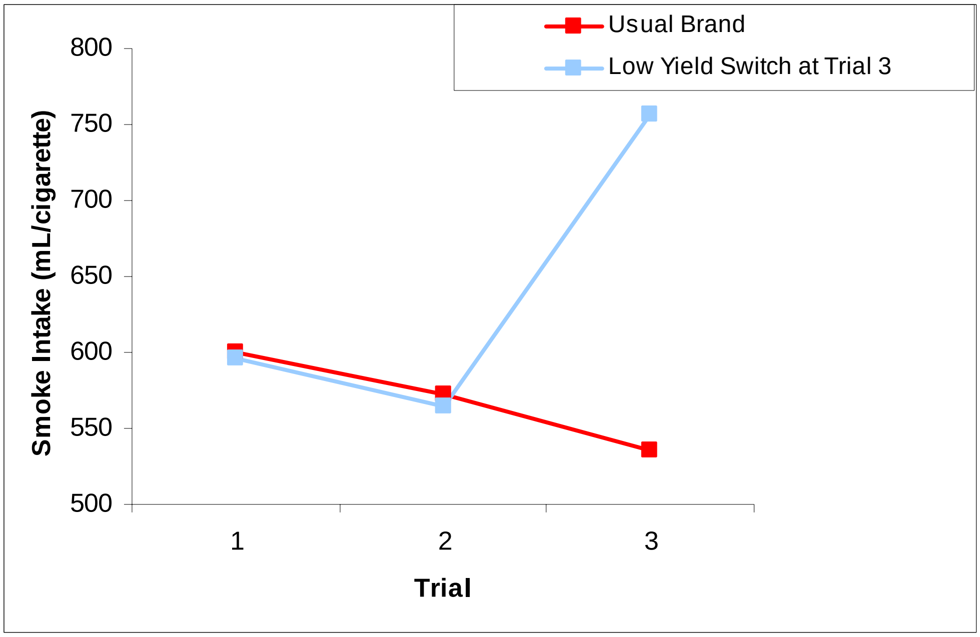
Puffing behaviour also varied between men and women. Although females took one extra puff per cigarette on average, males took significantly larger puffs (57.8mL, SD=11.6) than females (47.3mL, SD=10.1; t=3.7, p<.001). As a consequence, smoke intake was 71ml or 12% greater among males (638.3mL, SD=214.1) than females (567.6, SD=178.7; t=1.4, p= .18). No other demographic variables were associated with smoke intake; however, participants who smoked more cigarettes per day waited longer in between puffs (r = .26, p=.04), with a non-significant trend towards lower smoke intake per cigarette (r = -.22, p=.09).

5.2 The Effect of Switching to a "Low-Yield" Cigarette Brand

5.2.1 Brand Switching and Puffing Behaviour

Trial 3 of the field study was designed to examine whether switching to a "low-nicotine" brand was associated with any compensatory changes in smoking behaviour. A total of 27 participants were randomly selected to smoke the "low-yield" *Matinee Extra Mild* brand (4mg of nicotine) at Trial 3. Approximately 73% of these participants found it "very different" smoking another brand, and only one participant reported noticing no difference at all. As Figure 6 illustrates, smoke intake per cigarette was 40% greater among those who switched to the "low-yield" brand (779.2 ml, SD=331.0) versus those who smoked their usual "regular-yield" brand (553.2 ml, SD=240.5; t =-2.8, p=.007). The increase in smoke intake was mainly accomplished through higher puff volumes among "low-yield" smokers (58.3mL, SD=16.1), compared to "regular-yield" smokers (49.3mL, SD=11.5; t=2.32, p=.02). There were no significant changes in smoking topography measures over the course of the 5-day trial among smokers in either condition; however, brand switchers increased their cigarette consumption from Trial 2 to Trial 3, relative to participants in the usual brand condition (+1.4 vs. -1.2 CPD; t=2.4, p=.03). Overall, participants who smoke *Matinee Extra Mild* increased both the number of cigarettes per day, as well as the intensity with which they smoked each cigarette.

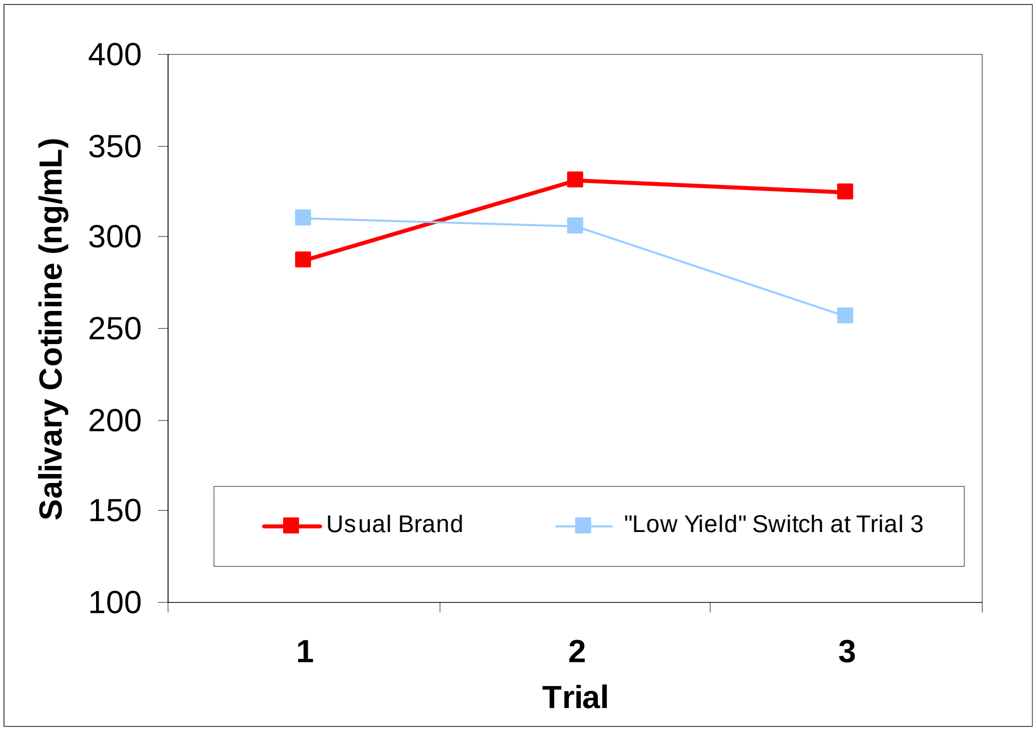
Figure 6. Effect of switching to a "low-Yield" brand on smoke intake



5.2.2 Brand Switching and Nicotine Uptake

Salivary cotinine serves as a biological measure of nicotine uptake. In the current study, cotinine was assessed to examine the extent to which nicotine uptake changed following a switch to a "lower" yield cigarette brand. Among usual-brand smoking, salivary cotinine levels were similar across the three one-week trials (Trial 1=297.4 ng/mL, SD=143.5; Trial 2=319.4 ng/mL, SD=139.5; and Trial 3=291.7 ng/mL, SD=138.1). At Trial 3, there was a non-significant trend towards lower cotinine levels among "low-yield" switchers (258ng/mL, SD=146.5), relative to usual brand smokers (325ng/mL, SD=123.5; t=1.8, p=.08). Cotinine levels decreased 12% between Trial 2 to Trial 3 among brand switchers (299.2 vs. 262.4ng/mL; t=1.7, p=.07), significantly less than would be predicted from the 64% decrease in ISO nicotine yields from smokers' usual brand smoked at T2 and the low-yield brand smoked at T3 (means=.95mg and .36mg, respectively). In other words, the change in nicotine yield did not translate into equivalent changes in nicotine uptake among participants. Figure 7 shows the change in cotinine levels over the course of the three trials.

Figure 7. Effect of switching to a "low-yield" brand on salivary cotinine



Note that, among usual-brand smokers, saliva samples were collected later in the day at Trial 2 (+2.7 hours, t=4.1, p<.001) and at Trial 3 (+1.9 hours, t=3.3, p=.003), compared to Trial 1. As a result, participants in the usual-brand condition may have smoked a greater number of cigarettes shortly before the saliva sample was collected at Trial 2 and 3 versus Trial 1. This may account for the higher cotinine levels observed at Trials 2 and 3 among usual-brand smokers.

Overall, these findings indicate that smokers increased the intensity of their puffing behaviour following a switch to a "low" nicotine yield brand, such that no significant changes in nicotine uptake were observed.

5.3 Cigarette Testing Protocols

The results from the previous section help to characterize puffing behaviour for both "regular" and "low-yield" smoking. The next section examines the correspondence between these "human" measures of puffing and the puffing parameters used to test cigarettes in each of the leading testing protocols.

5.3.1 Cigarette Testing Protocols and Puffing Behaviour

Each of the 21 brands smoked by participants was purchased and tested under five different testing regime: the ISO, Massachusetts, Canadian, Compensatory, and Human Mimic regime. The mean puff count was recorded for each of the testing regimes. The smoke intake for each brand was calculated by multiplying the puff count by the puff volume, and represents the total volume of smoke that was generated by the machine testing protocol and analysed for tar, nicotine, and carbon monoxide. The mean puffing parameters for each testing regime are presented in Table 9. Note that the last column Table 9 also ranks the total smoke intake of each testing regime with respect to the smoke intake observed among participants in the field study.

As Table 9 indicates (see following page), there was wide variability in the total smoke intake between the testing regimes. In other words, the puffing parameters used by each machine-testing protocol generated much different volumes of smoke. Among "regular-yield" brands, the Human Mimic regime generated the greatest smoke intake, which ranked in the 64th percentile of smoke intake among participants from the field study. Smoke intake generated under the Canadian and Massachusetts regimes ranked in the 55th and 53rd percentiles of human smoking, respectively. The ISO and Compensation protocols generated substantially lower machine smoke intakes, ranking in the 6th and 7th percentiles of human smoking, respectively.

Table 9. Comparison of smoke intake and smoking topography between human smoking behaviour and international testing standards.

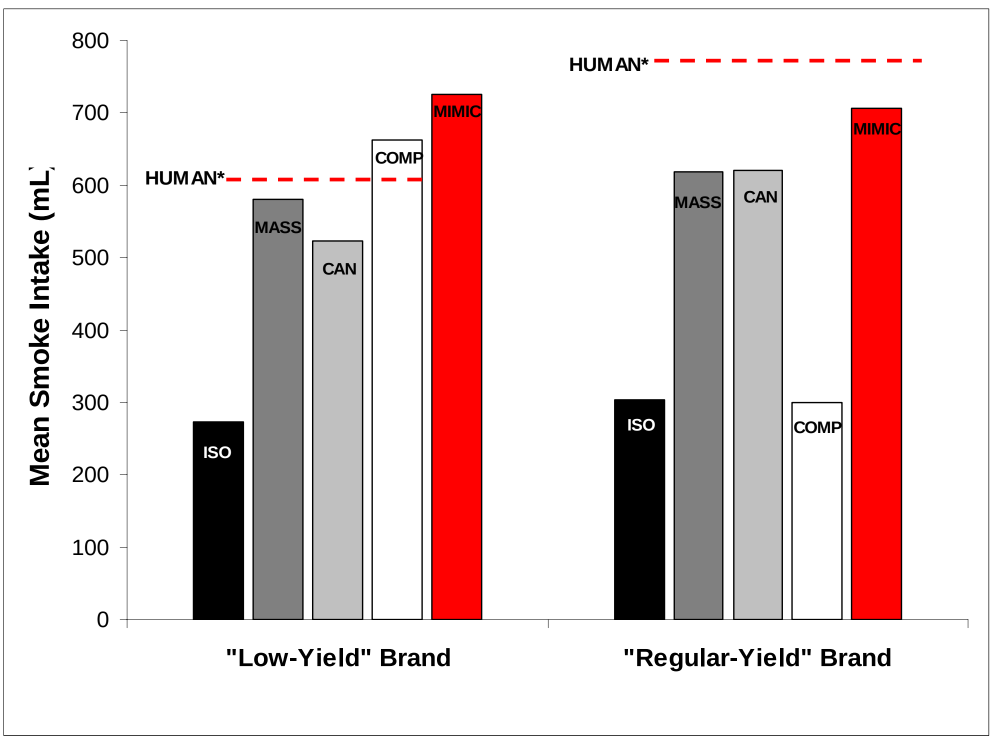
	Puff Number	Puff Duration (secs)	Puff Frequency (secs)	Flow Rate (ml/sec)	Puff Volume (ml)	Smoke Intake (ml)	Human Intake Percentile
Regular Yield*							
ISO	8.5 (0.9)	2.0 (-)	60.0 (-)	17.5 (-)	35.0 (-)	304.0 (34.8)	6%
Massachusetts	13.7 (1.6)	2.0 (-)	30.0 (-)	22.5 (-)	45.0 (-)	618.3 (74.0)	53%
Canadian	11.2 (1.0)	2.0 (-)	30.0 (-)	27.5 (-)	55.0 (-)	621.2 (44.4)	55%
Compensatory	8.6 (0.8)	2.0 (-)	66.0 (-)	17.0 (-)	34.9 (-)	300.1 (58.3)	7%
Human Mimic	13.2 (3.4)	1.4 (0.2)	35.1 (15.7)	38.1 (4.4)	53.3 (6.2)	705.7 (213.3)	64%
Low Yield†							
ISO	7.8 (-)	2.0 (-)	60.0 (-)	17.5 (-)	35.0 (-)	273.2 (-)	0%
Massachusetts	12.9 (-)	2.0 (-)	30.0 (-)	22.5 (-)	45.0 (-)	581.1 (-)	29%
Canadian	9.5 (-)	2.0 (-)	30.0 (-)	27.5 (-)	55.0 (-)	523.4 (-)	21%
Compensatory	10.4 (-)	2.0 (-)	36.0 (-)	32.0 (-)	64.0 (-)	662.4 (-)	42%
Human Mimic	12.5 (-)	1.5 (-)	29.1 (-)	38.7 (-)	58.0 (-)	725.0 (-)	50%

* "Regular Yield: Mean Tar = 11.8, Nicotine=1.1 † "Low-Yield": Tar = 4mg, Nicotine=0.4mg

For the low-yield brand, the Human Mimic regime again produced the greatest machine smoke intake, ranking in the 50th percentile of human smokers. The Compensatory was next, ranking in the 42nd percentile, whereas the Massachusetts and Canadian regimes ranked in the 29th and 21st percentiles, respectively. Meanwhile, the ISO regime produced a lower smoke intake than was recorded from any of the 59 smokers in the field study. In addition, every condition except the Human Mimic regime underestimated the flow rate observed among human smokers. In other words, the ISO, Massachusetts, Canadian, and Compensatory regimes achieved their smoke volumes with lower intensity puffing than was observed among human smokers.

Figure 8 illustrates the differences in smoke intake across testing regimes. As Figure 8 indicates, the Canadian regime produced an equal volume of smoke as the Massachusetts regime for "regular-yield" brands and a lesser volume of smoke for the "low-yield" brand, despite having more intense puffing parameters. This is due to a smaller number of puffs drawn under the Canadian regime, which reflects a higher burn rate when more intensive puffs are drawn on the cigarette.

Figure 8. Smoke intake predicted by testing protocols versus human intake.



* "Human" refers to mean smoke intake recorded among participants using the CReSSmicro device.

The Figure 8 illustrates the large discrepancy in smoke intake between regular and low-yield brands for the Compensatory regime. This discrepancy reflects the "compensatory" nature of the testing parameters, which are more intense for "lower-yield" brands. The figure also shows the discrepancy between the smoke intake recorded among smokers using the CReSSmicro device and the smoke intake produced by the Human Mimic regime. This discrepancy was the result of different puff counts between participants and the Filtrona machine while conducting the Human Mimic testing regime. (The Filtrona machine was programmed to use the puff frequency recorded from human smokers, and to continue drawing puffs until the cigarette butt reached 23mm in length—the ISO standard.) Overall, participants took an average of 11.6 puffs while smoking their usual brand, compared to 13.1 machine puffs. In the "low-yield" smoking condition, participants took 13.6 puffs, versus 12.5 machine puffs. As a consequence, the Human Mimic regime produced 17% more smoke volume than participants for "regular-yield" brands and 7% less smoke volume for "low-yield" brands. These discrepancies should be taken into account when examining the cigarette yields from the Human Mimic regime, below.

5.3.2 Testing Protocols and Cigarette Yields

The smoke generated by each protocol was analysed for levels of nicotine, tar, and carbon monoxide (CO). The primary objective of including the Human Mimic regime, was to generate cigarette yields that approximated the levels of nicotine, tar and CO to which participants in the field trial were exposed. These "Mimic" yields could then be used as a benchmark to evaluate the standard testing protocols. As the following sections demonstrate, cigarette yields can be examined in several ways, including their absolute level, their concentration in a given amount of smoke, and their relation to each other.

Absolute values

Table 10 shows the tar, nicotine, and CO yields for regular and "low-yield" brands tested under each of the five regimes. As the Table 10 indicates, the Human Mimic regime generated twice the nicotine, and more than double the tar and CO as the ISO regime for "regular-yield" brands. Both the Massachusetts and Canadian regimes generated even greater levels of tar, nicotine, and CO as the Human Mimic regime, whereas the Compensatory regime generated similar yields as the ISO regime.

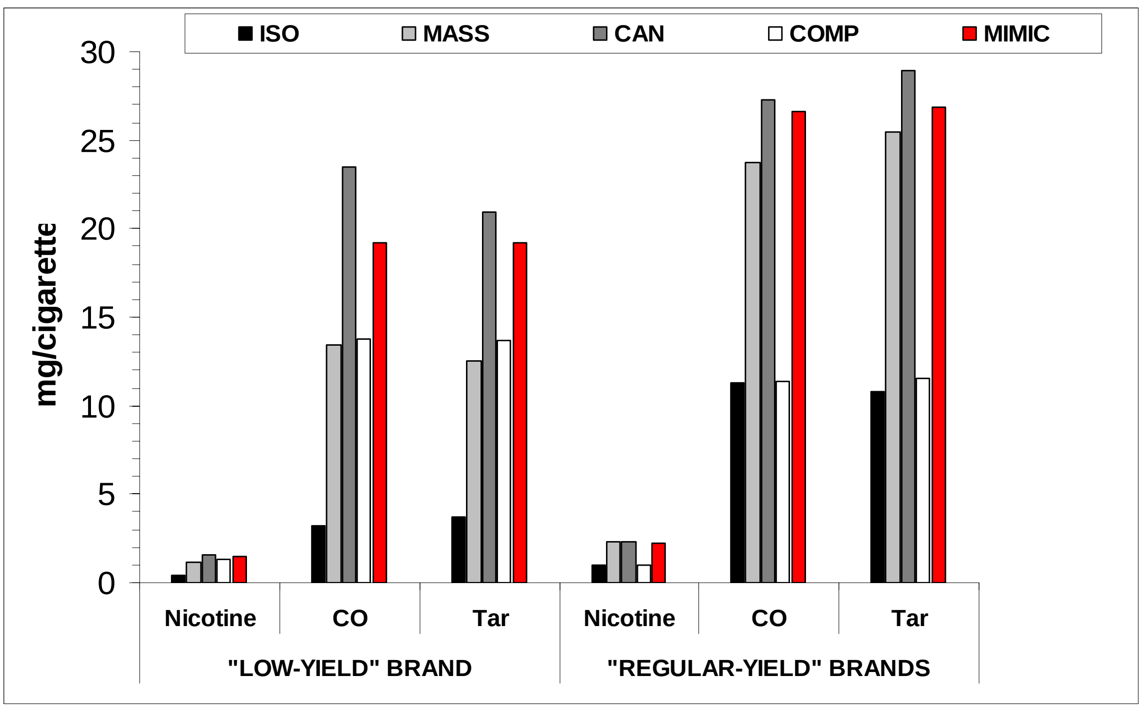
Table 10. Differences in cigarette yields according to testing regime

	ISO	MASS	CAN	COMP	MIMIC
"Regular-Yield" Brands					
Nicotine mg	1.0 (0.2)	2.2 (0.3)	2.3 (0.3)	1.0 (0.2)	2.0 (0.6)
Tar mg	12.0 (2.4)	25.7 (3.9)	30.3 (3.7)	11.6 (1.5)	25.1 (9.0)
Carbon Monoxide	11.8 (1.9)	23.6 (3.6)	27.9 (4.2)	11.5 (1.7)	25.0 (6.45)
"Low-Yield" Brand†					
Nicotine mg	.4	1.2	1.6	1.4	1.5
Tar mg	4.9	12.5	22.9	13.7	16.6
Carbon Monoxide	4.4	13.4	22.9	13.8	19.2

† Note: no standard deviations are listed given that only one low-yield brand was tested in the current study.

For the "low-yield" brand, the differences between the Mimic and the ISO regime were even more pronounced. The Mimic regime generated yields between three and four times greater than the ISO regime. The Canadian regime generated slightly higher yields than the Mimic regime, whereas the Massachusetts regime generated relatively lower levels for the "low-yield" brand. The yields generated by the Compensatory regime were somewhat higher than the Massachusetts regime, though still less than the Mimic regime. Note that the Canadian regime generated greater constituent yields than either the Massachusetts or the Mimic regime, despite generating less smoke. In other words, although the machine "inhaled" less smoke under the Canadian regime, this smoke was more concentrated, due to the 100% vent-blocking condition. Figure 9 illustrates the differences in smoke yields across the different testing regimes.

Figure 9. Nicotine, tar, and carbon monoxide (CO) yields under ISO, Canadian, Massachusetts & Compensatory testing regime



*CO = ppm / cigarette

The nicotine yields produced under the ISO regime were highly correlated with the Canadian (*r* =.75, *p*<.001), the Massachusetts (*r* = .88, *p*<.001), and the Compensatory regime (*r* = -86, *p*<.001), but not with the Human Mimic nicotine yields (*r* = -.08, p> .10). The same pattern was observed for tar and CO yields.

Concentration of Yields

The "absolute" levels of nicotine, tar, and CO shown in Figure 9 were generated under different smoking conditions and measured from different volumes of cigarette smoke. Expressing the levels of smoke constituents as concentrations can account for some of these differences across testing protocols. Table 11 shows the concentrations of tar, nicotine, and CO per litre of smoke.

Table 11. Concentration of smoke constituents per Litre of smoke, by testing protocol

	ISO	MASS	CAN	COMP	MIMIC
"Regular-Yield" Brands					
Nicotine (mg/1000ml)	3.3 (0.6)	3.8 (0.5)	3.6 (0.4)	3.5 (0.4)	3.1 (0.5)
Tar (mg/1000ml)	38.6 (9.4)	43.4 (8.8)	46.4 (7.3	41.2 (7.4)	38.9 (7.1)
CO (ppm/1000ml)	38.2 (9.6)	39.4 (6.0)	42.3 (5.6)	40.3 (5.3)	39.8 (6.9)
"Low-Yield" Brand					
Nicotine (mg/1000ml)	1.7	2.0	3.1	2.0	2.1
Tar (mg/1000ml)	17.5	21.5	42.4	20.7	22.9
CO (ppm/1000ml)	15.6	23.1	42.4	20.8	26.5

Table 11 indicates that the concentrations of nicotine, tar, and CO are more similar across testing regimes than the absolute levels presented in Table 10. For "regular-yield" brands, the difference in concentrations between the ISO protocol and the other regimes is generally around 10%. In fact, the "regular-yield" brands tested under the ISO regime produced concentrations that were almost identical to the concentrations generated under the Human Mimic protocol. The "low-yield" brand produced somewhat larger differences in concentrations across protocols. For example, the tar and CO concentrations under the Canadian protocol are more than twice the concentrations in the ISO protocol. These results suggest that the difference in absolute levels between protocols isn't simply due to a greater or lesser amount of smoke generated by each protocol. Rather, the smoking conditions also affect the concentration of nicotine, tar, and CO in given unit of cigarette smoke.

Ratio of Yields

Ratios of cigarette yields indicate how nicotine, tar, and CO vary in relation to each other. Given that smoking behaviour is generally assumed to be driven by nicotine, nicotine ratios indicate the levels of tar and CO smokers can expect to receive when extracting their nicotine dose. For example, a brand with lower tar/nicotine may be more favourable from a public health perspective than a brand with higher tar/nicotine. Table 12 (see following page) shows the mean ratio of tar/nicotine and CO/nicotine under each testing protocol.

As Table 12 indicates, there were considerable differences in the nicotine ratios across testing protocols. Among brands tested by the Canadian protocol, the range of tar/nicotine ratios was between 11.8 and 14.4—a difference of approximately 20% in the amount of tar delivered for a fixed amount of nicotine. There was a general trend towards higher tar/nicotine ratios as the intensity of the smoking regimes increased from ISO, to Massachusetts, to Human Mimic, to the Canadian regime.

Table 12. Ratio of tar and carbon monoxide to nicotine, by testing protocol

	ISO	MASS	CAN	COMP	MIMIC
“Regular-Yield” Brands					
Tar / Nicotine	11.4	11.4	13.0	11.6	12.5
(SD)	(1.0)	(0.9)	(0.7)	(1.2)	(1.4)
CO / Nicotine	11.3	10.5	11.9	11.5	12.7
(SD)	(1.4)	(1.4)	(1.2)	(1.2)	(1.4)
“Low-Yield” Brand					
Tar / Nicotine	10.2	10.5	13.8	10.1	10.9
CO / Nicotine	9.1	11.3	13.8	10.9	12.6

The tar/nicotine ratio for some brands may be more sensitive to different testing conditions than others. The ISO nicotine yield of a brand was strongly related to the change in tar and nicotine ratios. For example, lower ISO nicotine yields were associated with greater differences in the tar/nicotine ratios between the ISO and Canadian regime ($r = -.66$, $p = .004$) regime. In other words, brands that generated low nicotine yields under the ISO protocol were more likely to deliver higher tar/nicotine ratios under more intense smoking conditions.

Overall, these findings suggest that the testing protocols generate significantly different constituent profiles for the same brands, both in terms of the “raw” amounts of tar, nicotine, and CO, as well as the concentration and relative amounts of these constituents in cigarette smoke. In other words, the testing protocols provide much different characterizations of potential toxicity of cigarette brands. Compared to the yields generated under a testing regime that “mimicked” human smoking behaviour, the ISO protocol systematically underestimated human exposure levels for virtually every measure.

5.3.3 Cigarette Yields as a Predictor of Nicotine Uptake Among Smokers

The most common use of cigarette yields is to predict levels of individual exposure associated with a particular brand. For constituents such as nicotine, biological measures of uptake are available to test the extent to which the machine-tested nicotine yields are associated with the levels of exposure (i.e. cotinine). In the current study, we examined the association between cotinine levels collected from participants in the field study and the machine-tested cigarette yields from each of the five testing regimes. We also examined whether the individual measures of puffing behaviour collected from respondents were associated with cotinine and interacted with the nicotine yields in any way.

A linear regression model was run to examine predictors of cotinine. In Step 1, cigarettes per day (CPD), mean smoke intake, and the time of day the salivary cotinine sample was collected were entered into the model. All of the demographic variables were then entered. Only one variable—gender—was significant and remained in the model, whereas age, height, weight, and ethnicity were dropped from subsequent steps. Appendix H presents results the final model from Step 1.

In the second step of the model, two-way interaction variables were added. The interaction between CPD and smoke-intake was significantly associated with cotinine, and resulted in a significant increase in the total variance accounted for by the model (R^2 change=.21, p =.001). This relationship was consistent across trials for usual brand smoking, as well as for “low-yield” smoking at Trial 3. The results for Step 2 are presented in Appendix H.

In the third step, machine generated nicotine yields were entered into the model. (Note that a separate model was run for each of the testing protocols; results for each of the models are presented in Appendix H.) A summary of the results from these models is provided in Table 13. As the table indicates, only the Human Mimic yields were significantly associated with salivary cotinine levels, and that even human mimic yields were only modestly associated with cotinine. In other words, the nicotine yields of the ISO, Massachusetts, Canadian, and Compensatory models were not associated with nicotine uptake among participants, after adjusting for puffing behaviour and demographic variables. Also note that none of the machine generated yields were significantly associated with cotinine in bivariate analyses.

Table 13. Association between nicotine yield (mg) and saliva cotinine at Wave 1[†]

Testing regime	Beta*	*t* value	*P* value	Part Correlation	R^2
ISO	.25	1.90	.07	.24	.47
Massachusetts	.11	.78	.44	.10	.40
Canadian	.17	1.21	.23	.16	.45
Compensatory	-.23	1.6	.12	-.21	.44
Human Mimic	.37	2.5	.02	.31	.51

* Standardized beta

[†] Yields were entered into separate models and all values are adjusted for gender, time of cotinine sample, CPD, mean inhalation volume, and CPD x smoke intake.

A model incorporating the "intake-elasticity" variable was also run. Note that because the intake-elasticity variable incorporates both smoke intake and nicotine yield, it was treated as an interaction variable and entered into the model on the second step. The results indicate that the intake-elasticity variable was strongly associated with cotinine (β=.05, Partial r = .59), although the model with the intake-elasticity variable accounted for less variance in cotinine than the more parsimonious model incorporating the CPD x smoke intake interaction (R^2=.41 versus R^2=.51). In other words, there was no advantage to using the intake-elasticity variable.

Overall, the results indicate that the machine-tested cigarette yields bear little association with measures of nicotine uptake among participants. Indeed, even the Mimic yields that were derived from actual measures of human puffing behaviour were only moderately associated with individual levels of nicotine uptake.

5.4. Self-Report Puffing Behaviour

As the previous section indicates, physiological puffing behaviours are an important predictor of nicotine uptake and general exposure. The following section examines the extent to which smokers can accurately report these physiological measures of puffing. More specifically, the following section: 1) Characterizes responses to these self-report measures, 2) Show the relation between self-report measures at different timepoints, 3) Examines the association between self-report measures and CReSSmicro measures of puffing behaviour, and 4) Examines their association with nicotine uptake. In order to distinguish between self-report measures and their corresponding CReSSmicro measure, all self-report variables have been capitalized in the following section. In other words, "Puff Number" refers to the self-report measure administered in the surveys, whereas "puff count" refers to the actual number of puffs recorded by the CReSSmicro device during the one-week smoking trials.

5.4.1 Self-Report Versus CReSSmicro Measures of Puffing Behaviour

Participants in the field study were administered self-report measures on four separate occasions: during the initial recruitment telephone survey and immediately following each of the three one-week CReSSmicro trials. Table 14 (see following page) provides their responses to these measures at each of the four timepoints.

Table 14. Self-reported puffing behaviour: descriptive statistics (n=51)

Item	Recruitment Phone Survey	T1 Post-Cress Survey	T2 Post-Cress Survey	T3 Post-Cress Survey
Puff Number Scale (%)				
Only a few puffs on each cigarette	3.5	3.4	0.0	2.1
More than a few puffs, but not as many as you could	49.1	47.5	57.6	52.1
As many puffs as you can	47.4	49.2	33.9	45.8
Puff Depth (%)				
Not at all deeply	5.2	5.1	0.0	2.0
Somewhat deeply	65.5	62.7	70.4	59.2
Very deeply	22.4	25.4	16.7	20.4
As deeply as possibly	6.9	6.8	13.0	18.4
Puff Strength (%)				
You just puff, you don't really inhale	1.8	3.4	0.0	6.3
Inhale well back into your mouth	3.5	3.4	7.4	14.6
As far back as your throat	14.0	11.9	7.4	52.1
Only partly into your chest	54.4	52.5	57.4	27.1
As deeply into chest as possible	26.3	28.8	27.8	6.3
Put Cigarette Down (%)				
Never	10.3	5.1	7.4	12.2
Not at all often	13.8	23.7	31.5	20.4
Often	56.9	59.3	44.4	55.1
Very often	19.0	11.9	16.7	12.2

Table 14. Continued

Item	Recruitment Phone Survey	T1 Post-Cress Survey	T2 Post-Cress Survey	T3 Post-Cress Survey
Butt length (%)				
Half of the cigarette or less	6.8	0.0	1.9	0.0
Most of the cigarette	35.6	35.6	24.1	22.9
Nearly to the butt	49.2	47.5	61.1	64.6
Right to the butt	8.5	16.9	13.0	12.5
Puff Number (mean/SD) On average, how many puffs do you take on each cigarette?	14.2 (7.0)	11.2 (4.1)	12.4 (4.6)	12.6 (5.1)
Puff Frequency (mean/SD) On average, how long do you let the cigarette burn between puffs?	34.9 (43.4)	20.4 (26.8)	27.8 (42.2)	22.2 (32.9)

As Table 14 indicates, few respondents endorsed the "least intense" options for puff depth, strength, the puff number scale, or butt length. In addition, there was considerable variability in the number of puffs reported by participants, as well as the average frequency of puffs.

The post-trial measures may differ with the phone measures for two reasons: first, because of the different mode of administration (face-to-face vs. phone survey); and second, because participants have already answered the questions at least once, and recently completed the one-week trial with the CReSSmicro device. Table 15 examines potential differences between these two measures and their relation with the physiological puffing measures at Trial 1. (See Appendix I for the complete correlation matrix).

Table 15. Correlation between individual CReSSmicro and self-report measures of puffing at Trial 1

Item	CReSSmicro Measure	Pre-use Phone Survey	Post-Cress Survey
Puff Number (scale)	Puff count	-.06	.07
	Total intake	-.02	.08
Puff Number (open)	Puff count	.20	.30
	Total intake	.12	.05
Puff Depth	Puff volume	-.01	.22
	Mean flow rate	.09	.26
	Total intake	.20	.30*
Inhale Strength	Puff volume	.07	.07
	Mean flow rate	-.11	-.13
	Total intake	.11	.10
Puff Frequency	Puff frequency	.61**	.72**
	Total intake	.47**	.48*
Put Cigarette Down	Puff frequency	.27*	.30
	Total intake	.25	.33*
Butt length	Puff Number	.02	-.18
	Total intake	.05	-.05

*p< .05 **p<.01

As Table 15 indicates, the correlations varied considerably across puffing behaviours. For example, the Puff Number "scale" was virtually uncorrelated to puff count, whereas the "open-ended" Puff Number item was moderately correlated with puff count for both the pre and post-trial surveys. In some cases, the correlations between self-report and physiological measures of puffing differed between the pre and post-trial surveys. For example, the Puff Depth measure was uncorrelated to either puff volume or flow rate in the pre-trial survey, in contrast to the moderate correlations observed for the post-trial Puff Depth measure. Overall, there appears to be a trend towards increasing correlations from the pre to post-trial surveys. The self-report measure with the highest correlations was the measure of Puff Frequency. Both the pre-trial and post-trial versions of this item were strongly correlated with both puff frequency and smoke intake, as measured by the CReSSmicro.

A linear regression was conducted to examine which individual or combinations of self-report measures were associated with CReSSmicro measures of total smoke intake. Self-report measures with bivariate correlations greater than 0.10 were entered into a linear regression model predicting total smoke intake at Trial 1, adjusting for gender. Interaction variables were entered in the second step of the model. The results indicate that the most parsimonious model (R^2 = .17, p=.02) included only gender and self-reported Puff Frequency (β=1.9, p = .003, Part r =.47). Adding Puff Depth and a Puff Frequency x Puff Depth interaction variable (β=.65, p= .09, Part r =.26) provided a modest improvement in overall variance (R^2 change=.15, p=.05). Note that the same model was significant when using measures from the post-trial survey, rather than the pre-trial telephone survey.

Overall, these findings indicate a modest relationship between cross-sectional measures of self-report puffing behaviour and physiological measures recorded by the CReSSmicro device.

5.4.2 Changes in Self-Report Puffing Behaviour and Smoke Intake Across Trials

One important consideration for self-report measures concerns their sensitivity to changes in puffing behaviour over time. For each self-report measure of puffing, a difference score was calculated by subtracting the value at Trial 3 by the value at Trial 2. Differences were also calculated for the physiological measures of puffing behaviour collected through the CReSSmicro at Trial 2 and 3. (Note that changes between Trials 2 and 3 were used because the brand-switching condition ensured a reasonable degree of change among physiological measures against which to validate the self-report measures.)

Table 16 shows the “within-subject” correlations between changes in self-reported and physiological measures of puffing behaviour between Trials 2 and 3. As Table 16 indicates, change in self-report Puff Number was significantly correlated with changes in puff count over the same period. Change in the self-report Puff Depth was also moderately correlated with changes in total smoke intake (r = .28, p=.08). A complete correlation matrix is provided in Appendix J. The same correlation matrix was generated after splitting the sample into the brand-switching and usual brand conditions. There were no significant differences in the patterns of results. Overall, it would appear that self-report measures of puffing behaviour are somewhat less stable over time than the physiological measures collected through the CReSSmicro device, which exhibited strong correlations across trials, as indicated earlier in Table 7.

Table 16. Changes in self-report and physiological measures of puffing behaviour between Trial 2 and Trial 3 (n=51)

Post-Use Survey	CReSSmicro Measure	Correlation
Puff Number (scale)	Puff count	.31*
	Total Intake	.24
Puff Number (open)	Puff count	.02
	Total Intake	.01
Puff Depth	Puff volume	.18
	Mean flow rate	.05
	Total Intake	.28
Puff Strength	Puff volume	.07
	Mean flow rate	-.02
	Total Intake	.13
Puff Frequency	Puff frequency	.16
	Total Intake	.15
Put Cigarette Down	Puff frequency	.07
	Total Intake	-.01
Butt length	Puff count	.04
	Total Intake	.04

* $p < .05$

A linear regression was conducted to examine whether combinations of self-report variables were related to changes in total smoke intake between Trials 2 and 3. Self-report measures with bivariate correlations greater than 0.1 were entered into a linear regression model predicting total smoke intake, adjusting for gender. A model including only self-report Puff Depth (β=74.6, Part r =.32, p=.05) was the most parsimonious model (R^2 =.13, p=.09). No other variables or interactions were significant. In other words, puff depth was the only self-report puffing measure that was associated with physiological changes in smoke intake.

We also examined whether self-report measures could discriminate between "usual-brand" smokers and those who were switched to the "low-yield" brand in Trial 3. Recall that participants who were switched to the "low-yield" brand for Trial 3 demonstrated significantly greater CReSSmicro measures of puff volume and total smoke intake relative to participants in the control condition, as noted in Section 5.1.7. We examined whether self-report puffing measures also differed between these groups. The results indicate that, compared to "usual brand" smokers at Trial 3, participants who switched to a low-yield brand reported smoking more of the cigarette (t=2.2, p=.03), reported taking more puffs per cigarette (t=1.9, p=.07), and reported puffing more deeply (t=2.9, p=.01). Overall, it would appear that the physiological changes in puffing intensity observed among "brand-switchers" were accompanied by increases in self-reported measures of puffing.

5.4.3 Self-Report Puff Behaviour as a Predictor of Nicotine Uptake

Perhaps the most important test of self-report measures is the extent to which they are associated with biological measures of uptake. A linear regression was conducted to examine whether self-report puffing measures were associated with salivary cotinine levels at Trial 1. Self-report measures were selected from the pre-trial telephone survey given that these would provide the greatest generalizability to other population-based phone surveys. The first step of the regression model included the main-effect variables of gender, cigarettes per day, time of saliva sample, and Human Mimic nicotine yield—the variables previously found to be associated with cotinine, as described in Section 5.1.1. In the second step of the model, self-report measures of puffing that were correlated 0.1 or greater with cotinine were entered. Two-way interaction variables were entered in a third step.

Table 17. Self report cotinine predictors at Trial 1(n=51)

	Beta*	***t***	***p***	**Part correlation**
Pick-up time	0.37	3.12	0.00	0.36
Gender (Males=reference)	0.08	0.64	0.52	0.07
CPD	0.07	0.57	0.57	0.07
Nicotine Yield (Human mimic)	0.23	1.93	0.06	0.22
Puff Depth (self-report)	0.27	2.17	0.04	0.25
Butt length (self-report)	0.27	2.27	0.03	0.26
Puff Depth x Butt length	0.89	1.67	0.10	0.19

* Standardized Beta Model R^2= .26, p =.002

As Table 17 indicates, the addition of two self-report variables, Puff Depth and Butt Length, accounted for a significant proportion of variance in cotinine (R^2 change= .17 p=.004) after adjusting for gender, CPD, time of saliva collection, and nicotine yield. A two-way interaction variable between Puff Depth and Butt Length was moderately associated with cotinine levels, although it failed to reach conventional levels of significance (*Part r* =.19, p=.10).

5.4.4 Changes in Self-Report Puffing and Nicotine Uptake Across Trials

A second linear regression model was conducted to examine whether changes in cotinine from Trial 2 to Trial 3 were associated with changes in self-report measures from the post-trial surveys. As Table 18 shows, changes in self-report measures of Puff Strength and Puff Number (open-ended) were significantly associated with changes in cotinine over the same time interval. No interactions were significant.

Table 18. Self-report predictors of cotinine change (n=44)

	Beta*	***t* value**	***p* value**	**Part correlation**
Change in CPD	0.12	0.86	0.40	0.12
Nicotine Yield (Human Mimic)	0.21	1.47	0.15	0.21
Puff Strength change (self-report)	-0.28	-1.94	0.06	-0.27
Puff Number change (self-report)	0.26	1.87	0.07	0.26

* Standardized Beta Model R^2= .21, p =.045

5.4.5 Summary

Overall, these findings provide some preliminary evidence that smokers are able to accurately report their puffing behaviour. In some cases, self-reported puffing was associated with measures of exposure, including changes in exposure over time. However, there were inconsistencies across models in terms of the individual self-report items that predicted smoke intake and salivary cotinine.

5.5. Self-Report Measures of Puffing in the ITC Survey

The ITC survey provided an opportunity to examine self-report measures of puffing behaviour in population-based surveys. The following section provides a brief description of the ITC Sample, responses to the puff measures from the four nationally representative samples, as well as preliminary analyses of the relation between self-report puffing behavior, demographic variables, and measures of consumption.

5.5.1 Sample

A total of 7,802 adult smokers responded to the Wave 2 of the ITC survey. Approximately 79% were recruited with the original cohort at Wave 1 (conducted 8-months earlier), and the remaining 21% were recruited at Wave 2 to "replenish" the original cohort members lost to attrition. A total of 70% (n=5,408) of Wave 2 respondents also completed the Wave 3 survey. Table 18 shows the sample sizes and Wave 3 follow-up rates for each country. Appendix Table 19 shows the sample characteristics of Wave 2 respondents by country.

Table 19. ITC sample size at Wave 2 and 3.

	CAN	US	UK	AUS	Total
Wave 2 Respondents	2,004	1,896	1,928	1,976	7,802
Wave 3 Respondents	1,430	1,072	1,312	1,431	5,245
Follow-up Rate	71.3%	57.0%	68.0%	72.4%	67.2%

5.5.2 ITC Measures of Self-Report Puffing Behaviour

Three measures of self-reported puffing were included in the Wave 2 survey ("Butt Length," "Puff Strength," and the "Puff Number" scale). The Puff Strength question was re-administered at Wave 3, along with a measure of Puff Frequency. As noted in the Methods section, all of the measures were derived from the field study of smoking behaviour. Table 20 shows responses to each of the five measures.

Table 20. ITC self-report puffing behaviour (n=7,302)

	CAN	**US**	**UK**	**AUS**	**Total**
Butt length –Wave 2 (%)					
"Half or less"	11.2	15.3	11.0	5.5	10.8
"Most of cigarette"	26.6	29.3	36.4	33.6	31.6
"Nearly to the butt"	41.3	37.9	40.4	42.4	40.5
"Right to the butt"	20.9	17.2	12.2	17.5	17.1
Puff strength –Wave 2 (%)					
"Don't inhale into chest at all"	2.9	2.8	3.4	2.3	3.0
"A little into chest"	33.9	31.2	34.4	29.8	34.9
"Deeply into chest"	48.1	51.0	37.3	41.8	48.2
"As deeply as possible"	14.1	14.0	11.5	12.1	13.9
Puff number –Wave 2 (%)					
"Only a few puffs"	10.0	10.4	10.3	6.6	8.8
"More than few"	50.5	56.1	56.2	57.8	53.6
"As many as you can"	39.5	33.5	33.5	35.6	37.6
Puff strength –Wave 3 (%)					
"Don't inhale into chest at all"	1.9	1.3	3.2	2.9	2.4
"A little into chest"	33.5	36.3	42.8	35.1	36.8
"Deeply into chest"	53.1	48.2	45.1	50.7	49.4
"As deeply as possible"	11.5	14.2	8.9	11.3	11.4
Puff frequency –Wave 3					
Mean (SD)	36.5 (43.7)	36.1 (45.2)	33.1 (50.0)	28.3 (40.3)	33.4 (44.0)

5.5.3 ITC Predictors of Self-Report Puffing Behaviour

A linear regression was conducted to examine whether demographic variables and measures of consumption were associated with self-reported puffing behaviour. Each of the four measures of puffing behaviour served as the dependent variable in separate regression models. Appendix J includes full results for each model. Several patterns emerged across models. Cigarettes per day demonstrated the strongest association with each of the puffing measures: Butt length (*Part* r = .14, p<.001), Puff Strength (*Part* r = .15, p<.001), Puff Number (*Part* r = .18, p<.001), and Puff Frequency (*Part* r = .07, p<.001). Age was also significantly associated with each of the puffing measures: Butt length (*Part* r = -.09, p<.001), Puff Strength (*Part* r = -.09, p<.001), Puff Number (*Part* r = .10, p<.001), and Puff Frequency (*Part* r = -.15, p<.001). In other words, younger smokers and those who smoked more cigarettes per day consistently reported more intensive puffing. In addition, education level was negatively associated with Butt Length (*Part* r = -.03, p<.001) and Puff Strength (r = -.04, p<.001), intention to quit was negatively associated with Puff Strength (*Part* r = -.08, p<.001) and Puff Number (*Part* r = -.05, p<.001), and Income was negatively associated with Puff Strength (*Part* r = -.03, p=.02).

Several country-level differences were also noted. Canadian respondents reported shorter Butt Lengths than US (*Part* r = .08, p<.001) and UK respondents (*Part* r = .08, p<.001), as well as a greater number of puffs than UK respondents (*Part* r = .05, p<.001). Canadian and US respondents reported stronger puffing than UK respondents (*Part* r = .05, p<.001 for both), whereas Australian respondents taking more frequent puffs than Canadians (*Part* r = .07, p<.001). No interactions were significant in any of the models. It should also be noted that the magnitude of the “significant” associations observed in these models is small. The significance of these variables is mainly a reflection of the large sample size in the analysis.

5.5.4 ITC Brand-Related Predictors of Self-Report Puffing Behaviour

One potential use of self-report measures in population-based surveys is to examine compensatory smoking behaviour in response to changes in cigarette brands. Among ITC respondents, brand-related information was only available for a sub-sample of 1,413 Canadian respondents (71% of all Canadian respondents). For this sub-sample, ISO nicotine yields were matched with participants' "usual" cigarette brand. The ISO nicotine yield was then entered in the final step of the linear regression models reported in Table 20 (i.e. adjusting for cigarette consumption and demographic variables). As Table 21 indicates, ISO yield was significantly associated with Puff Number and Puff Frequency; however, as in earlier models, the magnitude of these associations were modest.

Table 21. Linear regression ISO nicotine yield (n=1,413)†

	Beta*	***t* value**	***p* value**	**Part *r***
Butt Length (Wave 2)	-.03	-1.25	.21	-.03
Puff Strength	.03	1.09	.28	.03
Puff Number	-.05	-2.05	.04	-.05
Puff Frequency	-.07	-2.61	-.01	-.07

† Adjusting for gender, age, education, income, CPD, and intention to quit

* Standardized Beta

Overall, it would appear that the ISO nicotine yield was generally not related to measures of self-report puffing among Canadian respondents.

5.5.5 Changes in Self-Report Puffing Behaviour Across Survey Waves

As Section 5.5.3 indicated, Puff Strength was significantly associated with CPD among ITC respondents. The compensatory nature of cigarette smoking suggests that reductions in the number of cigarettes per day (CPD) or changes in cigarette brand may have implications for puffing behaviour, as participants attempt to regulate their nicotine intake. A linear regression was conducted to examine whether changes between Waves 2 and 3 in CPD or "usual" cigarette brand were associated with changes in Puff Strength. (Recall that Puff Strength was the only self-report measure of puffing behaviour to be asked at both Waves 2 and 3 of the ITC survey.) First, there was a reasonably strong correlation between measures of Puff Strength at Waves 2 and 3 (r =.59, p<.001), suggesting moderate stability over time. The results of the linear regression failed to reveal any significant association between changes in Puff Strength, changes in CPD and usual brand smoking, or any of the demographic variables entered into the model (see Appendix K). Australian respondents reported somewhat fewer changes in puff strength relative to Canadian respondents (*Part r* = .03, p= .03), although the magnitude of this difference was modest. Overall, although there was a reasonable degree of change in self-reports of Puff Strength between waves 2 and 3 of the ITC survey, this changes was not associated with any of the individual variables we examined in the analyses.

6.0 DISCUSSION

To our knowledge, this research represents the most comprehensive independent study to examine smoking topography, brand switching, and nicotine uptake outside a laboratory setting. This study also provides the first independent evidence on the parameters of puffing behaviour among Canadian smokers. These parameters were collected using novel technology that permitted “naturalistic” measures of puffing behaviour outside the laboratory setting. Overall, participants reported that the CReSSmicro device was easy to use, and caused only modest changes to their normal smoking behaviour. The “user-friendliness” of the device is supported by the fact that participants smoked well over 6,000 cigarettes through the device over the course of the study.

6.1 Naturalistic Measures of Puffing Behaviour

The puffing behaviour collected through the CReSSmicro device provides a unique opportunity to examine naturalistic measures of puffing behaviour among a sample of Canadian smokers. Overall, the data indicates a high degree of stability in puffing behaviour within the same smoker over time, but considerable variability between smokers. Total smoke intake –the amount of smoke participants inhaled from each cigarette—varied widely among individuals smoking their usual brand of cigarettes: participants in the top quartile of smoke intake inhaled approximately two and a half times the volume of smoke as individuals in the lowest quartile of smoke intake. Puffing behaviour also varied between male and female smokers. The results indicate that female smokers took more puffs per cigarette, but significantly smaller puffs than males, such that they inhaled less smoke overall, per cigarette, than males. This is consistent with previous laboratory-based studies of puffing behaviour[96,97], as well as previous reports of lower cotinine levels among females.[98,99]

There are several reasons why females exhibit less intense puffing behaviour and lower overall levels of smoke intake. First, lower levels of smoke intake among females may reflect differences in the rate of nicotine metabolism among women, although the research is inconclusive on this issue.[100, 101,102] Lower levels of intake among women may also reflect differences in body mass and size. Body mass is a factor in the clearance of nicotine from the body, whereas differences in lung capacity may account for the lower puff volume observed among females.[101] Overall, the gender differences in puffing behaviour and nicotine uptake observed in the current study may have important implications for understanding risk-exposure among women. They make also have implications for understanding cigarette design: internal research documents from tobacco manufacturers indicate that some brands have been designed to respond to the less intense puffing patterns among women. For example, research from *British American Tobacco* found that slim cigarettes provide greater ease of draw compared to other "low-tar" cigarettes, and respond well to females' lighter draw tendencies.[102]

The results from the current study also indicate that puffing behaviour varied widely between smokers of a single brand. Indeed, the variability in smoke intake within the two most popular brands was equal to, or greater than the variability observed among all smokers. These findings highlight the importance of individual nicotine "thresholds" and their variability across smokers. Some individuals are simply lighter smokers and pursue lower levels of nicotine, whereas others smoking the same brand have higher nicotine thresholds and must smoke each cigarette more intensely. Differences in nicotine thresholds are related to an individual's nicotine metabolism: individuals with faster metabolic rates need to smoke more intensely in order to regulate nicotine levels.[101]

There is some evidence that smokers with greater nicotine thresholds smoke brands with higher ISO nicotine yields, although the extent of this self-selection appears to be relatively modest.[51,103] In other words, each cigarette brand seems to recruit smokers with a range of nicotine thresholds and there is only a modest association between the nicotine yield of a product and puffing intensities for usual brand smokers.[39,104,105] The current findings are consistent with this research: puffing behaviour and cotinine levels of participants varied widely within brands and there was no discernable association between ISO nicotine yield and the intensity of puffing among “regular-yield” brands.

There was, however, a strong association between puffing behaviour and nicotine uptake among smokers. Total smoke intake, or inhalation volume, derived from measures of puff volume and puff number, was a strong predictor of nicotine uptake. The interaction between cigarettes per day and smoke intake was the strongest predictor of nicotine uptake measured in the current study. This interaction represents the total smoke exposure for each individual, taking into account both the total number of cigarettes and the smoke extracted from each cigarette. Overall, these findings suggest that individual differences in how each cigarette is smoked have important implications for overall risk exposure.

In terms of the specific parameters of puffing behaviour, the current results for “regular” brand yields are somewhat more intense than previous research for usual-brand smoking,[16] but generally consistent with more recent studies.[106,107] As industry scientists have noted, widespread changes to cigarette designs, such as the introduction of filter ventilation, appear to have shifted the “normal” parameters of puffing behaviour toward more intensive smoking: "We have found a trend within the department for smokers to increase the volume of smoke drawn from cigarettes as the standard deliveries have been reduced by manufacturers.”[108] The current findings may be further evidence of this trend. It should be noted, however, that the puffing parameters observed in the current study for “low-yield” smokers may be somewhat different than the parameters among those who smoke *Matinee Extra Mild* –the “low-yield” brand—as their usual brand. Nevertheless, the inhalation volumes among the “switchers” in the current study were consistent with data from other studies from those who smoke “low-yield” products as their usual brand.[106]

6.2 Changes in Response to a "Low-Yield" Cigarette Brand: Smoker Compensation

This study provides strong support for behavioural compensation in response to changes in brand yield. The naturalistic measures of smoking topography are consistent with laboratory-based findings that smokers make substantial changes to their puffing behaviour when switching from "regular" to "low-yield" cigarettes in order to maintain their level of nicotine intake. The compensatory changes observed in the current study were stable, with no observable degradation over the course of five days. It would appear that participants also attempted to compensate by increasing their daily consumption: participants who were switched to the "low-yield" brand increased their daily cigarette consumption by approximately 1.5 cigarettes or 8% per day while smoking the "low-yield" brand. This is consistent with previous research which suggests that smokers compensate through changes in the number of cigarettes, as well as the intensity with which each cigarette is smoked.[24,109]

Overall, the 12% reduction in salivary cotinine levels observed among the "low-yield" switchers was significantly less than the 64% reduction in nicotine yield when compared to their usual brand. Nevertheless, it would appear that most smokers stopped short of complete compensation. It simply may not have been possible for smokers to compensate for such a large change in nicotine yield, particularly while using the CReSSmicro device, which can interfere with filter vent-blocking (see Section 6.6, below). Perhaps for this reason, it is rare for smokers to switch between products with such a large discrepancy in nicotine yields, at least outside of research studies.

The current findings are generally consistent with previous research on smoker compensation. For example, two of the largest brand-switching studies randomised substantial numbers of smokers to "low-yield" brands and followed them over a period of six months.[110,111] In the one study,[111] nicotine compensation was essentially complete; in the other, it was estimated to be approximately 80%.[110] Studies of spontaneous brand switching depict the same pattern: smokers increase the intensity of their smoking to compensate for lower-yield products.[24] These studies have important public health implications. Smokers who spontaneously switch to a "low-yield" brand are often driven by a desire to reduce the health consequences of smoking and may result in some smokers delaying quitting.[112] The current study contributes to the evidence on compensatory smoking, which negates most or all of the potential health effects of switching to a "low-yield" product.

6.3 Testing Protocols and Human Smoking Behaviour

In their 1936 paper, the originators of the *Cambridge Filter Method* state that cigarette testing protocols should, "sufficiently approximate the conditions of human smoking" (p.836).[10] The results from the current study indicate that the ISO protocol fails this basic criterion. The findings indicate that the ISO testing parameters systematically underestimated every measure of puffing behaviour recorded among human smokers. The average smoke intake from the ISO regime ranked only in the 7th percentile of human smokers for "regular yield" brands, and fell below the lowest smoke intake among "low-yield" smokers. It should also be noted that the smoke collected through the ISO regime was drawn at a much lower flow-rate than was observed among human smokers (18ml/sec vs. 38ml/sec). Flow-rate has important implications for filter efficiency, as well as the proportion of diluting air that enters through the porous paper in the tobacco rod and through filter vents. As a consequence, flow rates affect the concentration of constituents, as well as the ratio of tar to nicotine.[48] Flow rates are also associated with greater depth of inhalation and greater lung exposure to the toxic constituents in tobacco smoke.[113] Indeed, the changes in inhalation patterns induced by "low-yield" cigarettes are thought to be responsible for an increase in the incidence of adenocarcinoma of the lung among smokers, a form of lung cancer that is specifically associated with deeper lung exposure.[113,114]

The three alternative testing protocols examined in this study represented an improvement on the ISO method; however, none reflected "intensive" human smoking. The puffing parameters used in the Canadian and Massachusetts regimes fell somewhere near the mean for "regular-yield" smoking, whereas the Compensatory protocol drastically underestimated the puffing parameters of "regular-yield" smoking, almost to the same extent as ISO. These results suggest that the "starting point" for the compensatory regime (40ml puffs drawn every 60 seconds) was simply too low. For "low-yield" smoking, all three alternative protocols drastically underestimated human puffing parameters. The Compensatory regime was closest to the actual smoke intake for "low-yield" smoking, although it still only ranked in the 42nd percentile of human smokers.

It may seem counter-intuitive that the Canadian regime did not generate greater smoke intake than the Massachusetts regime, given the greater intensity of the puffing parameters (55ml puffs and 100% vent blocking vs. 44ml puffs and 50% vent blocking, respectively). However, more intensive puffing and complete ventilation blocking has the effect of increasing the burn rate of the cigarette. In other words, larger, faster puffs that are drawn with the filter ventilation completely blocked consume more of the cigarette rod with each puff and reduce the total burn time of the cigarette. Because the Canadian and Massachusetts regimes draw puffs at the same frequency, the more intensive puffing parameters of the Canadian regime resulted in a lower number of puffs per cigarette as the cigarette rod was consumed more quickly (11.2 vs. 13.7, respectively). Nevertheless, as the following section indicates, the Canadian regime generated more concentrated smoke per puff, and produced greater constituent yields than the Massachusetts regime for every cigarette tested in the current study.

6.4 Testing Protocols, Cigarette Yields, and Human Exposure

The Human Mimic regime provided an opportunity to evaluate the ISO, Massachusetts, Canadian, and Compensatory cigarette yields, against yields generated under "realistic" human smoking conditions. For "regular-yield" brands, the results from the Mimic regime suggest that smokers typically ingested double the tar, nicotine, and carbon monoxide than was indicated by either the ISO and Compensatory regimes. The

Massachusetts regime generated yields closest to the Mimic yields for regular-yields brands, whereas the yields from the Canadian regime were somewhat higher than the mean Mimic yields.

For the “low-yield” brand, the discrepancy between the ISO and Mimic yields was even greater than for “regular-yield” brands: the Mimic regime suggests that participants were exposed to tar, nicotine, and CO levels more than four times greater than the ISO yields. Both the Massachusetts and Compensatory protocols fell slightly below the mean Mimic yields, whereas the Canadian yields were slightly above the mean.

Overall, the constituent yields from the different testing protocols are consistent with what one would expect from the testing parameters: the ISO regime systematically underestimated exposure for all brands; the Compensatory regime failed with respect to “regular-yield” brands; whereas the Massachusetts and Canadian protocols were generally at or slightly above the mean of human measures of intake and exposure. It should be noted that both the Canadian and Massachusetts protocols were originally designed to reflect intensive smoking conditions; in fact, the Canadian protocol is often referred to as a “maximum” smoking regime. However, the current results would seem to suggest that these regimes reflect “average” smoking conditions, rather than intensive ones. Given that the majority of Canadian, U.S., and U.K. consumers smoke “low-yield” brands, these alternative protocols may even fall short of the average smoke intake for the vast majority of smokers.[115,116]

As Section 5.3.1 indicated, there was some discrepancy between the mean number of puffs recorded from participants and the number taken by the Filtrona machine when conducting the Human Mimic regime. This discrepancy generated 17% more smoke for “regular-yield” brands and 7% less smoke for the “low-yield” brand compared to mean inhalation volumes recorded from participants. As a result, the Mimic values for “regular-yield” brands may be slightly exaggerated, whereas the “low-yield” values may represent a slight underestimate.

To our knowledge, this is the first independent study to use brand elasticity to predict nicotine uptake. Brand elasticity functions as a type of summary measure for how different product features, such as filter ventilation, interact with smoker behaviour to produce different patterns of exposure. (Ideally, these product variables would be entered directly into the analytical models; however, they were unavailable for the current analysis.) The elasticity variable used in the current study was associated with cotinine levels, but not to a greater extent than cigarettes per day and measures of intake alone. One potential explanation for this null finding is that the brand data used to calculate elasticity was almost ten years old. Tobacco manufacturers periodically make design changes to their brands and any changes over the past ten years to the brands in the current study would introduce measurement error into the elasticity variable and reduce the likelihood of detecting "actual" differences between the brands.

Further research is needed to evaluate the value of brand elasticity as a predictor of exposure. However, as Jarvis et al. have noted[51], nicotine preferences, rather than product features, seem to be the most important determinant of nicotine deliveries. Design related factors that appear to deliver differences under the ISO testing protocol, are typically "over-ridden" by compensatory behaviours. It should be noted that all of the cigarettes on the Canadian market have more than enough nicotine to satisfy even "high threshold" smokers without requiring unreasonable puffing intensities. It is not the case that "low-yield" cigarettes are made from low-nicotine tobacco; rather, the total nicotine content from "low-yield" products is typically equal to or even greater than the nicotine content in "regular-yield" products.[117,118] It is only under the deceptive testing conditions of the ISO protocol that "low-yield" brands appear to contain less tar and nicotine. Indeed, "low-yield" status is almost entirely due to the smoke dilution through the filter vents under the ISO protocol[118]: a secondary analysis of Phillip Morris data[119] revealed an almost perfect correlation ($r = 0.93$, $p<.001$) between ISO nicotine yield and the percentage of filter ventilation.[120] In other words, it isn't the case that the smoke from ventilated cigarettes is inherently different than smoke from unventilated brands; rather, the "low-yields" simply reflect the fact that the ISO regime draws in a considerable proportion of air mixed with the smoke, when testing cigarettes.

The effect of filter ventilation is also apparent in the concentration of nicotine and tar in cigarette smoke. The results provide a comparison on nicotine and tar yields from the ISO regime (0% ventilation blocking) and the Canadian regime (100% ventilation blocking) that illustrates this effect. Among the low ventilated "regular-yield" brands there is only a 10% increase in the concentration of nicotine, and a 20% increase in the concentration of tar from the ISO to the Canadian regimes. However, for the highly ventilated "low-yield" brand, the nicotine concentration increased by 82% and the tar yield increased by 142%. In other words, once the filter ventilation is blocked, the concentration of the smoke constituents increases significantly, and "low-yield" products begin to perform much the same as "regular-yield" brands. Overall, filter ventilation allows smokers to titrate their nicotine more effectively. In short, smokers can and do extract whatever level of nicotine they desire from virtually any brands on the market.

The variability in puffing behaviour and cotinine levels has important implications for how cigarette yields should be interpreted. The current results suggest that the yields from the Massachusetts and Canadian protocols are no better at predicting cotinine levels than ISO yields. Indeed, even the Mimic yields, which were derived from actual puffing behaviour, were only moderately correlated with salivary cotinine levels. Given the heterogeneity of smokers using each brand, there are inherent limitations to using a single mean value to predict individual exposure. As the current study demonstrates, this limitation is present even if the mean puffing parameters for each brand can be accurately predicted and replicated by the machine. In short, no testing protocol will be capable of providing accurate <u>individual</u> estimates of exposure.

Some observes have suggested that one way to make cigarettes yields more relevant to individual smokers may be to express cigarette yields in terms of ratios to nicotine.[7] If nicotine is the driving force behind smoking behaviour, then it may make sense to "anchor" yields to nicotine. In other words, nicotine ratios help to "adjust" for the fact that individuals extract different levels of nicotine, and communicates the proportion of toxic constituents (e.g., tar) that smokers might expect from a brand when reaching their nicotine level. This approach rests upon the assumption that, although the total amount and concentration of tar and nicotine change under different smoking conditions, the ratios of constituents are relatively fixed. However, as the current results indicate, the ratios do change across smoking conditions. For example, the ratio of tar/nicotine for the "low-yield" brand tested under the ISO regime increased by 36% when the same brand was tested under the Canadian regime. This suggests that smokers who reach their nicotine threshold under puffing conditions similar to the Canadian regime stand to ingest 36% more tar compared to smokers who reach the same nicotine threshold only under the less intensive puffing parameters of the ISO regime. In short, tar and nicotine ratios are not constant across different smoking conditions, at least not to the extent that is commonly assumed. As a consequence, expressing cigarette yields as nicotine ratios is unlikely to make machine tested cigarette yields much more relevant to individual smokers.

Several researches have noted that many of these issues might be minimized by comparing cigarette brands at the same nicotine level. Each of the "standard" testing regimes (i.e., the ISO, Massachusetts, and Canadian regimes) test different brands at the same puffing conditions; however, the different design properties of brands ensure that these puffing conditions produce much different levels of nicotine within the same testing protocol. For example, for brands in the current study, the smoking conditions used by the Canadian regime produce nicotine yields with a range between 1.6 and 2.8mg. As a consequence, the denominator for the tar/nicotine ratios differs across brands tested under the same protocol. To compare ratios from similar doses of nicotine (i.e., to ensure that the denominator in the tar/nicotine ratio is the same across brands), some brands would need to be smoked at much more intensive levels.

The Compensatory regime tested in the current study attempts to accomplish this by varying the smoking conditions in an attempt to equalize nicotine levels across brands. However, as the current results indicate, the Compensatory puffing regime was not successful in mirroring the differences in human smoking behaviour across brands. As a consequence, instead of achieving a nicotine yield of 1mg across all brands, the

Compensatory regime yielded a range between 0.8 and 1.2mg. The Human Mimic nicotine yields would also suggest that using 1mg of nicotine as the benchmark for exposure is too low. Other compensatory alternatives have recently been suggested and are currently under consideration by a WHO committee charged with the responsibility to revise the ISO regime.[121]

Overall, the current results indicate that, whatever metric is used to express cigarette yields—absolute levels, concentrations, or ratios—testing protocols must account for two fundamental realities of human smoking behaviour: 1) There is great natural variability in puffing behaviour within any one brand, and 2) Smokers will adjust their behaviour when switching products to account for differences in design and nicotine delivery. The findings indicate that none of the testing protocols examined in the current study fully account for realities. However, this is not to suggest as the tobacco manufacturers have argued, that the ISO regime is no worse than the other alternatives examined in the current study. The ISO regime systematically underestimates risk exposure, and exaggerates the differences between ventilated and un-ventilated brands to a far greater extent than the other testing regimes. This was true for regardless whether one consider the absolute levels, concentrations, or ratios of nicotine, tar, and carbon monoxide. In short, the ISO protocol introduces deceptive differences between brands that, when communicated directly to smokers, are prone to misunderstanding and misuse.

6.5 Self-report Measures of Smoking Behaviour

To our knowledge, this was the first study to attempt to validate self-report measures of puffing using physiological measures of smoking behaviour. The results from the field study suggest modest correlations for certain parameters, such as Puff Frequency, and to a lesser extent for measures of Puff Depth and Puff Number. There was a trend towards higher correlations in the Post-Trial surveys, compared to the recruitment telephone survey. It may be that using the CReSSmicro device and participating in the study may have caused respondents to become more aware of their puffing behaviour.

There were several inconsistencies noted in the self-report data. For example, the Post-Trial survey measures of Puff Depth and Puff Frequency were correlated at .80 (p<.001) at Trial 1, but only .18 at Trial 2 (p=.22), and .14 at Trial 3 (p=.34). The reasons for these discrepancies are unclear. There were also inconsistencies across the models predicting intake and exposure. For example, Puff Depth and Butt Length predicted levels of cotinine at Trial 1 in cross-sectional analyses; however, Puff Strength and Puff Number were associated with changes in cotinine between Trials 2 and 3. However, there was a general pattern in which one measure of either Puff Depth or Strength, and one measure of puff number—Puff Number, Frequency, or Butt Length— were present in each of the models. Given that puff volume and puff number are the two determinants of smoke intake, this is consistent with what one might expect.

It is not entirely clear, however, why the individual variables varied across models. One possibility is that some self-report measures may be less sensitive to changes, perhaps because the size of meaningful differences may escape awareness. For example, a 20% difference in puff frequency only amounts to approximately 6 seconds for the average participant. This magnitude of change may simply escape detection.

Given the high frequency, recentness, and apparent stability of puffing behaviour, it seems unlikely that some of the biases and cognitive errors typically associated with retrospective self-reports, such as telescoping, would be responsible.[122] However, the cognitive phenomenon known as "rounding" may be at play for open-ended measures of Puff Number and Puff Frequency. Rounding occurs when respondents give prototypical answers to questions, such as rounding time into minutes, rather than seconds. More generally, the distribution of responses for some of the self-report measures raises questions about their structure. For example, very few respondents endorsed the "lowest" response categories for the Puff Number scale and Puff Depth. This suggests that at least some of the response options could be revised to better discriminate between the smokers clustered in the remaining categories. Some of the response options may also have been unclear to respondents. For example, the Puff Strength measure was intended to provide physiological reference points for respondents. However, “mouth,” “throat,” and “chest” were all included as reference points and may have caused confusion among respondents as to the ordinality of the measures. In other words, “inhale well back into your mouth” may have been construed by some respondents as more intense than “…only partly into your chest.” Overall, the self-report measures included in this study would benefit from additional pilot-testing and perhaps some qualitative research to identify more intuitive phrasing or reference points to improve the reliability of responses.

The results from the ITC survey provide some support for moderate correlations between the age of smokers, daily cigarette consumption, and the intensity of self-report puffing. Several between-country differences were also observed, but the magnitude of these differences was modest, and their statistical significance is primarily a reflection of the large sample size.

There was no association between the ISO nicotine yield of brands and self-report puffing behaviour, or changes to cigarette brands and changes in self-report puff strength. It should be noted, however, that these analyses were limited both by the number of self-report measures included in the ITC survey, as well as a lack of brand-specific data. For example, changes in cigarette brands between waves 2 and 3 of the ITC survey would only be expected to result in changes to puffing behaviour if the brands were significantly different in some meaningful way, such as the tobacco blend or filter ventilation level. Changes in puffing would not be expected if the brands were generally similar versions of the same product, but from different manufacturers, for example. The current analyses were not able to make this distinction and, therefore, may obscure meaningful associations between brands and self-report.

Subsequent to the completion of this study, we became aware of another study to have examined the validity of self-reported measures of puffing.[123] Etter and Perneger had participants complete a survey and correlated these measures with salivary cotinine levels. Two self-report measures produced significant bivariate associations with cotinine: a *smoking intensity* question ("Indicate on a scale between 0 and 100, the intensity of your smoking") and a *quantity of smoke* question ("What is the total quantity of smoke that you inhale every day? This quantity depends upon the number of cigarettes you smoke, the depth of inhalation, the number of puffs, etc.") The smoking intensity variable was significantly associated with cotinine after adjusting for cigarettes per day, and type of cigarette (full flavour, etc.).

Kozlowski and colleagues have also examined self-report measures in the related area of cigarette vent blocking. Overall, this research suggests that self-report vent blocking is largely unrelated to actual blocking: many smokers whose cigarette butts confirm vent-blocking fail to report covering the vent holes, while at the same time, there is often little objective evidence of blocking among smokers who report having done so.[103,124]

Overall, the current findings provide only limited preliminary support for the validity of self-report measures of puffing behaviour. However, given the potential value of self-report measures, this area warrants further research. For example, in October 2005, in an effort to reduce cigarette-related fires, Canada will implement the first national regulation on cigarette ignition propensity. The law will require cigarettes to self-extinguish 75% of the time when tested according to a standard protocol.[125] Although extensive testing suggests that the new restrictions will indeed reduce the ignition propensity of cigarettes, the tobacco industry has actively opposed the legislation on the grounds that the changes required to design reduced ignition-propensity cigarettes may be more toxic to smokers.[126] Valid measures of self-reported puffing behaviour would help to evaluate any such changes in puffing behaviour and smoke intake among Canadian smokers, relative to those in other countries.

6.6 Limitations

The current study has several limitations. First, the participants in the field study were not necessarily representative of smokers in the population at large. We selected a sample that smoked "regular-yield" brands and who were not planning to quit in the near future. Nevertheless, the current study provides data from over 20 different cigarette brands, including a range of nicotine and tar yields.

A second limitation is that smokers were provided with only one "low-yield" brand when switching down from their usual brand. This was done to control for differences across brands, but the results may not translate to what happens when smokers spontaneously switch to a "low-yield" brand of their choice. In addition, the design did not control for any "novelty effect" in the brand-switching condition. However, the increases in puffing behaviour and smoke intake are entirely consistent with previous research and we did not observe any attenuation or degradation of this effect over the course of 4 to 5 days of "low-yield" smoking, as would be expected with a novelty effect.

A third limitation concerns vent-blocking. Measures of vent-blocking were not collected from participants in the field study. As a result, the vent-blocking conditions for the Human Mimic testing were set at 50%, based upon the few population based studies that have been conducted.[103] This limitation is mitigated somewhat by the fact that most of the twenty "regular-yield" brands included in the study were either un-vented or had minimal ventilation. As a result, lip and finger placement on the filter would have had little or no effect on the levels of tar, nicotine, or carbon monoxide delivered to participants. However, measures of vent-blocking would have been informative in assessing compensation to the ventilated *Matinee Extra Mild* brand in the "low-yield" condition.

It should also be noted that using the CReSSmicro device may interfere with "naturalistic" vent-blocking. When cigarettes are inserted into the device, the perforations on the cigarette filter sit immediately outside the mouthpiece. Participants may find it awkward to grip the filter directly, and those who do may not obscure the vents in the usual fashion. One consequence is that "low-yield" smokers may have increased the intensity of their puffing behaviour to compensate for the diluted smoke from the unblocked vents.

A fourth limitation concerns the use of salivary cotinine as the “gold standard” for assessing intake. As indicated earlier in the discussion, cotinine levels vary somewhat over the course of a day and also subject to individual differences in metabolism. Future studies should try to standardize the time of saliva collection in order to minimize the variability associated with this measure.

Finally, these findings should be generalized to smokers in other countries with caution because it is known that Canadian cigarettes differ from other international brands on several important features –including tobacco blend, additives, and processing.[127,128]

Future research should consider measuring individual smoke constituents, rather than tar alone. Although tar is often referred to as a single substance, it includes more than 3,500 different compounds, 55 of which have been identified as possible human carcinogens.[129] Clearly, tar is not a homogeneous substance and its use as a measure of toxicity obscures critical differences in the amount and importance of individual chemicals in tobacco smoke. Indeed, similar levels of tar have markedly different compositions across different products, different markets, and even within the same product tested under different testing protocols.[130] As a consequence, future testing protocols and regulatory standards should be based upon key individual smoke constituents, rather than the misleading notion of tar.

Future research should also incorporate physical design measures into analytical models. Variables such as the percentage of filter ventilation, tobacco weight, paper porosity, and tobacco blend can account for as much as 90% of the variation between brands in cigarette yields. These design features interact with human smoking behaviour to determine the toxicity of the product, and should feature more prominently in independent research. For example, including these variables into the ITC data set would allow for more sophisticated analyses to examine potential associations between self-report puffing and brand characteristics.

6.7 Implications

Cigarette testing protocols have important implications for risk communication and regulations intended to reduce cigarette toxicity. Article 9 of the Framework Convention on Tobacco Control (FCTC) includes provisions for testing the contents and emissions of tobacco products, as well as for regulating these contents and emissions. As the FCTC is ratified by a growing number of countries, there is an urgent need to articulate an alternative to the ISO regime and to stipulate the provisions included in Article 9.

In May 2005, the International Standards Organization convened a working group to revise the testing protocols (ISO TC 126 WG9). Of the 32 experts in attendance, 11 were from public health agencies and 17 were from the tobacco industry. The objective of the ISO working group is to develop "…a robust and practical smoking regime that as far as possible is representative of smokers' behaviour." In contrast, the World Health Organization's own committee, *TobReg*, has stated the need for a testing regime that will "…approximate the maximum exposure level to which an ordinary smoker could reasonably be expected to be subject when smoking the specific product."[75]

As these parallel initiatives proceed, both groups should bear in mind the limitations of machine testing protocols. As the current findings help to demonstrate, cigarette yields are not indicators of health risk, and a reduction in constituent yields does not constitute a reduction in risk. The potential risk of a product must take into account how people use the product (e.g., whether they compensate for reduced yields by increasing their intake), as well as incentives for people to use the product –such as making the cigarettes "easier to smoke"— that may delay quitting among existing smokers or facilitate smoking initiation. Biological indicators of disease and epidemiological data are the only appropriate measures of reduced harm. Hence, cigarette emission testing should be only one component of a comprehensive testing program that includes measures of human intake (e.g. puffing topography), biological measures of exposure, and indicators of disease. These realities will not change, regardless of how the ISO testing protocol is revised.

Perhaps most important, cigarette yields should not be communicated as indicators of intake or risk exposure in any form. Until there is persuasive evidence to indicate that the differences in cigarette yields reflect meaningful differences in health risk, there is no benefit to presenting them directly to consumers, who will inevitably interpret lower yield products as less hazardous. In addition, the differences in yields must be large enough that they will not be easily overridden by compensatory behaviours, such as changes in puffing, or changes to the way the cigarette is held. There is a growing consensus that the ISO yields should be removed from all cigarette packages, and this appears set to happen in both Canada and Australia.[75] In addition, the tobacco industry should be restricted from using ISO yields in any of its advertising or marketing directed at consumers, even if they are accompanied by "warnings" or disclaimers, such as those that currently appear in the United States.

Nevertheless, various regulators are seeking to regulate the levels of known toxicants in cigarette smoke, and there is a need for a standardised method of generating the smoke from which to measure these toxicants. Several proposals are currently under review by the ISO working group and WHO's *TobReg* committee. Beyond the questions surrounding the actual testing parameters, other important questions confront these groups, including how, if at all, cigarette yields should be regulated, as well as how to communicate risk to smokers without using quantitative yields. Alternative approaches, such as the use of descriptive information on smoke constituents, have been proposed and merit further consideration.[75]

6.8 Conclusions

Overall, the current findings underscore the serious flaws in the current international testing regime. The ISO testing protocol is based upon entirely unrealistic smoking parameters that lead to deceptively low cigarette yields and create artificial distinctions between cigarette brands. Failure to remove or revise these methods will only perpetuate this deception and substantiate false industry advertising.

The tobacco industry has been anticipating a change in the testing protocols for several decades. A senior executive from British American Tobacco summarized the industry's position in 1984, as follows:

> The [Federal Trade Commission], and other authorities, may call for a change in the standard smoking machine test procedure. Around the group, the strategy, therefore, should be to do everything possible to maintain the present standard test procedure. If, however, the FTC or any other authority takes action to change the procedure, the strategy should then be to stretch out the discussions (both with the authorities and later at ISO) until exhaustive studies have established that an alternative procedure was in fact more relevant.[131]

It is critical that the process of revising the testing protocols be guided by the interests of public health. The current findings represent one of the early attempts to build the evidence base on the leading candidates to replace the ISO testing regime. To this end, the current results highlight the need to develop tools to evaluate human exposure and smoking behaviours. More effective and less intrusive physiological measures will be important in this process, as will the development of valid self-report measures of puffing behaviour.

7.0 APPENDICES

7.1 APPENDIX A: Phone Survey

Baseline Telephone Survey	
intro	Hello, my name is ________ and I am calling from the Survey Research Centre at the University of Waterloo. We are conducting a research survey on smoking. Can I ask someone 18 years of age or over a few questions to see whether anyone in your household qualifies for the survey? 1 - Yes Go to **elig** 2 - Child-no adult available Go to **child** 3 - No adult smoker in household Go to **Ineligibility statement** 4 - No adult in household Go to **Ineligibility statement** 5 - No/Respondent refuses Go to **reluctant**
child	I would like to speak to an adult age 18 or older in your household who smokes - is there a better time to call back to speak to them? 1 - Yes May we speak to them now? goto **intro2** 2 - No adult smokers in household Thank you for your help. **end** 3 - No/Don't know Thank you. We'll try again at another time.
intro2	How many people age 18 or older live in your household, including yourself? [enter number]
	How many of these adults, including yourself, smoke cigarettes at least daily? [enter number]
	I'd like to speak to the smoker in your household who is at least 18 years old whose birthday is coming up next. Would that be you? 1=if person on phone goto **elig** 2=if other smoker Can I speak to that person now? If yes: **repeat intro** IF NECESSARY: We need to select somebody at random. With each call we make, we ask to speak to the person whose birthday is coming up next. This helps us to ensure that we have a representative sample as some groups of people are less likely to answer the phone.
elig	How many years have you smoked? if less than 1 year, goto Ineligibility statement
	Do you smoke every day or less than every day? 0= Less than everyday goto Ineligibility statement 1= Every day

	Have you smoked 100 or more cigarettes over your lifetime? 0= No goto **inelig** 1= Yes goto **consent**
consent	We are looking for smokers who would be willing to answer a survey on smoking behaviour that is part of an international research project. The survey would take about 20 minutes. Your answers to this survey will be kept absolutely confidential. All personal information, including your name and address, will be kept strictly confidential and will not be shared with any person or group that is not associated with this survey. Finally, the survey has received ethics clearance from the Office of Research Ethics at the University of Waterloo. Would you be willing to participate in the survey? 1 - yes goto **consent1** 2 – no goto **refuse**
consent1	Thanks for your help. Please let me know if you'd like to skip any questions you'd prefer not to answer. There are no right or wrong answers- we're most interested in your personal opinions and you can decide to stop answering questions at any time. ➢ goto **cigsday**
refuse	I'm sorry to have reached you at a busy time. The survey will only take a few minutes and we could really use your help for this study. If this is an inconvenient time, could I call you back at another time? 1 - yes goto **reschedule** 2 – no goto **thanks**
thanks	Thank you for your help, sorry to have bothered you.
	Survey Begins Here
1. cigday	On average, how many cigarettes do you smoke each day, including both factory-made and roll-your own cigarettes? [enter number]
2. cigtype	Do you smoke factory-made cigarettes, roll-your-own cigarettes, or both? 1=Factory made only 2=Roll-you-own only 3=Both
3. factryo	For every 10 (ten) cigarettes you smoke, about how many are roll-your-own? [enter number]
4. employ	Are you currently employed outside the home? 0= No 1= Yes

5. smwork	Is there any difference between the number of cigarettes you smoke during a workday and the number you smoke during a non-working day? 0=No 1=Yes
6. brand	What brand of [cigarettes/ roll-your-own cigarettes] do you smoke more than any other?
7. brandfrq	In the last 6 months, how often did you smoke this brand? **READ** 01 – Always 02 – Almost always 03 – About half of the time 04 – Less than half the time
8. adct1	How soon after waking do you usually have your first smoke? **(Do not read)** 01 – minutes [enter] 02 – hours [enter]
9. adct2	Do you consider yourself addicted to cigarettes? Would you say… **READ** 01 – Not at all 02 – Yes–somewhat addicted 03 – Yes–very addicted
10. adct3	How hard would you find it to go without smoking for a whole day? **READ** 01 – Not at all hard 02 – Somewhat hard 03 – Very hard 04 – Extremely hard
11. intent	Are you planning to quit smoking: **READ** 01 – Within the next month? 02 – Within the next 6 months? 03 – Sometime in the future, beyond 6 months 04 – Not planning to quit ➢ If 1,2,3 goto **Q.Quitdat** ➢ If 4, goto **Q.quitease**
12. quitdat	Have you set a firm date? 01 – Yes 02 – No
13. quitease	If you decided to give up smoking completely in the next 6 months, how easy or hard would it be? **READ** 01 – Not at all hard 02 – Somewhat hard 03 – Very hard 04 – Extremely hard

14. quitnum	How many times have you ever tried to quit smoking? [enter number]
15. quitlen	Of all the times you tried to quit smoking, what was the longest period you stayed off cigarettes completely? [enter days] [enter months] [enter years]
16. educ	What is the highest level of formal education that you have completed? **DO NOT READ** 01 – Grade school or some high school 02 – Completed high school 03 – Technical or trade school or community college (some or completed) 04 – Some university (no degree) 05 – Completed university degree 06 – Post-graduate degree
	I'm now going to ask you some question about how you smoke. Try to answer each one as best as possible.
17. puff1	When you smoke, how much of the cigarette do you usually smoke? **READ** 01 – Right to the butt 02 – Nearly to the butt 03 – Most of the cigarette 04 – About half of the cigarette or less
18 puff2	Which of the following best describes how strongly you usually inhale when you smoke? **READ** 01 – You inhale as deeply into your chest as possible 02 – You inhale only partly into your chest 03 – You inhale as far back as your throat 04 – You inhale well back into your mouth 05 – You just puff, you don't really inhale
19. puff3	Which of the following statements best describes how many puffs you usually take when you smoke a cigarette? **READ** 01 – You only take a few puffs on each cigarette 02 – You take more than a few puffs, but not as many as you could 03 – You take as many puffs as you can on each cigarette
20. puff4	On average, how many puffs do you take on each cigarette? [enter Number]
21. puff5	When you smoke, how deeply do you inhale? **READ** 01 – Not at all deeply 02 – Somewhat deeply 03 – Very deeply 04 – As deeply as possibly

22. puff6	On average, how long do you let the cigarette burn in between puffs? [enter seconds] [enter minutes]
23. puff7	After you light a cigarette, how often do you usually put your cigarette down or hold it away from your mouth when you smoke? 01 – Never 02 – Not at all often 03 – Often 04 – Very often
24. puff8	How do you usually hold a cigarette when you smoke it? Do you: **READ** 1 – rest the cigarette between 2 fingers 2 – hold or pinch the filter between two fingers 3 – hold or pinch the filter between more than 2 fingers
25. puff9	Do you usually cover the filter with your hand while smoking? **READ** 1 – Not at all 2 – A little bit 3 – A lot 4 – As much as possible
26. puff10	**Are each of the following statements true or false:** The way a smoker PUFFS on a cigarette can affect the amount of tar and nicotine a smoker takes in. 1 – True 2 – False
27. puff11	The way a smoker HOLDS a cigarette can affect the amount of tar and nicotine a smoker takes in. 1 – True 2 – False
28. puff12	Filters reduce the harmfulness of cigarettes. 1 – True 2 – False
29. puff13	The nicotine in cigarettes is the chemical that causes most of the cancer. 1 – True 2 – False
30. age	What is your current age? [enter]
31. sex	Note sex (ask only if necessary) 1 – Male 2 – Female

32. income	Which of the following categories best describes your annual household income, that is the total income before taxes, or gross income, of all persons in your household combined, for one year? **READ** 01 – Under $10,000 02 – $10,000 to $29,999 03 – $30,000 to $44,999 04 – $45,000 to $59,999 05 – $60,000 to $74,999 06 – $75,000 to $99,999 07 – $100,000 to $149,999 08 – $150,000 and over
33. race	People in Canada come from many racial and cultural groups. I am going to read you a list. Are you: (READ) IF RESPONDENT ANSWERS "MIXED" OR "BIRACIAL" PROBE FOR SPECIFIC GROUPS (E.G., "WHITE", "BLACK"). (Check all that apply) 01 – White 02 – Chinese 03 – South Asian (for example, East Indian, Pakistani, Sri Lankan, etc.) 04 – Black 05 – Filipino 06 – Latin American 07 – Southeast Asian (for e.g., Cambodian, Indonesian, Laotian,Vietnamese, etc.) 08 – Arab 09 – West Asian (for example, Afghan, Iranian, etc.) 10 – Japanese 11 – Korean 12 – Aboriginal (that is, North American Indian, Métis, or Inuit), or 13 – Another group?
34. line	In addition to this telephone number, are there any other telephone numbers, not including cell phones, connected in your home? 1 – Yes goto **lines** 2 – No goto **end**
35. lines	How many, if any, of these, are used mainly for personal calls, rather than business calls, fax or Internet?

36. End	Those are all my questions- thank you for your help. Before we close, I’d like to mention that the University of Waterloo is conducting a related study on smoking behaviour. This related study is part of an international project using cutting edge technology to examine smoking behaviour. Very briefly, the study involves smoking cigarettes through a little hand-held device that would measure how much you puff on your cigarette and how deeply you puff. The device fits in the palm of your hand and your cigarette will fit in the mouthpiece- it does not interfere with the smoke from the cigarette and is easy to use. We will be providing adult smokers in the Waterloo region up to $180 in appreciation for their participation. We will be selecting participants within the next week, would you be interested in hearing more about the study at that time? If yes: That’s great. When would be a convenient time to reach you? If no: Thank you anyway.
37. goodbye	Thank you again for your time. Do you have any questions about the survey? If you have any further questions about your participation in the survey you are welcome to contact Dr. Susan Sykes at the Office of Research Ethics at the University of Waterloo, or Geoffrey Fong at the Department of Psychology. Would you like either of their phone numbers? Thanks. Goodbye. **End**

7.2 APPENDIX B: Telephone Recruitment Script

Recruitment Script
Hello, my name is ________________ and I'm calling from the University of Waterloo about the smoking study. I'm calling to arrange a time for the next week during which you'll be using the device- is now a good time? Just before we book a time, I'd like to go over the next few steps in the study. As you'll recall, we'd like you to use the device for another week from _________ [dates], exactly as before. Just like before, we'll pay you up to $60 for your time. We'd then like you to use the device for one final week. This week, from ____ to ____ [insert dates], will be the same, except that we will be asking some participants to use the device while smoking a different brand of cigarette than your regular brand. We will select these participants at random immediately before this final week: we will be providing you with a supply of cigarettes free of charge for this last week ,regardless of whether you will be selected to smoke your regular brand or a different brand. We'll pay you another $60 for this last week of using the device. If you are selected to smoke a different, the cigarette brands will be major brands, only a lighter-yield from your own. In order to participate in the next stage of the study, you would need to agree to smoke another brand if you were to asked to do so in the last week. Would that be OK? Finally, as before we will be asking you collect cigarette butts, fill out a daily diary and provide a saliva sample at the end of each week. Of course, all of the data you provide would be absolutely confidential and no one outside of our research team would ever see your individual responses or measurements. Do you have any questions?
I'd like to arrange a time to drop off the device Would it be more convenient for you to visit us at our lab on the University of Waterloo campus, or would you prefer that we send 2 of our research assistants to your home? **Day:**______________________ **Time:**__________________ [For participants travelling to UW, we will provide them with a map and directions in the information letter.] Many thanks for agreeing to be in this field study. We will see you on [day] at [time]. We will give you a call the day before to confirm the appointment. If you need to contact us for any reason, here is our phone number: 888-4567 x3507. Before we go, are there any questions I can answer for you?

7.3 APPENDIX C: Post-Trial Questionnaire

Post-Trial Questionnaire	
	***Note: Questions to be read out loud to participants**
1a.	How much of the cigarette did you usually smoke when using the device? 1 – Right to the butt 2 – Nearly to the butt 3 – Most of the cigarette 4 – About half of the cigarette or less
2a.	Which of the following best describes how strongly you usually inhaled when you smoked, when using the device? 1 – You inhale as deeply into your chest as possible 2 – You inhale only partly into your chest 3 – You inhale as far back as your throat 4 – You inhale well back into your mouth 5 – You just puff, you don't really inhale
3a.	Which of the following statements best describes how many puffs you usually took when you smoked a cigarette using the device? 1 – You only take a few puffs on each cigarette 2 – You take more than a few puffs, but not as many as you could 3 – You take as many puffs as you can on each cigarette
4a.	On average, how many puffs did you take on each cigarette when using the device ____________ (please write number)
5a.	How deeply did you normally inhale when smoking using the device? 1 – Not at all deeply 2 – Somewhat deeply 3 – Very deeply 4 – As deeply as possibly
6a.	On average, how long did you let the cigarette burn in between puffs hen using the device? ____________ (enter number of seconds)

7a.	How often did you usually put your cigarette down or hold it away from your mouth after lighting a cigarette when using the device? 1 – Never 2 – Not at all often 3 – Often 4 – Very often
8a.	How did you usually hold a cigarette when you smoked using the device? Did you: 1 – rest cigarette between 2 fingers 2 – hold or pinch the filter between two fingers 3 – hold or pinch the filter between more than 2 fingers
9a.	Did you usually cover the cigarette filter with your hand while smoking using the device? 1 – Not at all 2 – A little bit 3 – A lot 4 – As much as possible
10.	How easy or hard was the device to use? 1 – Very easy 2 – Easy 3 – Neither easy nor hard 4 – Hard 5 – Very hard
11.	How "natural" did it feel to smoke through the machine? 1 – Not at all 2 – A little bit 3 – A lot
12.	How much, if at all, did using the device change <u>how</u> you smoked a cigarette? 1 – Not at all 2 – A little bit 3 – A lot
13.	What adjustments to your smoking, if any, did you make when smoking through the machine? Please describe: ______________________________ ______________________________ ______________________________

14.	I'd like you to please show me how you held the device when you used it to smoke. Please place a cigarette in the device and show me how you would puff. **Note filter coverage/blocking:** 1 – Yes 2 – No
15.	Did you try to hold the cigarette at all while using the device? 1 – Not at all 2 – Sometimes 3 – All the time
Additional questions to be completed only during the final visit by "switcher", following Trial 3.	
16.	How different, if at all, did you find smoking another brand? 1 – Not at all 2 – A little bit 3 – A lot
17.	How much, if at all, did switching brands change how you smoked a cigarette? 1 – Not at all 2 – A little bit 3 – A lot
18.	What adjustments to your smoking, if any, did you make after switching brands? Please describe: ______________________________ ______________________________ ______________________________

7.4 APPENDIX D: CReSSmicro Calibration Protocol

Machine Number: ____________________ Status: Pre-Trial / Post-Trial

Subject ID Number: __________________ Scale Factor: _________

Block 1—20 ml Puff Volume				
Puff #	**Puff Vol**	**Average Flow**	**Syringe puff vol**	**Machine puff vol**
	20 ml	25 ml/sec		
	20 ml	25 ml/sec		
	20 ml	25 ml/sec		
	20 ml	40 ml/sec		
	20 ml	40 ml/sec		
	20 ml	40 ml/sec		
	20 ml	55 ml/sec		
	20 ml	55 ml/sec		
	20 ml	55 ml/sec		

Block 2—35 ml Puff Volume				
Puff #	**Puff Vol**	**Average Flow**	**Syringe puff vol**	**Machine puff vol**
	35 ml	25 ml/sec		
	35 ml	25 ml/sec		
	35 ml	25 ml/sec		
	35 ml	40 ml/sec		
	35 ml	40 ml/sec		
	35 ml	40 ml/sec		
	35 ml	55 ml/sec		
	35 ml	55 ml/sec		
	35 ml	55 ml/sec		

Calibration Protocol cont.

Block 3—50 ml Puff Volume				
Puff #	**Puff Vol**	**Average Flow**	**Syringe puff vol**	**Machine puff vol**
	50 ml	25 ml/sec		
	50 ml	25 ml/sec		
	50 ml	25 ml/sec		
	50 ml	40 ml/sec		
	50 ml	40 ml/sec		
	50 ml	40 ml/sec		
	50 ml	55 ml/sec		
	50 ml	55 ml/sec		
	50 ml	55 ml/sec		

7.5 APPENDIX E: Daily Diary

Daily Smoking Diary

Day 1: Monday, March 31st

1. In total, how many cigarettes did you smoke? _________

2. How many cigarettes did you smoke through the the hand-held device: _________

3. How many cigarettes did you smoke not using the machine? _________

4. What time of day did you smoke your <u>first</u> cigarette after waking? _________

5. What time of day did you smoke your last cigarette of the day? _________

6. How many cigarette butts did you collect today? _________

COMMENTS

(Please write any comments for the day here)

7.6 APPENDIX F: Compensatory Testing Parameters

Brand	ISO Nicotine (mg)	Puff Volume (ml)	Puff Frequency (seconds)
Matinee Extra Mild King	0.1	76	24
DuMaurier Edition Regular	0.4	64	36
DuMaurier Ultra LIght Regular	0.6	56	44
Benson & Hedges Special King	0.7	52	48
DuMaurier Light Regular	0.8	48	52
DuMaurier Special Mild	0.9	44	56
Players Extra Light Regular	0.9	44	56
Players Light Smooth Regular	0.9	44	56
Export "A" Extra Light Regular	0.9	44	56
Players Light Regular	0.9	44	56
DuMaurier Regular	1.0	40	60
Craven A Light Regular	1.0	40	60
DuMaurier Light King	1.0	40	60
Number 7 Light King	1.0	40	60
Export "A" Light Regular	1.1	36	64
DuMaurier King	1.1	36	64
Players Light King	1.1	36	64
Export "A" Medium Regular	1.1	36	64
Rothmans King Size	1.2	32	68
Craven "A" Regular Size	1.2	32	68
Export "A" Regular Size	1.3	28	72

*Note: Vent blocking =50%, Puff duration=2 seconds, and Butt length=Tipping + 3mm / 23mm for all brands.

7.7 APPENDIX G: "Human mimic" Testing Parameters

Brand	Puff Volume (ml)	Puff Frequency (seconds)	Puff Duration (seconds)
Matinee Extra Mild King	58	29	1.5
DuMaurier Edition Regular	47	23	1.2
DuMaurier Ultra LIght Regular	54	32	1.5
Benson & Hedges Special King	65	24	1.7
DuMaurier Light Regular	62	35	1.7
DuMaurier Special Mild	54	31	1.4
Players Extra Light Regular	57	25	1.6
Players Light Smooth Regular	58	34	1.2
Export "A" Extra Light	58	27	1.6
Players Light Regular	66	50	1.6
DuMaurier Regular	48	47	1.4
Craven A Light Regular	54	33	1.4
DuMaurier Light King	45	23	1.3
Number 7 Light King	43	84	1.3
Export "A" Light Regular	52	27	1.3
DuMaurier King	42	32	1.2

*Note: Vent blocking =50% and Butt length=Tipping + 3mm / 23mm for all brands.

7.8 APPENDIX H: Predictors of Salivary Cotinine (Trial 1)

Linear Regression (n=41)

Step 1: Main effects only

Variable	Beta*	*t* value	*P* value	Part Correlation
Collection Time of Day	0.18	1.15	0.26	0.18
Cigarettes per Day (CPD)	0.34	2.19	0.04	0.33
Gender (Male=reference)	0.16	1.05	0.30	0.16
Smoke Intake per cigarette	0.28	1.81	0.08	0.28

* Standardized beta R^2=.21, p = .08

Step 2: Main effects + Interaction term

Variable	Beta*	*t* value	*P* value	Part Correlation
Collection Time of Day	-0.86	-2.56	0.02	-0.34
Gender (Male=reference)	0.34	2.36	0.02	0.31
Cigarettes per Day (CPD)	0.47	3.32	0.00	0.44
Smoke Intake per cigarette	-1.21	-2.63	0.01	-0.35
CPD x Smoke Intake Saliva	1.95	3.38	0.00	0.45

* Standardized beta R^2=.39, $p < .001$

Step 3a: Main effects + Interaction term + ISO Nicotine Yields

Variable	Beta*	*t* value	*P* value	Part Correlation
Collection Time of Day	0.46	3.42	0.00	0.44
Gender (Male=reference)	0.33	2.39	0.02	0.31
Cigarettes per Day (CPD)	-1.17	-2.65	0.01	-0.34
Smoke Intake per cigarette	-0.77	-2.35	0.03	-0.30
CPD x Smoke Intake	1.85	3.31	0.00	0.43
ISO Nicotine Yield	0.25	1.89	0.07	0.24

* Standardized beta R^2=.47, p = .001

Step 3b: Main effects + Interaction term + Massachusetts Nicotine Yields

Variable	Beta*	*t* value	*P* value	Part Correlation
Collection Time of Day	0.41	2.84	0.01	0.38
Gender (Male=reference)	0.30	2.06	0.05	0.28
Cigarettes per Day (CPD)	-1.18	-2.48	0.02	-0.33
Smoke Intake per cigarette	-0.89	-2.57	0.01	-0.35
CPD x Smoke Intake	1.90	3.18	0.00	0.43
Massachusetts Nicotine Yield	0.11	0.78	0.44	0.10

* Standardized beta R^2=.40, p = .006

Step 3c: Main effects + Interaction term + Canadian Nicotine Yields

Variable	**Beta***	***t* value**	***P* value**	**Part Correlation**
Collection Time of Day	0.44	3.15	0.00	0.42
Gender (Male=reference)	0.32	2.17	0.04	0.29
Cigarettes per Day (CPD)	-1.22	-2.67	0.01	-0.35
Smoke Intake per cigarette	-0.87	-2.60	0.01	-0.34
CPD x Smoke Intake	1.93	3.37	0.00	0.45
Canadian Nicotine Yield	0.17	1.21	0.23	0.16

* Standardized beta R^2=.45, p = .003

Step 3d: Main effects + Interaction term + Compensatory Nicotine Yields

Variable	**Beta***	***t* value**	***P* value**	**Part Correlation**
Collection Time of Day	0.44	3.19	0.00	0.42
Gender (Male=reference)	0.30	2.11	0.04	0.28
Smoke Intake per cigarette	-1.00	-3.03	0.00	-0.40
Cigarettes per Day (CPD)	-1.41	-3.03	0.00	-0.40
CPD x Smoke Intake	2.21	3.83	0.00	0.50
Compensatory Nicotine Yield	-0.23	-1.62	0.12	-0.21

* Standardized beta R^2=.44, p = .003

Step 3e: Main effects + Interaction term + Human Mimic Nicotine Yields

Variable	**Beta***	***t* value**	***P* value**	**Part Correlation**
Collection Time of Day	-1.15	-3.45	0.00	-0.43
Gender (Male=reference)	0.35	2.59	0.01	0.32
Cigarettes per Day (CPD)	0.55	4.06	0.00	0.50
Smoke Intake per cigarette	-1.35	-3.13	0.00	-0.39
CPD x Smoke Intake	2.17	4.00	0.00	0.50
Human Mimic Nicotine Yield	0.37	2.51	0.02	0.31

* Standardized beta R^2=.51, $p < .001$

7.9 APPENDIX I: Pre-Trial Self-Report Correlation Matrix

	Smoke intake (Cress)	Puff Count (Cress)	Puff Volume (Cress)	Mean Flow (Cress)	Puff Freq. (Cress)	Butt Length	Strongly Inhale	Puff # (scale)	Puff # (open)	Deeply Inhale	Puff Freq.	Put down cig
Smoke intake (Cress)	--	--	--	--	--	--	--	--	--	--	--	--
Puff Count (Cress)	.77***	--	--	--	--	--	--	--	--	--	--	--
Puff Volume (Cress)	.47***	-.19	--	--	--	--	--	--	--	--	--	--
Mean Flow (Cress)	.30*	.11	.39***	--	--	--	--	--	--	--	--	--
Puff Freq. (Cress)	.71***	.63***	.27*	.10	--	--	--	--	--	--	--	--
Butt Length	.05	.02	.04	-.07	-.04	--	--	--	--	--	--	--
Strongly Inhale	.11	.06	.07	-.11	-.07	.23*	--	--	--	--	--	--
Puff # (scale)	-.02	-.06	.03	-.11	.09	.15	.31**	--	--	--	--	--
Puff # (open)	.12	.20	-.10	.02	.12	.07	.24	.23	--	--	--	--
Deeply Inhale	.20	.22	-.01	.09	.11	.25*	.59***	.45***	.48***	--	--	--
Puff Freq.	.47***	.48***	.08	.28*	.61***	-.01	.02	.04	.32**	.01	--	--
Put down cig	-.25	-.30*	.05	.09	.27*	.05	-.36***	-.16	-.21	-.25*	.27**	--
Cotinine	.09	-.09	.21	.08	.19	.31*	.29*	-.01	.06	.34**	.03	.01

N=42 * p <.10 **p<.05 ***p<.01

APPENDIX I cont. Post-Trial Self-Report Correlation Matrix

	Smoke intake (Cress)	Puff Count (Cress)	Puff Volume (Cress)	Mean Flow (Cress)	Puff Freq. (Cress)	Butt Length	Strongly Inhale	Puff # (scale)	Puff # (open)	Deeply Inhale	Puff Freq.	Put down cig
Smoke intake (Cress)	--	--	--	--	--	--	--	--	--	--	--	--
Puff Count (Cress)	.77***	--	--	--	--	--	--	--	--	--	--	--
Puff Volume (Cress)	.47***	-.19	--	--	--	--	--	--	--	--	--	--
Mean Flow (Cress)	.30*	.11	.39***	--	--	--	--	--	--	--	--	--
Puff Freq. (Cress)	.71***	.63***	.27*	-.10	--	--	--	--	--	--	--	--
Butt Length	.11	.19	-.10	-.19	-.04	--	--	--	--	--	--	--
Strongly Inhale	.10	.04	.07	-.13	.02	.34***	--	--	--	--	--	--
Puff # (scale)	.08	.07	.06	.14	.14	.13	0.10	--	--	--	--	--
Puff # (open)	.05	.30*	-.31**	.03	-.10	.28**	.26*	.14		--	--	--
Deeply Inhale	-.29*	-.21	-.22	-.26	.55***	.26**	.15	-.07	.33***	--	--	--
Puff Freq.	.37**	.28*	.25	.28*	.61***	.15	.07	.12	.25*	.80***	--	--
Put down cig	-.33**	-.25	-.15	.21	-.30*	-.29**	.03	-.21	.03	.02	.10	--
Cotinine	.09	-.09	.21	.08	.19	.12	.25*	.04	-.06	.01	-.05	.08

n=42 * p <.10 **p<.05 ***p<.01

7.10 APPENDIX J: Self-Report & Physiological Puffing Behaviour— Changes Between Trial 2 and 3.

	Smoke intake (Cress)	Puff Count (Cress)	Puff Volume (Cress)	Mean Flow (Cress)	Puff Freq. (Cress)	Butt Length	Strongly Inhale	Puff # (scale)	Puff # (open)	Deeply Inhale	Puff Freq.	Put down cig
Smoke intake (Cress)	--	--	--	--	--	--	--	--	--	--	--	--
Puff Count (Cress)	.93***	--	--	--	--	--	--	--	--	--	--	--
Puff Volume (Cress)	.69***	.42***	--	--	--	--	--	--	--	--	--	--
Mean Flow (Cress)	.43***	.36**	.41***	--	--	--	--	--	--	--	--	--
Puff Freq. (Cress)	.59***	.61***	.30*	-.08	--	--	--	--	--	--	--	--
Butt Length	.04	.04	-.02	-.05	.07	--	--	--	--	--	--	--
Strongly Inhale	.13	.15	.07	.02	.18	.06	--	--	--	--	--	--
Puff # (scale)	.24	.31*	.09	.00	.11	.28**	.08	--	--	--	--	--
Puff # (open)	.01	.02	.10	-.17	.24	.14	.02	.38***	--	--	--	--
Deeply Inhale	.28*	.32**	.18	.05	.33**	.33**	.15	.39***	.46***	--	--	--
Puff Freq.	.15	.16	.20	.10	.25	.11	.27*	.17	.01	.11	--	--
Put down cig	.00	.07	-.06	.11	.19	-.10	.25*	-.26*	-.16	-.16	.03	--
Cotinine	-.09	-.09	.08	.16	.24	-.14	-.25*	.20	-.02	-.06	.04	-.15

n=42 * p <.10 **p<.05 ***p<.01

7.11 APPENDIX K: ITC Sample Characteristics

Wave 2 Characteristics of ITC Sample, by Country (n=7,802)

	CAN	US	UK	AUS	Total
Sex					
Female	47.1	46.1	50.4	45.1	47.2
Male	52.9	53.9	49.6	54.9	52.8
Age					
18-24	13.8	15.3	15.4	15.8	15.1
25-39	32.7	30.0	31.1	35.2	32.3
40-54	36.0	36.1	30.1	33.5	33.9
55+	17.5	18.7	23.4	15.6	18.8
Education					
12 years or less	45.4	41.3	61.6	61.3	53.9
More than 12 years	54.6	58.7	38.4	32.7	46.1
Ethnicity/Language					
White/English only	88.3	75.9	95.2	87.0	86.8
Other/Mixed	11.7	24.1	4.8	13.0	13.2
Income					
Low	28.6	35.2	27.5	26.0	29.2
Medium	34.5	36.6	34.1	34.7	64.2
High	28.6	21.8	30.3	33.2	28.6
Intention to Quit					
No Intention	24.7	31.1	38.2	27.8	30.2
Intention	75.3	68.9	61.8	72.2	69.8
CPD mean*	16.2	17.4	16.1	17.2	16.7
(SD)	(10.2)	(11.0)	(9.8)	(11.1)	(10.6)

*CPD=Cigarettes per day

7.12 APPENDIX L: ITC Predictors of Self-Report Puffing Behaviour

Linear regression: Predictors of self-reported Butt Length (n= 7,532)

	Beta*	*t* value	*p* value	Part *r*
Sex (Male=reference)	-.01	-.26	.80	-.01
Income	-.01	-.79	.42	-.01
Age	-.09	-6.1	<.001	-.09
Ethnicity	.01	.56	.58	.01
CPD	.14	9.6	<.001	.14
RYO cigarette	-.01	-.81	.42	-.01
Intention to quit	-.02	-.86	.39	-.01
Education	-.03	-2.69	.001	-.03
Country (CAN =Reference)				
US	-.09	-5.2	<.001	-.08
UK	-.10	-5.4	<.001	-.08
AUS	.03	-1.5	.14	-.02

* Standardized Beta R^2= .05, p<.001

Linear regression: Predictors of self-reported Puff Strength (n= 7,505)

	Beta*	***t* value**	***p* value**	**Part *r***
Sex				
(Male=reference)	0.01	0.51	0.61	0.01
Income	-0.01	-0.83	0.41	-0.01
Age	-0.10	-8.12	<.001	-0.09
Ethnicity	0.01	1.04	0.30	0.01
CPD	0.16	13.75	<.001	0.15
RYO cigarette	-0.02	-1.75	0.08	-0.02
Intention to quit	-0.08	-6.94	<.001	-0.08
Education	-0.04	-3.26	0.001	-0.04
Country (CAN =Reference)				
US	-0.09	-6.84	<.001	-0.08
UK	-0.09	-6.10	<.001	-0.07
AUS	-0.02	-1.15	0.25	-0.01

* Standardized Beta R^2= .09, p<.001

Linear regression: Predictors of self-reported Puff Number (n=7,448)

	Beta*	***t* value**	***p* value**	**Part *r***
Sex				
(Male=reference)	0.01	0.76	0.45	0.01
Income	-0.03	-2.31	0.02	-0.03
Age	-0.10	-8.88	<.001	-0.10
Ethnicity	-0.01	-0.88	0.38	-0.01
CPD	0.18	15.53	<.001	0.18
RYO cigarette	0.00	0.18	0.85	0.00
Intention to quit	-0.05	-4.04	<.001	-0.05
Education	0.00	0.14	0.88	0.00
Country (CAN =Reference)				
US	0.01	0.36	0.72	0.01
UK	-0.06	-4.48	<.001	-0.05
AUS	-0.02	-1.69	0.09	-0.02

* Standardized Beta R^2= .06, p<.001

Linear regression: Predictors of self-reported Puff frequency (n=7,415)

	Beta*	***t* value**	***p* value**	**Part *r***
Sex				
(Male=reference)	.03	1.85	.06	.03
Income	-.01	-.27	.79	-.01
Age	-.16	-10.22	<.001	-.15
Ethnicity	-.04	-2.69	.007	-.04
CPD	.07	4.57	<.001	.07
RYO cigarette	-.02	-1.29	-.20	-.02
Intention to quit	-.01	-.53	-.59	-.01
Education	.02	1.42	.16	.02
Country (CAN =Reference)				
US	.01	.61	.54	.01
UK	.04	1.91	.06	.03
AUS	.08	4.52	<.001	.07

* Standardized Beta R^2= .03, p<.001

Linear regression: Predictors of Wave 2-Wave 3 Changes in Puff Strength (n=4,314)

	Beta*	***t* value**	***p* value**	**Part *r***
Sex				
(Male=reference)	0.00	0.17	0.87	0.00
Income	0.02	1.16	0.25	0.02
Age	-0.01	-0.90	0.37	-0.01
Ethnicity	-0.01	-0.55	0.58	-0.01
CPD change	0.01	0.63	0.53	0.01
RYO cigarette	-0.01	-0.69	0.49	-0.01
Intention to quit	-0.01	-0.42	0.67	-0.01
Education	0.00	-0.25	0.81	0.00
Country (CAN =Reference)				
US	0.00	-0.05	0.96	0.00
UK	-0.03	-1.77	0.08	-0.03
AUS	-0.04	-2.17	0.03	-0.03

* Standardized Beta R^2= .001, p=.45

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