INVESTIGATION ON PUFFING TOPOGRAPHY PARAMETERS AND PRODUCT EVALUATION RECORDED DURING FIVE DAYS OF USE OF THE TOBACCO HEATING SYSTEM 2.2: A COMPARISON WITH CONTINUED COMBUSTIBLE CIGARETTE USE

G. de La Bourdonnaye[1], C. Haziza[1], P. Picavet[1], G. Baker[1], D. Skiada[1], K. Jarus-Dziedzic[2], and F. Lüdicke[1]
[1] Philip Morris International R&D, Neuchatel, Switzerland, [2] BioVirtus, Kajetany, Poland

Introduction and Objectives

Philip Morris International is currently developing potentially reduced risk products (RRPs) with the intention to reduce smoking-related morbidity and mortality. It is important to measure the way in which individuals consume the product compared to existing tobacco products.

This study is part of a global clinical program to assess Tobacco Heating System 2.2 (THS 2.2), a potentially reduced risk product. The objective was to demonstrate reduction in exposure to selected harmful and potentially harmful constituents after 5 days of use of THS 2.2 compared to combustible cigarettes (CC). This is reported in another poster.

A secondary objective was to assess the adaptation to THS 2.2 through puffing topography parameters and subjective effects.

Methods

- Open-label, randomized, controlled, 3-arm parallel groups, confinement study.
- 160 healthy Caucasian smokers aged between 21 and 65 years.
- Subjects smoked CC during 2 days at baseline prior to being randomized for 5 days in 1 of the following arms: *ad libitum* CC use; *ad libitum* THS 2.2 use; or Smoking abstinence (SA).
- Puffing topography is the description of puff characteristics (e.g. puff volume, duration or interval) and was assessed using a Smoking Puff Analyzer Mobile (SODIM®) with pressure and flow measurement capabilities.
- Puffing topography parameters were recorded at baseline for all subjects, and at Day 1 and Day 4 for both the CC and THS 2.2 arms.
- Product evaluation was assessed daily using the modified cigarette evaluation questionnaire (mCEQ).
- An analysis of variance (ANOVA), adjusted for baseline value, sex and daily cigarette consumption was applied to the puffing topography parameters with the study arm as a factor.
- The study was conducted in Poland in 2013 according to ICH GCP, approved by an Independent Ethic Committee, and registered at ClinicalTrials.gov (NCT01959932).

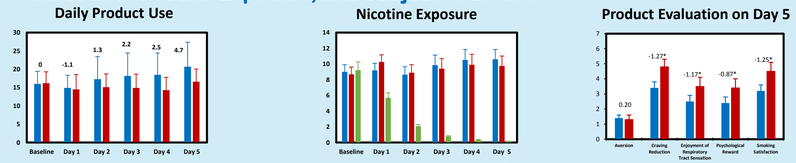
Variable	Visit	THS 2.2 (N=80)	CC (N=40)	SA (N=40)	Overall (N=160)
Subjects with assessable puffing topography parameters	Baseline	56	27	26	109
	Day 1	79	27		106
	Day 4	78	27		105

Results

Demographics

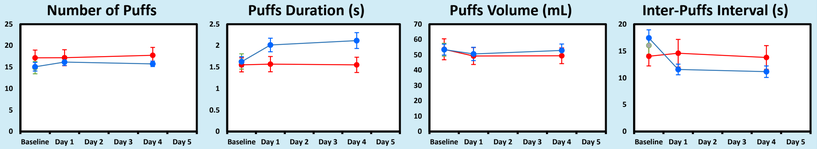
		THS 2.2 (N=80)	CC (N=40)	SA (N=40)	Overall (N=160)
Age [yr M ± SD]		37.6 ± 11.7	37.2 ± 11.7	35.9 ± 10.6	37.1 ± 11.4
Sex (male) [n(%)]		40 (50)	20 (50)	20 (50)	80 (50)
Number of CC/Day [n(%)]	10-19	44 (55.0%)	22 (55.0%)	21 (52.5%)	87 (54.4%)
	> 19	36 (45.0%)	18 (45.0%)	19 (47.5%)	73 (45.6%)

Product Use Nicotine Exposure, and Subjective Effects

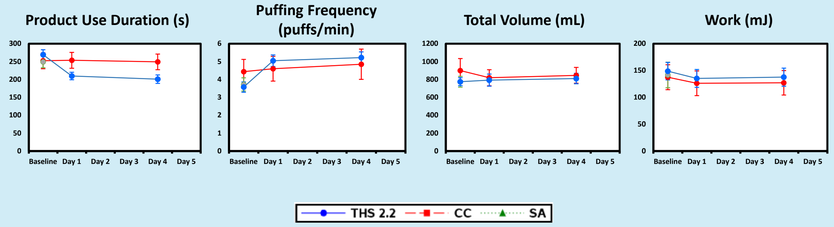


- The average daily product use between baseline and the end of exposure remained in the same range and was similar in the THS 2.2 and CC arms.
- The total nicotine exposure measured as nicotine equivalents was also similar in both arms throughout the exposure period (THS 2.2/CC ratio: > 99 % [95%CI: 83 -119%]).
- Product evaluation subscale scores showed that THS 2.2 was slightly less satisfying than CC after 5 days.

Puffing Topography



- Number of puffs was similar between the CC and the THS 2.2 arm on Day 4 (THS 2.2/CC ratio: 97.1% [95%CI: 89.4-105.5%]).
- Puffs were 32.25% longer in THS 2.2 arm on Day 4 [95%CI: 20.2-45.5%].
- Puffs volume was similar between CC and THS 2.2 arm on Day 4 (THS 2.2/CC ratio: 105.5% [95%CI: 95.6-116.5%]).
- Inter-puff interval were 32.2% shorter in THS 2.2 arm on Day 4 [95%CI: 22.7-40.5%].



- Product use duration was 22.4% shorter with THS 2.2 arm on Day 4 [95%CI: 13.6-30.2%].
- Puffs were 32.3% more frequent with THS 2.2 arm on Day 4 [95%CI: 18.3-48.1%].
- Total volume inhaled was similar between CC and THS 2.2 arm on Day 4 (THS 2.2/CC ratio: 105.3% [95%CI: 92.6-119.7%]).
- Work was similar between CC and THS 2.2 arm on Day 4 (THS 2.2/CC ratio: 96.8% [95%CI: 82.2-113.9%]).

Conclusions

- These results suggest an adaptation of product use after switching to a new product as of Day 1 with different characteristics to achieve the levels of nicotine desired by the THS 2.2 user.
- Differences observed in puffing topography parameters suggest an ongoing adaptation of product use throughout the study.
- Product evaluation however indicates an adaptation extending beyond the observation period of 5 days.

PMI SCIENCE
PHILIP MORRIS INTERNATIONAL

SRNT – 21ST Annual Meeting, Philadelphia, USA
25-28 February 2015

COMPETING FINANCIAL INTERESTS

The research described in this poster was sponsored by Philip Morris International