Topography Study of glo Hyper, a Tobacco Heated Product

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Abstract

Topography is useful in assessing the health risk of a tobacco product by measuring how a user consumes a product. User puffing behavior can impact the level of harmful and potentially harmful constituents (HPHCs) consumers are exposed to when using heated tobacco products (HTPs). A total of 194 US adults aged 21 years and older who used combustible cigarettes or HTPs as their primary source of nicotine were enrolled in a 28-day ambulatory topography study designed to evaluate puffing patterns after switching to the glo Hyper HTP. glo HTP comprises HTP consumables ("neo sticks") and the glo device, into which the neo stick is inserted prior to heating. The glo device has two fixed, user-selected modes ("Standard" and "Boost"). In Standard Mode, the glo device maintains a temperature setting of 250°C for a 4-minute heating session, while in Boost Mode, the glo device maintains a temperature setting of 260°C for a 3-minute heating session. Study participants were assigned to use one of four neo sticks-based on their self-reported usual brand cigarette or HTP. Three menthol neo stick variants, including one with a crushable menthol capsule, and one non-menthol variant were assessed. Topography parameters including puff duration, number of puffs per day, inter-puff interval duration, and number of glo Hyper device activations per day were captured using the Product Use and Behavior (PUB) instrument. On average, participants took 57.5 puffs per day and used an estimated average of five neo sticks per day. The overall mean puff duration was 1.66 seconds, overall mean inter-puff interval was 17.7 seconds, and study participants activated the device on average 4.9 times a day. Participants had similar puffing patterns regardless of neo stick variant used. Importantly, participants' puffing patterns aligned with the Health Canada Intense machine puffing regimen utilized in chemistry studies of glo HTP that demonstrated substantial overall reductions in HPHCs compared to combustible cigarettes. The findings of this topography study suggest that as actually used by consumers, the use of glo HTP reduces exposure to tobacco smoke constituents compared to combustible cigarettes.

Endpoints

Primary	
Arithmetic mean puff duration (Figure 2)	
Secondary	
Arithmetic mean: • Inter-puff interval duration per activation session (Figure 2) • Percent puffs per day in Standard and Boost modes (Figure 3) • Total puffs per day (Figure 4) • Number of HTP device activations per day (Figure 4)	
Product Evaluation Scale (PES) (Table 1, Figure 5)	
Overall Product Liking (OPL)	Intention to Use (ITU)

Results

Figure 1. PUB Instrument. Device PUB instrument connected to glo Hyper device, which is connected via Bluetooth® to the app on an electronic device provide for use by each subject during the study. Topography data is transferred to the Microsoft Azure cloud platform.

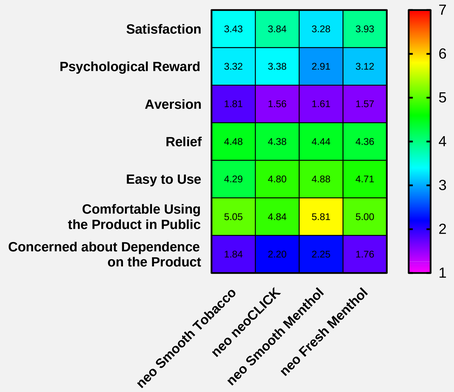

Table 1. Heat Map of Product Evaluation Questionnaire Scores. Each question was answered on a seven-point Likert scale ranging from 'not at all' (1) to 'extremely' (7).

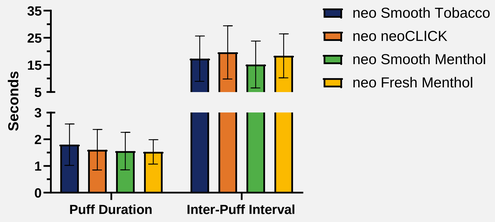

Figure 2. Arithmetic mean of puff duration of each of the study IPs. Error bars represent standard deviation.

Demographic	Category/Characteristics	Overall n (%)
Age (years)	Mean (standard deviation)	41.8 (11.4)
Sex, n (%)	Female	95 (49.0)
	Male	99 (51.0)
Ethnicity, n (%)	Hispanic or Latino	17 (8.8)
	Not Hispanic or Latino	175 (90.2)
	Not Reported	2 (1.0)
Race, n (%)	White	110 (56.7)
	Black or African American	74 (38.1)
	Asian	2 (1.0)
	American Indian or Alaska Native	2 (1.0)
	Multiple	5 (2.6)
	Not Reported	1 (0.5)

Table 2. Study Population Demographics

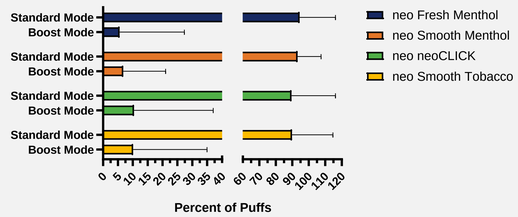

Figure 3. Arithmetic mean of Percent of Puffs per day in Boost and Standard Modes. Error bars represent standard deviation.

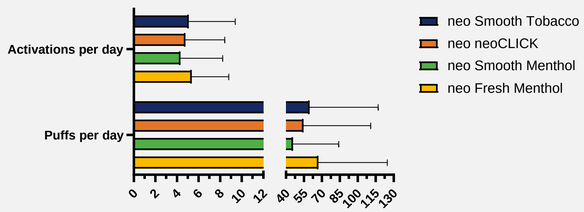

Figure 4. Arithmetic mean of number of activations per day and total number of puffs per day for each of the study IPs. Error bars represent standard deviation.

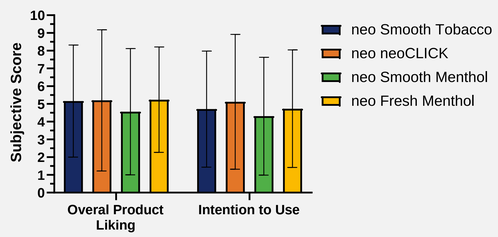

Figure 5. Overall Product Liking and Intention to Use Questionnaires were evaluated on a numerical rating scale from 0 (strongly dislike) – 10 (strongly like), or 1 (definitely would not use it) – 10 (definitely would use it), respectively. Error bars represent standard deviation.

Methodology

Study Design and Population
Seven site, 28-day ambulatory period, parallel-cohort, open label study.
Generally healthy adult males and females, aged 21 to 60 years old, who smoked at least 5 cigarettes or HTP sticks per day within 30 days prior to screening and had familiarity with modern smart phone/tablet technology. ClinicalTrials.gov identifier: NCT05307822.

IP Group Selection
Subjects that reported non-menthol UB cigarette/HTP use were assigned to the non-menthol neo stick variant. Subjects who reported menthol UB cigarette/HTP use were assigned to received one of the three menthol variants after optionally sampling them and determining which one they would like to use for the study. Once a particular menthol variant group had reached full enrollment, that neo stick variant was no longer available for sampling and selection.

Study Design
At the Enrollment Visit, subjects were provided an orientation to the glo Hyper device, neo sticks, PUB instrument, and PUB mobile application. Subjects were allowed to use non-combustible cigarettes or non-HTP tobacco/nicotine-containing products according to their normal use pattern.

The 28-day ambulatory period included a 14-day acclimation period followed by a 14-day product use Evaluation Period.

At the conclusion of the 28-day ambulatory period, subjects came back to the clinic to return the HTP and associated accessories, unused neo sticks, and PUB instrument. Subjects were asked if they used (and frequency) additional nicotine products, reported any AEs, complete PES, OPL, and ITU questionnaires, and as applicable, used the menthol feature of the neo neoCLICK HTP IP.

Summary and Conclusions

- **The arithmetic mean puff duration ranged from 1.53 sec ± 0.46 sec (neo Fresh Menthol) to 1.80 sec ± 0.71 sec (neo Smooth Tobacco) (Figure 2).**
- **The Inter-Puff Interval arithmetic mean per activation ranged from 15.15 sec ± 8.69 sec (neo Smooth Menthol) to 19.63 sec ± 9.80 sec (neo neoCLICK) (Figure 2).**
- **The arithmetic mean of the percent of puffs occurring in boost mode ranged from 5.56% ± 21.75% (neo Fresh Menthol) to 10.43% ± 26.62% (neo neoCLICK) (Figure 3).**
- **Total number of puffs per day and device activations arithmetic means ranged from 45.99 ± 38.10 and 4.32 ± 3.92 (neo Smooth Menthol) to 67.16 ± 57.49 and 5.37 ± 3.43 (neo Fresh Menthol), respectively (Figure 4).**
- **No trend was observed in PES scores. The highest mean PES subscale was Comfortable using the product in public (5.11 ± 2.10) and the lowest score was for Aversion (1.67 ± 1.00) (Table 1).**
- **Mean OPL and ITU scores were similar between the variants ranging from 4.56 – 5.24 and 4.31 – 5.12, respectively (Figure 5).**
- **The use of the glo HTP IPs appeared to be well tolerated by the study subjects. Overall, subjects had similar use patterns regardless of the neo stick variant.**

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