Emissions, puffing topography, mouth level exposure and consumption of two heated tobacco products among Japanese users

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Introduction

The objective of this study was to assess the emissions, puffing topography, mouth level exposure (MLE) and average daily consumption (ADC) of two glo™ heated tobacco products (HTPs) among regular HTP users in Japan.

Methodology

Test Articles

Two glo™ HTPs were assessed, shown in **Table 1**: glo hyper in base and boost modes, and glo 2.0, on which emissions, puffing behaviour, in-vitro and clinical data have previously been collected. [1-5]

Table 1. Study products and device characteristics

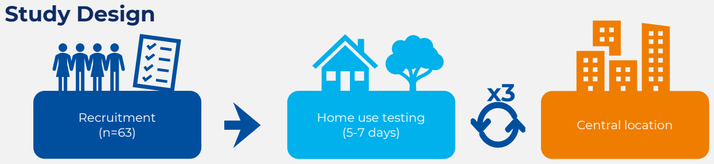
Product	Device	Heating mechanism	Heating profile	Format (tobacco weight)	Flavour
1	glo™ 2.0	Resistive	Standard [a]	KSSS (280 mg)	Menthol
2	glo™ hyper	Induction	Base [b]	DS (340 mg)	Tobacco
3	glo™ hyper	Induction	Boost [c]	DS (340 mg)	Tobacco

Abbreviations: KSSS, king size super slim; DS, demi-slim.
a-45 seconds to first puff, 3.5-min heating session at 240°C; b-20 seconds to first puff, 4-min heating session at 250°C; c-15 seconds to first puff, 3-min heating session at 260°C

Emissions

Emissions analysis was conducted by Labstat, Canada using a modified Health Canada intense (m-HCI) machine puffing regime of volume 55±0.5 mL, puff duration 2.0±0.1 s, puff interval 30±1 s, bell-shaped profile and 0% blocking of the perforations. (ISO/TR19478-1:2014) as described by Forster et al. (2018).[1] Percentage reduction of TobReg9 toxicants was determined relative to smoke from a 1R6F reference cigarette.

Study Design



Regular glo HTP users in Japan
- ≥5 sticks/day for at least 6 months
- Aged 21-64yrs
- Not trying or planning to quit
- Willing to use mentholated and non-mentholated products
- 44 male: 19 female
- Informed consent via ICF

ADC via daily consumption diary
- Each HTPs in turn for 5-7 days (randomised), in place of their usual product
- Followed by central location testing after each home placement
- 1-week supply of consumable (120% of self-declared consumption)

Puffing topography & MLE
- Measured using a desktop puffing analyser (SA7), *Figure 1*
- 2 repeats (1 stick per repeat), with 20 min break between each repeat
- Perceived sensory attribute scores via questionnaire

Puffing Topography Measurements

- Measured using a desktop puffing analyser (SA7), **Figure 1** [2,3]
- Puff-by-puff volume, duration, inter-puff interval, pressure drop and optical obscuration of aerosol
- Estimated MLE to NFDPM & nicotine via optical obscuration by machine calibration [2,3]

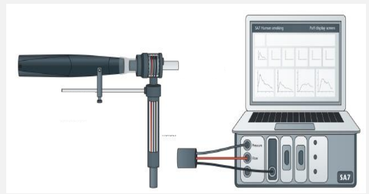


Figure 1. SA7 desktop puffing analyser

Results

Emissions

- NFDPM (nicotine-free dry particulate matter) and nicotine per stick was higher for glo hyper than glo 2.0, **Table 2**, with no difference between base & boost modes of glo hyper.
- Overall reduction in TobReg9 toxicants relative to 1R6F reference cigarette were similar among the three HTPs, **Table 3**.

Table 2. Concentration of nicotine, NFDPM and TPM in HTP aerosol

TobReg9 toxicant	glo 2.0	glo hyper (base)	glo hyper (boost)
Nicotine (mg/stick)	0.573	0.807	0.812
NFDPM (mg/stick)	12.6	17.6	18.0
TPM (mg/stick)	28.7	40.1	40.6

Abbreviations: NFDPM, nicotine-free dry particulate matter, TPM, total particulate matter. Number of puffs taken reflective of heating time of the device - ten puffs per consumable for Product 1 (3.5 min), nine puffs per consumable for Product 2 (4 min) and eight puffs per consumable for Product 3 (3 min).

Table 3. Percent reduction (%) of TobReg9 toxicants relative to 1R6F reference cigarette

TobReg9 toxicant	glo 2.0	glo hyper (base)	glo hyper (boost)
1,3-Butadiene	99.98	99.93	99.93
Acetaldehyde	93.89	91.80	90.87
Acrolein	98.78	98.22	97.88
Benzene	99.92	99.87	99.87
Benzo(a)pyrene	98.23	96.63	98.23
CO	99.45	99.45	99.39
Formaldehyde	96.86	95.47	94.82
NNK	97.55	93.19	94.76
NNN	91.23	85.03	87.67
Overall Reduction %	**97.32**	**95.51**	**95.94**

Abbreviations: CO, carbon monoxide; NNK, Nicotine-derived nitrosamine ketone; NNN, N-Nitrosonornicotine. Number of puffs taken reflective of heating time of the device - ten puffs per consumable for Product 1 (3.5 min), nine puffs per consumable for Product 2 (4 min) and eight puffs per consumable for Product 3 (3 min).

Puffing Topography, ADC and estimated MLE (Table 4)

- Differences in MLE (per stick & per day) between glo 2.0 and glo hyper were consistent with differences in machine yield, **Table 2**.
- Differences in puff number and session length were consistent with differences in heating time of the device, **Table 1**.
- Differences in puff volume and measured pressure drop were consistent with consumable format of glo 2.0 (KSSS, smaller diameter) vs glo hyper (DS, larger diameter), **Table 1.**

Table 4. Puffing topography, ADC and MLE attributes. Mean ± SD of n=63 participants.

Parameter	glo 2.0	glo hyper (base)	glo hyper (boost)
Puffing Topography			
Puff number	18 ± 7 [a]	21 ± 10 [a]	17 ± 7. [b]
Puff volume (mL)	57 ± 24 [b]	81 ± 68 [a]	69 ± 34 [a]
Puff duration (s)	1.9 ± 1.0 [a]	1.8 ± 1.03 [ab]	1.6 ± 0.7 [b]
Inter-puff interval (s)	9 ± 4 [a]	9 ± 4. [a]	9 ± 4 [a]
Session duration (s)	163 ± 57 [b]	179 ± 68 [a]	146 ± 45 [c]
Pressure drop (cmWG)	19 ± 8 [a]	11 ± 6 [b]	12 ± 6 [b]
Average daily consumption			
ADC (stick/day)	10.0 ± 4.5 [a]	9.6 ± 4.9 [b]	10.2 ± 4.9 [a]
Mouth level exposure			
NFDPM (mg/stick)	12.5 ± 5.8 [b]	19.9 ± 11.9 [a]	18.8 ± 9.0 [a]
NFDPM (mg/day)	132 ± 91 [b]	208 ± 184 [a]	207 ± 162 [a]
Nicotine (mg/stick)	0.8 ± 0.4 [b]	1.7 ± 1.1 [a]	1.5 ± 0.9 [a]
Nicotine (mg/day)	8.6 ± 6.0 [b]	17.5 ± 16.2 [a]	17.2± 14.5 [a]

Analysed using linear mixed model ANOVA (proc mixed), followed by Tukey's post hoc test. For a given parameter, values sharing the same alphabet letter are not significantly different (p>0.05); values not sharing the same alphabet letter are significantly different (p<0.05).

Conclusion

- Overall reduction of 95.5 – 97.3 % in the content of TobReg9 toxicants in the HTP aerosol relative to smoke from the reference cigarette.
- Estimated MLE to NFDPM was consistent with machine yields under m-HCI puffing conditions, suggesting that this machine puffing regime is broadly representative of human behaviour.
- This in turn suggests that the percentage reduction in TobReg9 toxicants is relevant to actual human use.

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