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Assessment of tobacco heating product THP1.0. Part 8: Study to determine puffing topography, mouth level exposure and consumption among Japanese users

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ABSTRACT

A four-arm study was undertaken in Japan to determine the puffing topography, mouth level exposure and average daily consumption by consumers of the tobacco heating products (THPs): the non-mentholated THP1.0(T), the mentholated THP1.0(M) and a tobacco heating system (THS). The extent of lip blocking of air inlet holes while using THP1.0(T) was also assessed. Groups 1, 2, and 4 included smokers, and group 3 included regular THP users. Smokers of 7–8 mg ISO nicotine free dry particulate matter (NFDPM) non-mentholated cigarettes took on average larger mean puff volumes from THPs than from conventional cigarettes, but puff numbers and durations were similar. Mouth level exposure to NFDPM and nicotine levels were significantly lower when using THPs than conventional cigarettes. Similar trends were observed among smokers of 7–8 mg ISO NFDPM mentholated cigarettes who used mentholated cigarettes and THP1.0(M). Regular users of commercial THS had similar puffing behaviours irrespective of whether they were using THS or THP1.0(T), except for mean puff volume which was lower with THP1.0(T). No smokers blocked the air inlet holes when using THP1.0(T). The puffing topography results support the machine puffing regime used to generate toxicant emissions data and *in vitro* toxicology testing.

1. Introduction

Cigarette smoking is one of the leading preventable causes of human diseases, such as cardiovascular disorders, chronic obstructive pulmonary disease and lung cancer (US DHHS, 2014). The cause of most smoking-related diseases is the inhalation of toxicants present in tobacco smoke (Farsalinos and Le Houezec, 2015), caused by the burning of tobacco in a cigarette, which produces more than 6500 compounds (Rodgman and Perfetti, 2013), of which around 150 are toxicants (Fowles and Dybing, 2003). As many of the toxicants are produced from combustion or pyrolysis of the tobacco (Baker, 2006) recent approaches to reducing the health risks related to tobacco use have concentrated on the heating rather than combustion of tobacco to reduce the level of combustion-derived toxicants in the inhalable aerosol (Forster et al., 2015; Gonzalez-Suarez et al., 2016; Schorp et al., 2012; Smith et al., 2016; Zenzen et al., 2012). Recently, British American Tobacco (BAT) developed a tobacco heating product (THP) THP1.0. This product heats rather than burns tobacco to release an aerosol with approximately 90% reduction in TobReg (9) toxicants than conventional cigarette smoke (Forster et al., 2017). THP1.0 comprises two functional parts: an electronic handheld device with a heating chamber, and a specially designed consumable to be inserted into the heating chamber (Eaton et al., 2017).

Murphy et al. (2015) and Murphy (2017) have proposed a new scientific framework to evaluate the reduced risk potential of tobacco and nicotine products. In the context of this framework, 'actual use' studies play a key part in determining whether

Abbreviations: THP, tobacco heating product; THS, tobacco heating system; ISO, International Organization for Standardization; NFDPM, nicotine-free dry particulate matter; BAT, British American Tobacco; FDA, Food and Drug Administration; MLE, mouth level exposure; TPM, total particulate matter; ADC, average daily consumption; SD, Standard Deviation; HCI, Health Canada intense.

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consumers will use the product in a manner that reduces their individual exposure or health risk compared with using other commercial tobacco and nicotine products. The US Food and Drug Administration (FDA) as part of the Modified Risk Tobacco Product Application guidelines recommend conducting 'actual use' studies where consumers interact freely with the products in their everyday environments, pre- and post-product launch (FDA, 2012).

'Actual use' studies provide an insight into consumer use behaviour such as the size and frequency of puffs taken, mouth level exposure (MLE) and number of interactions with the product per day. Studies reporting 'actual use' data for THPs are not widely available (Haziza et al., 2016; Lee et al., 2004; Lüdicke et al., 2017), likely due to the low numbers of commercially available devices, although several approaches to producing an aerosol by heating tobacco have been reported (Moennikes et al., 2008; Schorp et al., 2012; Stabbert et al., 2003). The commercially available THPs, Eclipse (R. J. Reynolds, Winston Salem, NC, USA), iQOS™ (Philip Morris International, New York, NY, USA), Ploom (Ploom, San Francisco, CA, USA), and glo™ (BAT; referred to as THP1.0 throughout), employ different methods of heating tobacco, with some of the more recent devices designed to control the heating profile (Eaton et al., 2017; Smith et al., 2016).

We report here a study with the objective of measuring puffing topography, MLE and average daily consumption (ADC) among Japanese smokers and THP users to characterise their use behaviour of non-mentholated and mentholated THPs [THP1.0(T) and THP1.0(M)] in comparison with commercially available combustible cigarettes (T189 and M322) and a tobacco heating system (THS). Study volunteers were smokers of non-mentholated and mentholated cigarettes who were naïve to the use of THPs and those who were regular users of the commercially available THP.

A number of research groups have explored various approaches for using the materials trapped by the filter as an indicator of smoke exposure (Pauly et al., 2009; Shepperd et al., 2006; St. Charles et al., 2009; Watson et al., 2004). Due to the fundamental differences in the kinetics of formation, transfer and retention of aerosol constituents in the mouth end section of the THP consumable compared with a conventional cigarette, further research to understand the relationship between flow and retention efficiency of constituents is needed before MLE from THPs can be estimated with a filter- or mouth-piece-based approach. In this study, an optical obscuration technique based on that described by Slayford and Frost (2014) was used to estimate MLE to nicotine free dry particulate matter (NFDPM), nicotine and menthol from THPs and the cigarettes.

These MLE estimates derived using real-time optical obscuration were collected using the modified holder of the puffing topography device (SA7, developed by BAT in collaboration with C-Matic Limited, Crowborough, UK) described by Cunningham et al. (2016). The estimates were further reinforced by duplicating a subset of the puffing topography records in the laboratory.

Several studies have claimed that some smokers block or partially block the ventilation holes on cigarette filters with their lips, thereby increasing their MLE (Baker and Lewis, 1997; Kozlowski et al., 1980, 1982, 1988, 1996). According to the THP1.0(T) use instructions, the user is asked to insert the consumable into the device and hold the device while puffing on the mouth piece. The study included a fourth arm designed to investigate potential lip blocking of the air inlet holes of the specially designed consumable of THP1.0(T) during use. Saliva stains on the used consumables were visualised by treating the tipping paper with ninhydrin solution. The maximum mouth insertion depth was defined as the distance from the mouth end to the furthest point of the visible ninhydrin staining (Baker and Lewis, 1997; Porter and Dunn, 1998).

2. Methods

2.1. Study products

THP1.0, developed by BAT, was evaluated in this study. A full description of the design and thermophysical properties of THP1.0 is reported by Eaton et al. (2017). In brief, THP1.0 is a handheld electronic device with a heating chamber designed for a specific tobacco consumable that is inserted and heated to a maximum temperature of 240 °C ± 5 °C to produce an inhalable aerosol. THP1.0(T) comprises the glo™ heating device with Bright Tobacco Kent Neostiks™, and mentholated THP1.0(M) comprises the glo™ heating device with Intensely Fresh Kent Neostiks™. The devices and consumables were sourced from Japan. Participants were provided with study cigarettes according to their usual tobacco product type: either 7 mg ISO (International Organization for Standardization [ISO] 4387:2000) (ISO, 2000) NFDPM non-mentholated cigarettes based on Lucky Strike Regular (T189) or 7 mg ISO NFDPM mentholated cigarettes based on Lucky Strike Menthol (M322). The THS was the commercially available iQOS™ with Essence tobacco HeatStick™, also sourced from Japan. All products were provided by the study sponsor. Cigarettes were provided in unbranded white packaging and the THPs were provided in branded packaging.

2.2. Study participants

The study was conducted in Tokyo, Japan, during 2016. Four groups of study participants were recruited by a market research agency following the International Code on Market Opinion and Social Research and Data Analytics (ICC/ESOMAR, 2016). Adult Japanese tobacco users between the ages of 21 years and 7 months and 64 years were eligible for inclusion in the study. Group 1 and 4 participants (smokers of non-mentholated cigarettes) were eligible if they smoked five or more non-menthol 7–8 mg NFDPM (ISO yield) cigarettes per day and had been smoking for more than 6 months. Group 2 participants (smokers of mentholated cigarettes) were eligible if they smoked five or more menthol 7–8 mg NFDPM (ISO yield) cigarettes per day and had been smoking for more than 6 months. Group 3 participants (THS users) were eligible if they reported using THS for five or more sessions per day and had been a user for a minimum of 3 months, including those who smoked commercial cigarettes in addition to using THS (dual users). Females were excluded if they reported that there was a possibility that they were pregnant. All participants were screened using a written questionnaire and provided written informed consent prior to participating in the study. Participants were informed that they were free to withdraw from the study at any time and received remuneration for their participation in the study.

2.3. Study protocol

Participants in Groups 1, 2 and 3 were provided with study products to use in place of their regular tobacco products over a 4-day familiarisation period. Participants were provided with enough product to cover their self-reported average daily consumption rounded up to the nearest pack for each familiarisation period. The products relevant to each group were presented in a randomised order in consecutive product placements (Fig. 1). Group 1 were provided with three non-mentholated products, cigarette T189, THP1.0(T) and THS. Group 2 were provided with two mentholated products, cigarette M322 and THP1.0(M). Group 3 were provided with two THPs, THP1.0(T) and THS with tobacco consumables. All participants received instructions on how to operate the THP devices before the placement. Participants were asked to replace a