



# Which parameters are suitable to evaluate e-vapour products puffing behaviour?

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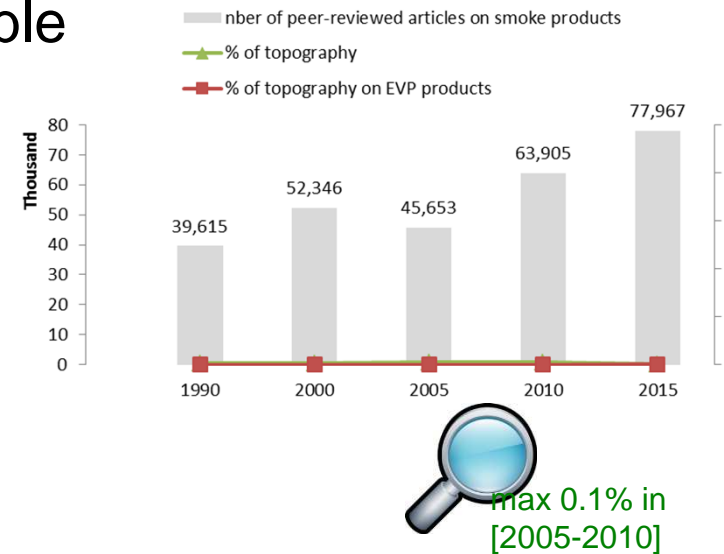
2015 CORESTA Joint Study Groups Meeting  
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# Product usage pattern

## Background

- On classical smoking products:  
limited peer-reviewed publications available
- FDA lack of data
- Recently focused
  - Coresta ECIG Task Force
  - Smoking Behavior Sub-group
- The growing popularity of e-vapour products (EVP) carries with it an increasing interest in the examination of vaping behaviour

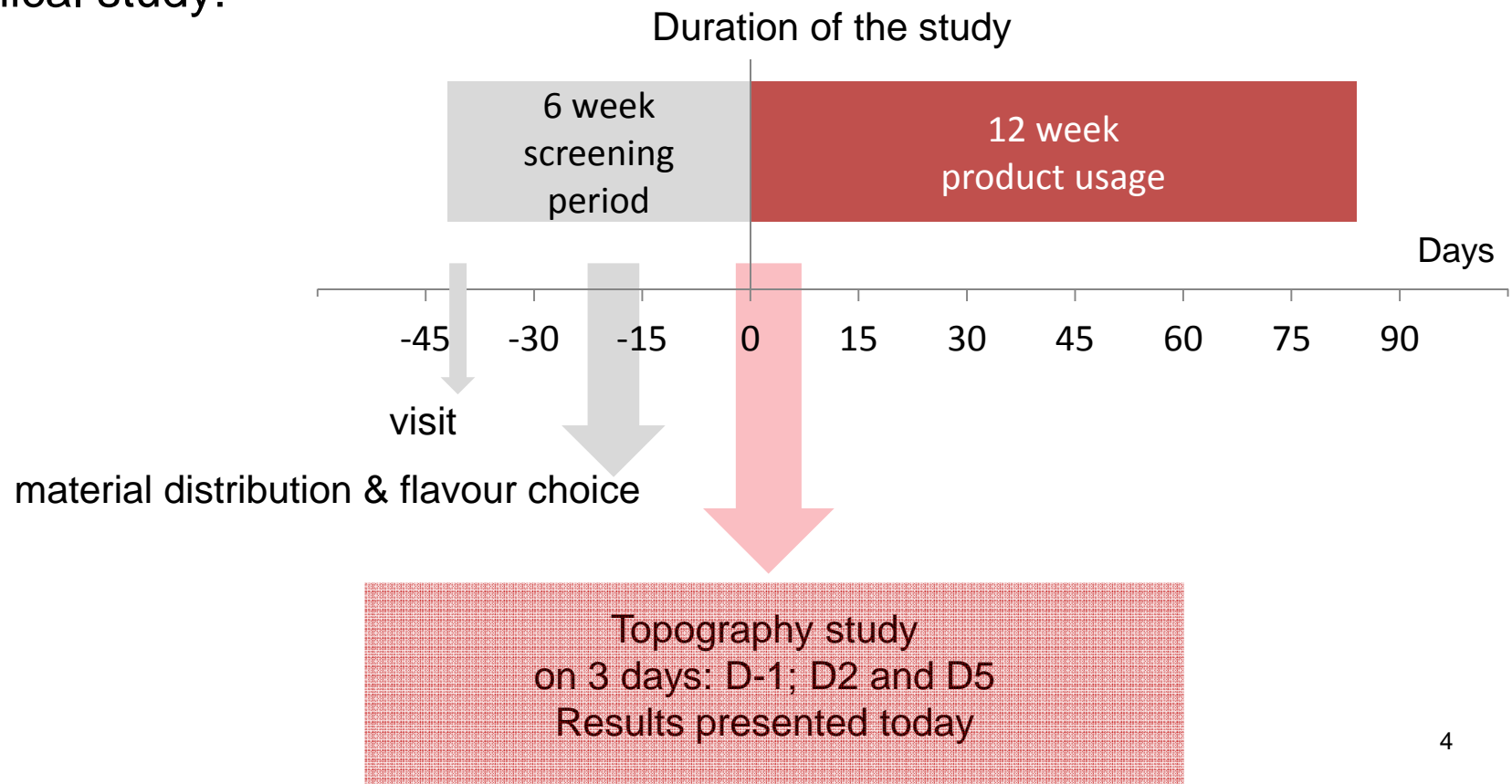


## Context

- This trial is to evaluate a first generation e-vapour product when used by usual smokers of conventional cigarettes
- As part of a product stewardship program to evaluate and assess e-vapour products prior to placing them on the market, a Randomised Parallel Group Multi-centre Study was conducted
  - Primary objectives: safety parameters (includes adverse effect, lung function tests, vital signs & clinical laboratory parameters...)
  - Secondary objectives: investigate potential effect of switching to the EVP on selected biomarkers of exposure, of effect, craving or withdrawal symptom
  - Exploratory objectives include the evaluation of product usage patterns

# Experimental Method /1

- Study design
  - Puffing topography evaluated during the confinement period of this clinical study:



# Study design

Between dream and reality

- Two flavour variants provided to 40 healthy adult smokers
- Randomised to either the EVP arm or conventional cigarette (CC) arm at a ratio of 3:1 respectively
  
- Volunteers / puff number with assessable puffing topography parameters:

Visit	CC	EVP		Total users per Day	Total #puffs
		EVP-1	EVP-2		
Baseline (D-1)	38			38	1187
Day 2	6	21	5	32	1937
Day 5	5	21	5	31	2543
<b>Total users per product</b>	<b>49</b>	<b>42</b>	<b>10</b>		

## Experimental Method /2

- Study material – non-invasive measurement device: **S**moking **P**ortable **A**nalysers **M**obile (SODIM<sup>®</sup>, France)



- Study product
  - EVP : 1<sup>st</sup> generation (cartridge)  
provides 20-40 puffs depending on individual usage pattern of the product
  - PG/Gly base with 2%Nicotine (w/w), 2 flavours (EVP-1 & EVP-2)
  - A new cartridge used at the beginning of each day, with a fully charged battery
  - *at libidum CC or EVP use* for a 4 hour period.



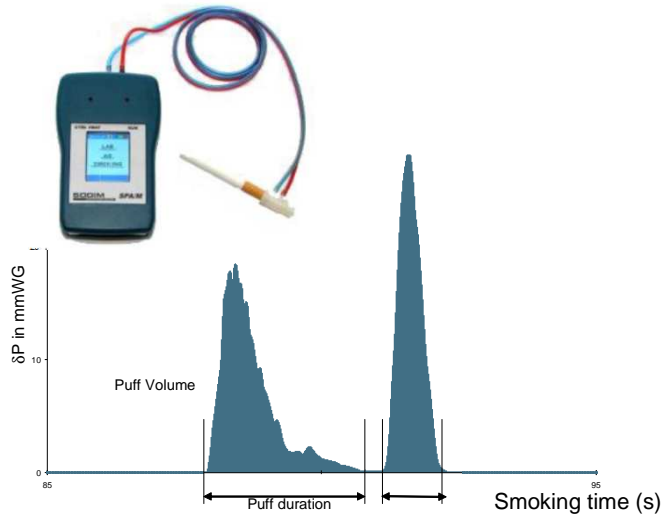
- Statistical analysis – An analysis of variance (ANOVA) with the study arm as a factor

## Results & discussion

- Validated topography device for use with e-cigarettes
  - EVP specification
  - Results on SM450 smoking machine
- Puff topography results from the 4-hour ad-lib use period
  - Overall mean per product
  - Individual puff per product
  - Distribution of puffs per product
- Puff topography results : evolution over the 5 Day-study, CC and EVP users

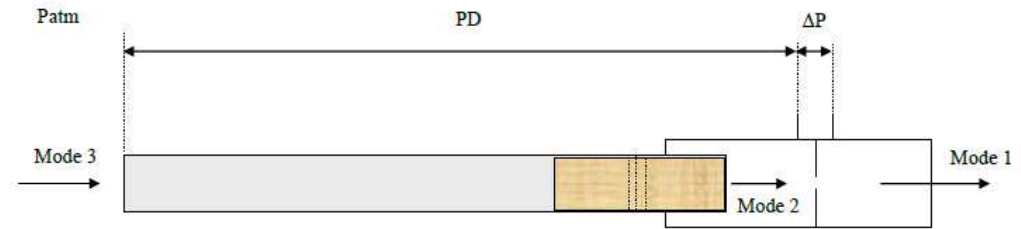
# Topography metrics

- Expression of the flow



- Outcomes of the SPAM SodAfc41 v3.20.5

- Time (puff start)
- Pressure capabilities: Mean Pressure Drop. Peak pressure Drop
- Flow capabilities: Puff Volume, total volume during the session, Puff Duration



Mode 1

$$Q_1 = A \times \sqrt{\frac{P_{cal}}{P_{atm} - PD}} \times (v_4 \times \Delta P^2 + v_3 \times \Delta P^{3/2} + v_2 \times \Delta P + v_1 \times \sqrt{\Delta P})$$

Mode 2

$$Q_2 = Q_1 \times \frac{P_{atm} - PD - \Delta P}{P_{atm} - PD}$$

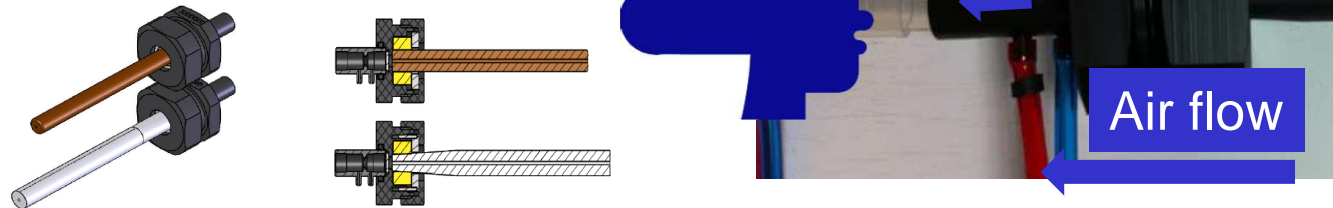
Mode 3

$$Q_3 = Q_1 \times \frac{P_{atm} - PD - \Delta P}{P_{atm}}$$



# EVP specification

- Product: creativity in EVP shape. mouth end (round, oblong, trapeze, ...)
  - Adaptor specifically designed by SODIM
  - fit with various shapes

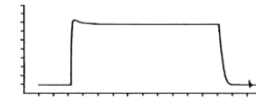


- 3 step validation
  - Flow calibration of each holder.
  - Adaptor effect: confirmation of no bias due to the dead volume
  - Entire set-up (EVP+adaptor+holder): accuracy & precision against SM450 smoking machine (sin and square wave).

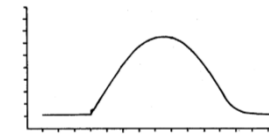
# Validated topography device for use with EVP

## Accuracy of the metrics

V (mL)	Precision			
	r , repetability (%)		R, intermediate precision (%) in 3 days	
	BS	SW	BS	SW
35	2.1	2.7	2.3	3.8
55	1.5	1.5	2.1	1.9
100	1.9	2.7	3.2	3.4



square wave profile



bell shape profile



- EVP +adaptor: the SPA/M performed well across a range of puff volume (20 – 100 mL), puff duration (1 – 9.9 s) using two puff profile sin and square wave.
  - Largest absolute error +4.7 mL for V=30 mL (SW)
  - Puff volume recorded where Flow rate within the puff : 1 – 120 ml/s
  - Puff frequency 50 ms (and 20 ms)
- Accuracy: % difference from target results <10%  
Intermediate precision results <5% over 3 days

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# 4-hour ad-lib use period results

Overall mean per product, per user

Visit	CC	EVP	
		EVP-1	EVP-2
Baseline (D-1)	38		
Day 2	6	21	5
Day 5	5	21	5
<b>Total users per product</b>	<b>49</b>	<b>42</b>	<b>10</b>



Variable	CC smokers N=49	EVP users N=52
Total # Puffs	1525	4142
# Puffs	31 (± 15)	79 (± 77)
Puff volume (mL)	55.4 (±12.1)	65.5 (± 33.4)
Total volume (mL)	1684 (± 854)	4589 (± 3927)
Puff duration (sec.)	1.9 (± 0.6)	2.7 (± 1.2)
Average flow rate (mL/sec.)	32.8 (± 7.2)	26.9 (± 9.2)
Peak flow rate (mL/sec.)	54.2 (± 12.9)	42.8 (± 13.6)

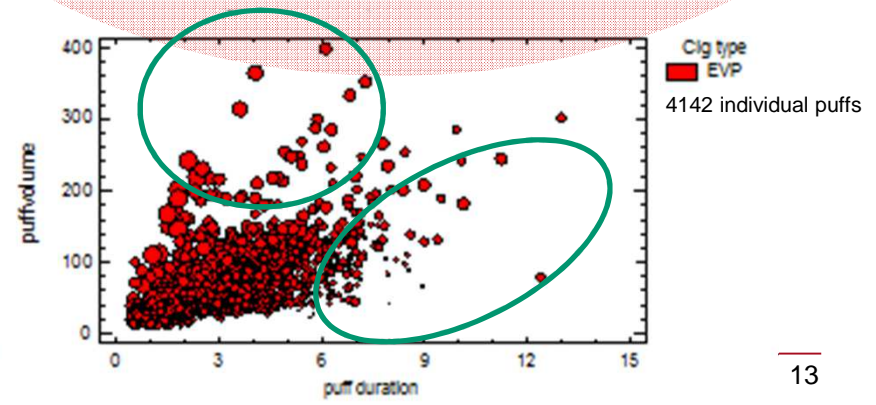
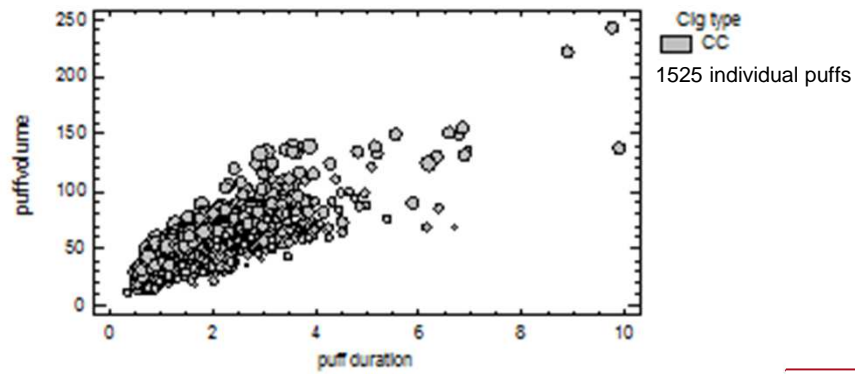
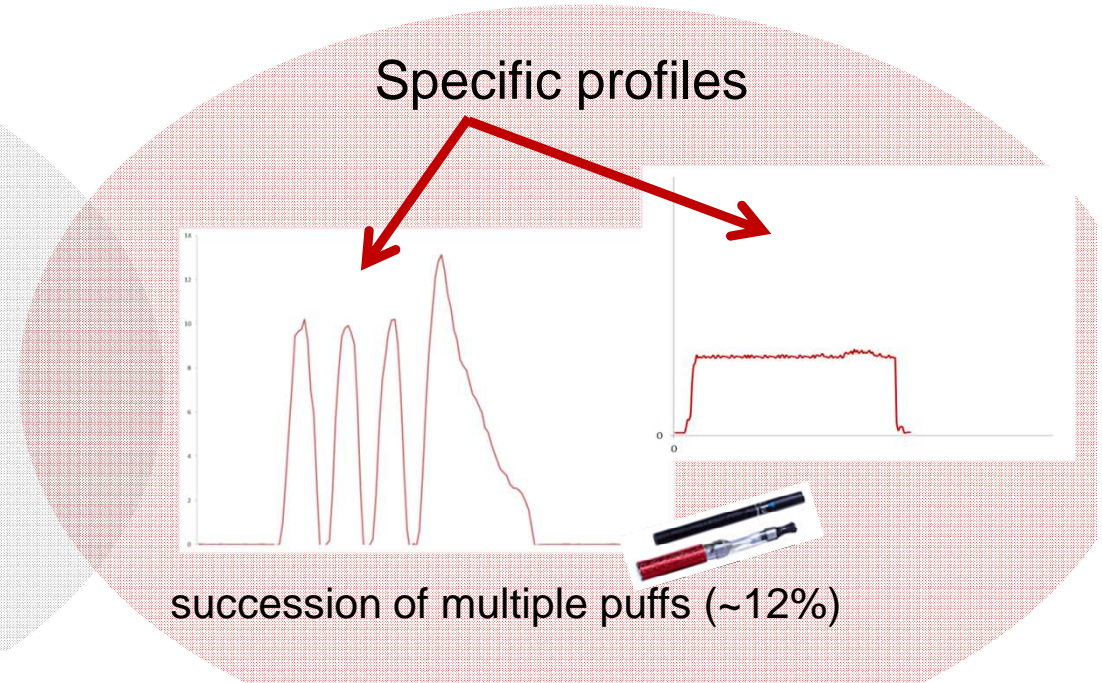
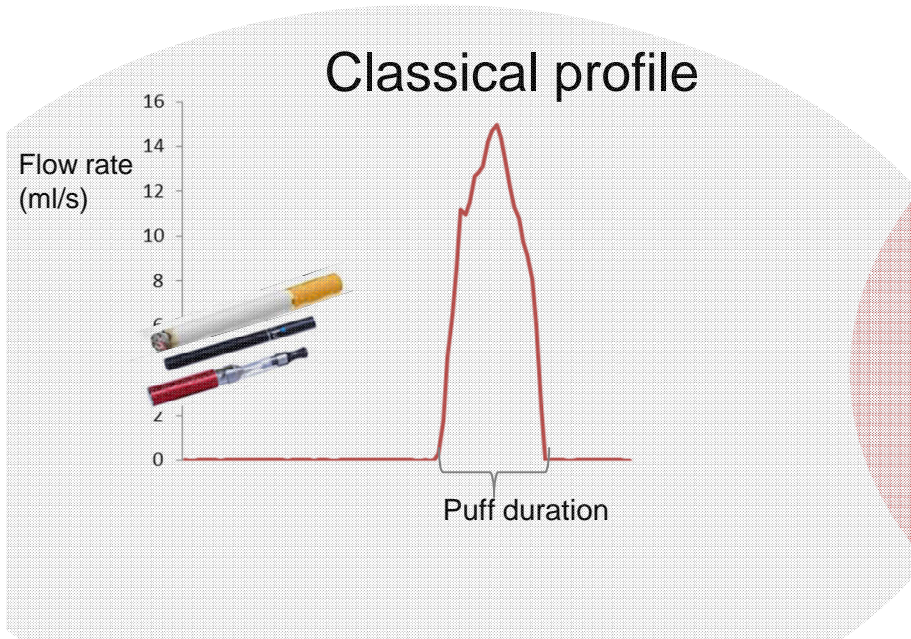
All variables: Mean figures show a statistically significant difference between CC and EVP users (p<0.01)

Mean and standard deviation

EVP-1 (N=42) & EVP-2 (N=10) gathered: no significant difference between the two flavours, except puff number

# Ad lib puff pattern results

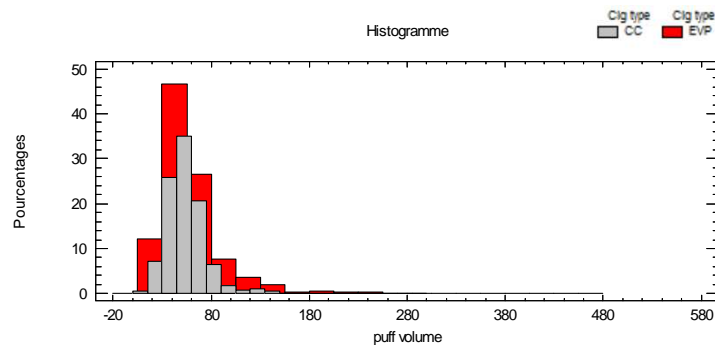
## Individual puff profile



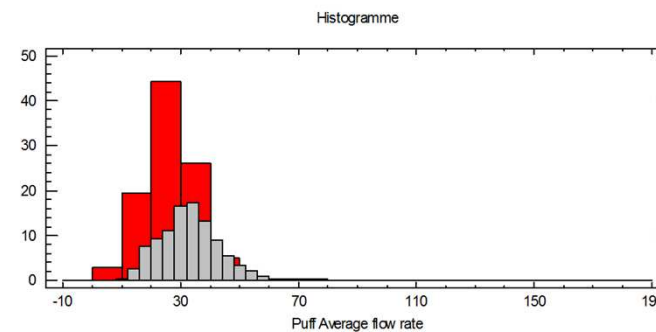
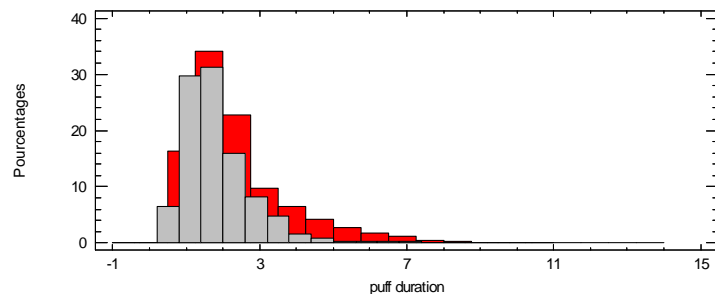
Variable X: puff duration  
Variable Y: puff Volume  
Bullet size= Puff Peak flow rate

# Distribution of puffs per product

- Distribution (expressed as a percentage of puffs) across a range of values for flow rate, puff volume and puff duration



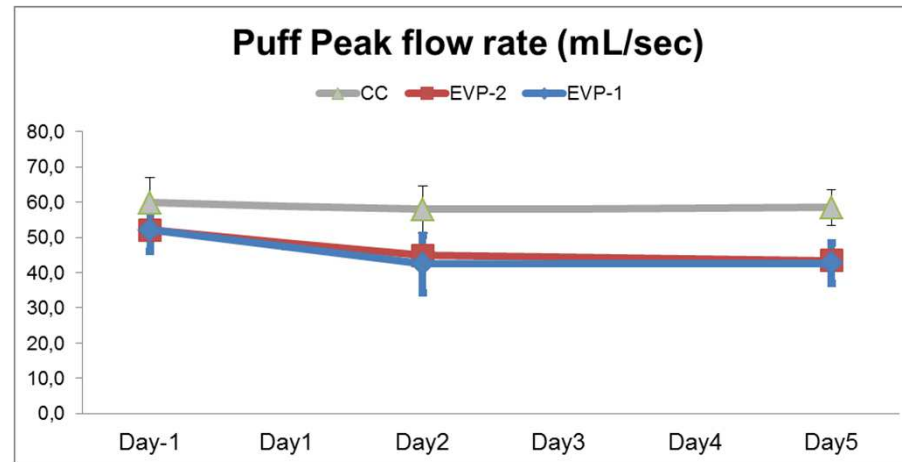
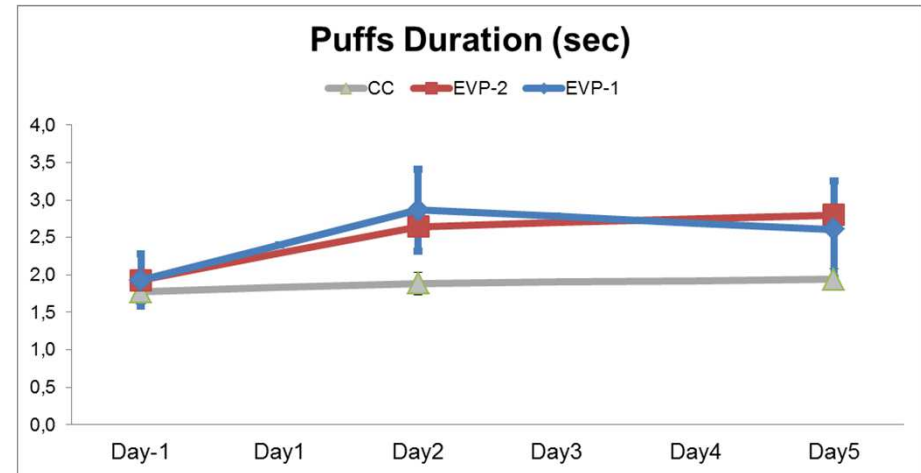
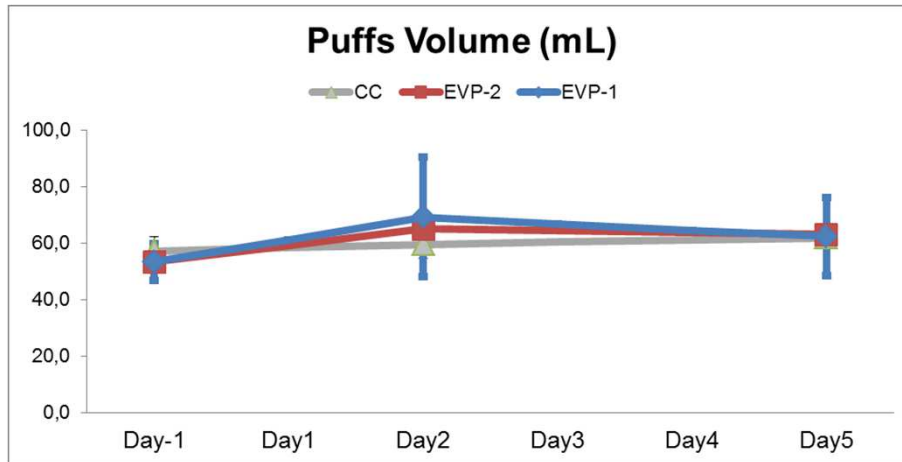
Variable	CC smokers N=49	EVP users N=52
Puff volume (mL)	55.4 ( $\pm 12.1$ )	65.5 ( $\pm 33.4$ )
Puff duration (sec.)	1.9 ( $\pm 0.6$ )	2.7 ( $\pm 1.2$ )
Average flow rate (mL/sec.)	32.8 ( $\pm 7.2$ )	26.9 ( $\pm 9.2$ )



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# Puff topography results : evolution over the study



No Statistically significant differences for the control CC over the 3 days.  
Mean and standard deviation



# Conclusions

## Is the device suitable for the study?

- Device:
  - Conventional topography device with adjustments (*inc.* adaptor calibration) can be used to assess the vaping behavior.
  - The SPAM is a suitable device to measure topography
- Within this particular study:
  - EVP vs. CC: short time study triggers an significant increase in puff duration, puff volume and lower flow rate.  
This is stable between Day3 and Day5.
  - EVP pattern highlight ~12% of multiple puffs.

# Conclusions

Which parameters are suitable to evaluate e-vapour products puffing behaviour?

- Classical parameter (puff Volume, duration, flow rate) obtained with conventional topography device with adjustments
- Additional parameter could be useful to reflect quick succession of multiple puffs

Open to discussion (via increasing peer reviewed publication or Smoking Behavior Subgroup meeting)

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