

Characterizing Puff Topography After 15 Days of Use of Nicotine Salt Pod System by Adult Smokers

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Objective

Data are presented from an open-label, single group product use study of adult smokers (n=30, 10-25 CPD) to evaluate puff topography using the Nicotine Salt Pod System (NSPS, JUUL Virginia Tobacco, 5% nicotine by weight). The primary objective was to characterize key topography parameters (puff duration, volume, peak and average flow rate, and inter-puff interval). Secondary objectives included assessing relationships between product use, and subjective effects, including appeal.

Methods

Subjects participated in a 15 day at-home product use study (Figure 1), and were directed to predominantly use the NSPS product *ad libitum* as the primary source of nicotine. On Day 1 and Day 15, subjects underwent puff topography evaluation, comprised of a 1 hour *ad libitum* product use session with the NSPS and the CReSS Pocket Topography device (Borgwaldt Group). Subjects also completed psychometric surveys on Day 1 and Day 15, including a Product Liking visual analog scale.

Figure 1: Testing Sequence

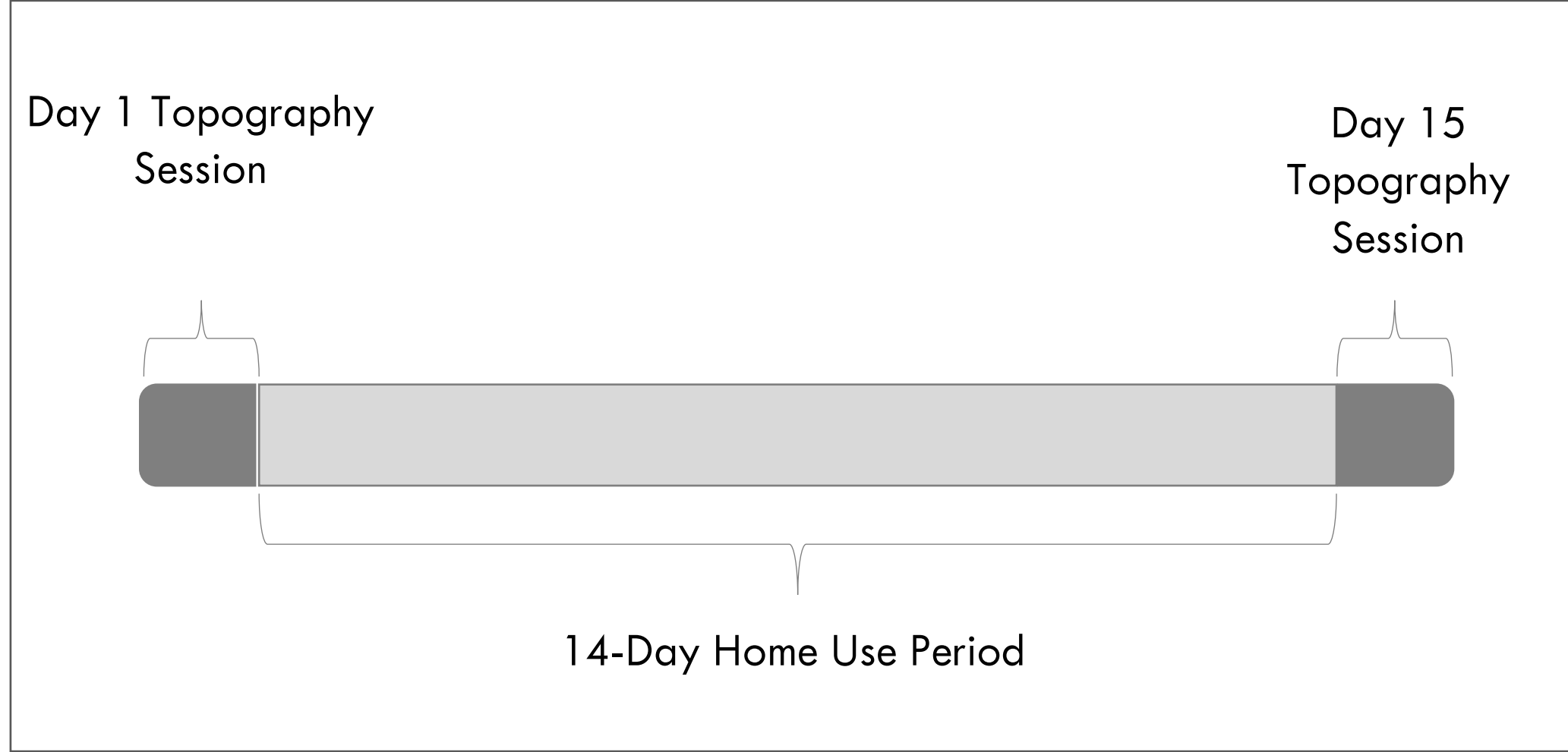


Table 1: Demographics (Safety Population)

N = 30		
Characteristic	Unit	Mean (SD) or %
Age	Years	40.5 (9.10)
BMI	kg/m ²	28.0 (4.96)
Male	%	50%
Caucasian	%	73.3%
African American	%	26.7%
Hispanic	%	6.7%
Current Cigarette Use	%	100%
Menthol Preferred	%	60%
CPD	#	16.6 (4.87)
Years Smoking	Years	22.8 (7.82)
E-Cig Ever Used	%	26.7%

Results – Demographics and Study Population

The study population consisted of 30 current adult smokers who reported smoking 16.6 ± 4.9 CPD for a mean of 22.8 ± 7.8 years (Table 1). Menthol cigarettes were preferred by 18 subjects (60%), and 8 (26.7%) had previously used ENDS products. Subjects were 40.5 ± 9.1 years old with a BMI of 28.0 ± 5.0, were 50% female and 27% African American.

Results – Home Use Period

Of the 30 subjects, 19 subjects self-reported 50 or more NSPS puffs per day during the 14-day at-home use period; 11 subjects self-reported fewer than 50 puffs per day (Figure 2). These were categorized in secondary analysis as “more frequent use” and “less frequent use” groups of subjects, with “more frequent” defined as NSPS use on at least 50% of reported days with more than 50 puffs per day.

Results – Topography

Out of 30 subjects in the safety population, data from 9 subjects were excluded from topography analysis due to CReSS data loss or inconsistency. This included 7 from the “more frequent” group and 2 from the “less frequent” group. For the 21 evaluable subjects overall), no significant differences in mean topography parameters were observed between Day 1 and Day 15.

As shown in Table 3, Mean puff duration was 1.99 ± 0.79s on Day 1 versus 2.14 ± 0.93 s on Day 15. Mean puff volume was 70.5 ± 30.5 mL on Day 1 versus 77.5 ± 50.3 mL on Day 15. Mean peak puff flow rate was 53.5 ± 14.8 mL/sec on Day 1 versus 48.4 ± 12.1 mL/sec on Day 15. Mean flow rate was 37.6 ± 11.4 mL/sec on Day 1 versus 34.9 ± 10.2 mL/sec on Day 15.

Trends in the more frequent and less frequent groups showed differentiation by Day 15. Average puff duration and volume increased in the “more frequent” group and decreased in the “less frequent” group, resulting in average puff durations one second longer on Day 15 (2.60 ± 1.06 s versus 1.58 ± 0.46 s) and nearly double the volume (102.9 ± 56.6 mL versus 55.0 ± 26.3 mL). The “more frequent” group also had greater initial liking of the product (Table 2) on Day 1 compared to the “less frequent” group (75.83 ± 18.35 versus 53.22 ± 15.18; 0-100 scale).



Figure 2: Self-Reported NSPS Use Intensity over 15 Days of At-Home Use

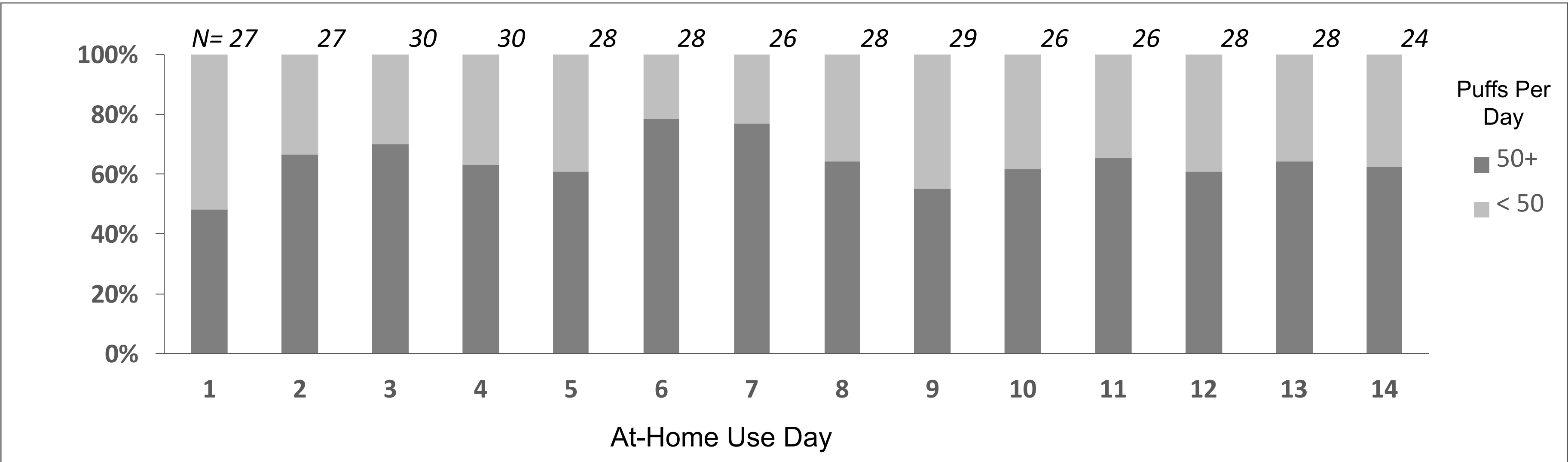


Table 2: e-Liquid Consumption and Product Liking During Topography Session

	Characteristic	Evaluable Subjects with CReSS Data Available**			All Subjects
		More Frequent Use (N=12)	Less Frequent Use (N=9)	Pooled Sample (N=21)	Safety Population (N=30)
Grams e-Liquid consumed mean (SD)	Day 1 (Baseline)	0.055 (0.0373)	0.068 (0.1018)	0.061 (0.0704)	0.067 (0.0664)
	Day 15	0.084 (0.0315)	0.037 (0.0172)	0.064 (0.0350)	0.082 (0.0763)
	Change from Baseline	0.029	-0.031	0.003	0.015
Pod equivalents consumed	Day 1 (Baseline)	7.1% (4.8%)	8.8% (13.2%)	7.9% (9.1%)	8.7% (8.6%)
	Day 15	10.9% (4.1%)	4.8% (2.2%)	8.3% (4.5%)	10.6% (9.9%)
	Change from Baseline	3.8%	-4.0%	0.4%	1.9%
Product Liking (0-100) mean (SD)	Day 1 (Baseline)	75.83 (18.35)	53.22 (15.18)	66.14 (20.22)	64.90 (20.39)
	Day 15	73.33 (18.21)	45.11 (20.14)	61.24 (23.44)	64.93 (21.99)
	Change from Baseline	-2.50 (22.52)	-8.11 (17.27)	-4.90 (20.16)	0.03 (21.04)

**This data excludes subjects with defective device on any day

Table 3: Summary of Key Topography Parameters in Subjects with Evaluable CReSS Data

Characteristic (SD)	Mean	When Measured	Evaluable Subjects with CReSS Data Available**		Pooled Sample (N=21)
			More Frequent Use (N=12)	Less Frequent Use (N=9)	
Puff Count (number of puffs)		Day 1 (Baseline)	55.8 (30.0)	60.4 (53.5)	57.8 (40.5)
		Day 15	85.6 (43.6)	73.4 (51.2)	80.4 (46.2)
		Change from Baseline	29.8 (34.8)	13.0 (76.3)	22.6 (55.4)
Puff Duration (ms)		Day 1 (Baseline)	2336 (848)	1716 (601)	2070 (799)
		Day 15	2599 (1056)	1579 (463)	2161 (983)
		Change from Baseline	263.0 (1024.6)	-137.4 (573.6)	91.4 (866.2)
Puff Volume (mL)		Day 1 (Baseline)	80.7 (39.0)	62.7 (15.7)	73.0 (31.9)
		Day 15	102.9 (56.6)	55.0 (26.3)	82.4 (51.7)
		Change from Baseline	22.2 (49.0)	-7.6 (30.1)	9.4 (43.7)
Peak Puff Flow Rate (mL / sec)		Day 1 (Baseline)	49.1 (14.4)	56.3 (15.7)	52.2 (15.0)
		Day 15	51.7 (9.9)	49.1 (12.0)	50.6 (10.7)
		Change from Baseline	2.6 (12.1)	-7.2 (17.4)	-1.6 (15.1)
Average Flow Rate (mL / sec)		Day 1 (Baseline)	35.1 (11.9)	39.2 (10.7)	36.9 (11.3)
		Day 15	38.1 (9.8)	34.6 (8.8)	36.6 (9.3)
		Change from Baseline	3.1 (9.0)	-4.6 (12.5)	-0.2 (11.0)
Inter-puff Interval (sec)		Day 1 (Baseline)	86.0 (55.3)	86.0 (38.6)	86.0 (47.7)
		Day 15	59.8 (41.0)	65.3 (42.1)	62.2 (40.5)
		Change from Baseline	-26.2 (44.3)	-20.7 (37.3)	-23.8 (40.5)

NOTE: This data excludes subjects with defective device on any day

Conclusions

- This study provides insights into key characteristics of topography patterns associated with NSPS use.
- Differences emerged in topography parameters in groups with different levels of self-reported NSPS usage during the ambulatory period, with the group with more frequent usage of NSPS during the home use period trending towards longer, more voluminous puffs in the recorded topography session.
- The subgroups also differed on their initial liking of NSPS, as the “more frequent” group scoring higher on Product Liking on Day 1. This may be a contributing factor to experimental participation and eventual outcomes.
- Both the effect of more frequent use and initial liking are areas for further research for their impact on topography metrics.

Study Limitations

This study explored topography in a limited number of subjects using a single tobacco flavor of NSPS. Topography was measured in a laboratory setting; real world use may vary. The puff counts recorded do not necessarily reflect device activations. The study highlighted the need for fully integrated data collection technologies among ENDS users.