Development and validation of a device to measure e-cigarette users' puffing topography

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INTRODUCTION
Initial attempts to measure puff volumes when puffing on e-cigarettes using known volumes generated from machine smoking led to inaccurate and variable data when using our existing puffing topography device (SA7[1]). Possible causes included condensation of excipients within the topography head and variation in insertion depth of e-cigarette in relation to the pressure orifice, which may cause a jetting effect of the aerosol if placed too close to the orifice.

OBJECTIVES
- Develop and validate a device to accurately measure puffing topography parameters when puffing on e-cigarettes
- Test the validated device to measure e-cigarette users' puffing topography

DEVICE MODIFICATIONS[2]

Spigot adapter to attach e-cigarettes to topography holder. Spigot removes jetting through orifice, which results in inaccurate puff volumes

Pressure ports on top to reduce excipients from blocking tubes

Removable cap allows access to orifice plate for cleaning

Bracket to support larger e-cigarette modular devices

Figure 1. Modifications to topography device

LABORATORY VALIDATION METHOD
Without e-cigarette
- Pressure calibration at flow rates of 17.5 and 120ml/s using calibrated pressure meter
- Flow rate calibration 2-120 mL/s using A14 syringe driver (Borgwaldt); a range of 33 flow rates
- Measurement of puff volume drawn by syringe driver and compared with burette volumes at 20, 40, 60 and 80 mL
- Four puffing regimes (volumes of 20-80 mL and durations of 1.5-3.0 s) tested in triplicate using sine, square, triangle and early triangle puff profiles (Table 1, Figure 2)

Table 1. Regimes used to test accuracy of puff volumes and duration measurements

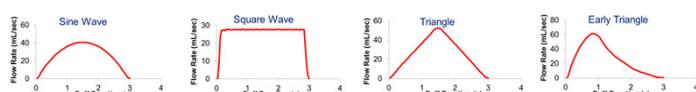| Regime	Puff volume (mL)	Puff duration (s)
1	20	1.5
2	40	2.0
3	60	2.5
4	80	3.0

Figure 2. Graphical representation of puff profiles

With e-cigarette
- Disposable, cartomiser- and tank-based rechargeable products puffed to exhaustion or a maximum of 150 puffs
- Each product tested in triplicate using three pre-defined puffing profiles across flow rates of 18.3-40.0 mL/s

Table 2. Regimes used to test accuracy of puff volumes from three e-cigarette types

Regime	Puff Volume (mL)	Puff duration (s)	Puff frequency (s)	Flow rate (mL/s)
1	55	3.0	30	18.3
2	80	3.0	30	26.7
3	120	3.0	30	40.0

E-CIGARETTE USERS' PUFFING TOPOGRAPHY STUDY
- 60 e-cigarette users attended a central location facility in U.K. on two occasions, to vape study products for a typical session length (self-determined)
- Users of cartomiser products provided with Vype Reload (n=32)
- Users of tank-based products provided with Vype ePen (n=28)

RESULTS
Without e-cigarette
- Pressure and flow calibration resulted in accurate and linear response for puff volume measurements.
- Puff volumes within ±1 mL of pre-set volume within range of 20-80 mL (Figure 3).
- Puff durations within ±0.1 s of values measured using original SA7 device, across the range of 1.5-3.0 s
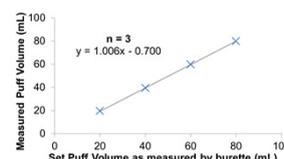

Figure 3. Measured vs Set puff volume

With e-cigarette
- Largest deviation in measured puff volume relative to pre-set volume across measurements was 8.2% (4.5 mL)
- Mean and standard deviation data for all three e-cigarette platforms and regime shown in Table 3.

Table 3. Measured puff volume data for three e-cigarette types

Device Type	Pre-set volume (mL)		
	55	**80**	**120**
	Measured Volume (mL) Mean (SD)		
Disposable	55.1 (0.2) n = 267	80.5 (0.3) n = 266	120.0 (1.1) n = 234
Rechargeable cartomiser-based	54.8 (0.2) n = 434	80.0 (0.3) n = 399	119.1 (0.6) n = 423
Rechargeable tank-based	55.0 (0.8) n = 450	80.4 (1.2) n = 451	120.0 (1.2) n = 452

USERS' PUFFING TOPOGRAPHY DATA
- Statistical differences observed between the two product user groups (Table 4)
- Users of the rechargeable tank-based device took fewer, but larger puff volumes, with longer inter-puff intervals
- No statistical differences in users' topography data between sessions (data not shown)

Table 4. Mean of users' replicate puffing topography data

Product User Group	Session Length (Min:s)	Puff number (#)	Mean Puff Volume (mL)	Mean Puff Duration (s)	Mean Puff Interval (s)	Mean Peak Flow Rate (mL/s)
Cartomiser (n=64)	6:54	21.1	52.2	2.0	23.2	39.0
Tank (n=55)	7:41	16.1	83.0	2.2	29.3	60.6
p value	0.417	0.022	0.000	0.382	0.039	0.000

CONCLUSIONS
- Modified puffing topography device successfully validated for puff volume and duration measurements against known values
- E-cigarette puff volumes within 8.2% of pre-set values, comparable to that observed for cigarettes (6%)[1]
- Statistically significant differences in puffing topography observed between users of rechargeable cartomiser-based and tank-based devices
- Modifications to topography head provide a robust system for measurement of e-cigarette users' puffing topography and demonstrate the need for fit for purpose topography devices when used with e-cigarettes
- Topography data support evaluation of e-cigarettes in a manner that is reflective of users' behaviours

REFERENCES
1. A Device to Measure a Smoker's Puffing Topography and Real-Time Puff-by-Puff "Tar" Delivery, Slayford S.J., Frost B.E., Beitrage zur Tabakforschung, 2014, 26 (2), 74 – 84.
2. Patent pending (UK application number 1420649.4 – unpublished).

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