ENDS Topography Across Multiple Platforms in an Ambulatory Setting

Gary M. Dull, Sarah Baxter-Wright, John Darnell, Milly Kanobe, Kristen Prevette, and Jeffrey Smith

RAI Services Company, 401 N. Main Street, Winston-Salem, NC, USA 27102

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Abstract

Topography, in the context of puffing behavior, is a methodology that is used to understand how consumers use a product. The Product Use and Behavior (PUB) instrument is a research tool that can effectively measure actual Electronic Nicotine Delivery Systems (ENDS) use patterns with negligible impact on ENDS performance in an ambulatory "real-world" setting. Three clinical studies were performed to evaluate the puffing patterns of healthy adult consumers of ENDS products as they switched from their usual brand (UB) cartridge-based, closed-system to one of four Vuse products (Vuse Alto, Ciro, Solo, and Vibe) over a 3-week ambulatory period. The nicotine concentrations varied across four different Vuse products from 1.5% to 5.0% and between four to seven flavors were assessed for each product. Subjects were assigned to a single nicotine concentration group and were either assigned a flavor or allowed to select a flavor within each Vuse product. Data for all flavors were combined for analysis for each nicotine concentration. The results across all Vuse products included mean puff duration (1.89 – 2.35 seconds), number of puffs per day (102.7 – 126.7 puffs), and subjective responses to the Product Evaluation Scale (PES), which provided a measure of the experience and reinforcing effects of the product. These results indicate little variation in puff duration, number of puffs per day, and PES scores relative to the ENDS product assessed, suggesting that product use may be more closely associated with subject behavior and product interaction rather than nicotine consumption. Additional investigation is required to better describe puffing patterns over time and how different factors impact use behavior.

Introduction

The use of ENDS has grown significantly over the last decade as individuals transition from the use of combustible cigarettes to other tobacco products. In contrast to understanding how smokers use combustible cigarettes, there are several significant challenges that make it difficult to characterize the behavior of ENDS consumers, such as the variation of devices and consumer use patterns, and the need for adequate parameters to describe how consumers use ENDS. The best approach to evaluate product use is in an ambulatory setting,[1] which allows subjects complete freedom to decide when and how to use a product. The PUB instrument provides the benefit of actual, "real-world" assessments with the accuracy and reliability of constant monitoring that is generally only available in confinement study settings.

The objective of these studies was to assess how ENDS users consume Vuse products, e.g., puff duration and number of puffs per day for each Vuse product. It should be mentioned that with END products, puff duration is a good indicator of subject exposure to nicotine and other aerosol components. Subjective responses to the Product Evaluation Scale (PES) questionnaire[2] were also obtained.

Materials and Methods

The Vuse products are shown in **Figure 1**. Four different Vuse products were used in three clinical studies as follows: (1) Vuse Alto, (2) Vuse Solo, and (3) Vuse Ciro and Vuse Vibe. Each product had a different nicotine concentration, and there were four to seven flavors for each product (**Table 1**). The PUB instrument, which was inserted between the Vuse cartridge and power unit, collected puffing data by measuring the start and stop times of each puff with a time/date stamp (**Figure 2**). The PES questionnaire was used to obtain subjective responses to each Vuse product. The PES is a validated, modified version of the Cigarette Evaluation Questionnaire. The questionnaire identified the individual's overall evaluation of their assigned product, and each question had a scoring scale ranging from 1 to 7, with 1 representing "NOT AT ALL" and 7 representing "EXTREMELY." Subjects were generally healthy adult users of ENDS and were instructed to use their assigned Vuse product in place of their usual brand ENDS during the 3-week study period (including a 1-week-acclimation period followed by a 2-week product use evaluation period in order to provide comprehensive topography data profiles).

Vuse Product	Vuse Alto 2.4%	Vuse Alto 5.0%	Vuse Solo	Vuse Ciro	Vuse Vibe
Nicotine (%)	2.4	5.0	4.8	1.5	3.0
Cartridge Fill (mL)	1.8	1.8	0.5	0.9	1.9
Assembled Product					

Figure 1. Vuse Products.

Table 1. Vuse Products – % Nicotine and Flavors.

Vuse Products %Nicotine, Flavors	Alto 2.4%	Alto 5.0%	Ciro 1.5%	Solo 4.8%	Vibe 3.0%
Flavor 1	Original	Original	Original	Original	Original
Flavor 2	Rich Tobacco	Rich Tobacco	Menthol	Menthol	Menthol
Flavor 3	Mint	Menthol	Mint	Mint	Mint
Flavor 4	Mixed Berry	Mixed Berry	Nectar	Nectar	Nectar
Flavor 5	--	--	Fusion	Fusion	Fusion
Flavor 6	--	--	Melon	Melon	Melon
Flavor 7	--	--	Tropical	Tropical	Tropical

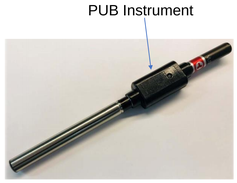

Figure 2. The PUB instrument is shown, inserted between a Vuse Solo cartridge and the power unit.

Conclusions

- These results indicate little variation in puff duration, number of puffs per day, and PES scores relative to the ENDS product assessed, suggesting that product use may be more closely associated with subject behavior and product interaction rather than nicotine consumption.
- Additional investigation is required to better describe puffing patterns over time and how different factors impact use behavior.

Results

- The number of subjects that completed the study with evaluable data varied from 48 to 63 for each study. Subjects included a mixture of White and Black/African-Americans, an approximately equal male/female distribution, and an average age of approximately 36 to 38 years across the products (**Table 2**).
- Data for all flavors per Vuse product were combined for analysis for each nicotine concentration. The mean puff duration ranged from 1.89 – 2.35 seconds and the mean number of puffs per day ranged from 102.7 – 126.7 puffs across all Vuse products (**Table 3**).
- The highest PES scores were for "Satisfaction", "Easy to use", and "Comfortable using the product in public". "Aversion" and "Concerned about dependence on the product" had the lowest PES scores (**Table 4**).

Table 2. Subject Demographics.

Demographics Parameter	Vuse Alto 2.4%	Vuse Alto 5.0%	Vuse Solo 4.8%	Vuse Ciro 1.5%	Vuse Vibe 3.0%
Safety Population (No. of Subjects who used IP)	75	71	75	55	52
No. of Subjects [Completers (%)]	71 (94.7)	69 (97.2)	73 (97.3)	50 (90.9)	51 (98.1)
No. of Subjects with Evaluable Data [Completers (%)]	62 (82.7)	63 (88.7)	58 (77.3)	48 (87.3)	48 (92.3)
Average Age (years)	35.6	36.9	36.6	34.7	37.7
Sex (M/F)	40/35	38/33	37/38	29/26	26/26
Ethnicity [n, (%)]	Non-Hispanic 71 (94.7)	Non-Hispanic 70 (98.6)	Non-Hispanic 74 (98.7)	Non-Hispanic 53 (96.4)	Non-Hispanic 49 (94.2)
Race [n, (%)]	Black or African American: 24 (32.0) White: 45 (60.0)	Black or African American 31 (43.7) White: 38 (53.5)	Amer Indian or Alaska Native: 7 (9.3) White: 66 (88.0)	Black or African American: 28 (50.9) White: 24 (43.6)	Black or African American: 33 (63.5) White: 14 (26.9)
Average BMI (kg/m^2)	30.54	29.46	30.06	30.38	31.56

IP = Investigational Product; BMI = Body Mass Index

Table 3. Topography Results—Puff Duration and Number of Puffs Per Day.

Vuse Product, % Nicotine (Number of Subjects)	Puff Duration (sec), Mean (SD)	Number of Puffs Per Day, Mean (SD)
Alto 2.4% (62)	2.35 (1.08)	118.2 (80.04)
Alto 5.0% (63)	2.14 (0.93)	117.9 (77.36)
Solo 4.8% (58)	1.89 (0.73)	102.7 (97.21)
Ciro 1.5% (48)	2.24 (1.04)	105.4 (103.95)
Vibe 3.0% (48)	2.04 (0.95)	126.7 (110.10)

Table 4. Summary of Product Evaluation Scale (PES) Scores for each Vuse Product.

PES Subjective Response	Vuse Alto 2.4%%	Vuse Alto 5.0%	Vuse Ciro 1.5%	Vuse Solo 4.8%	Vuse Vibe 3.0%
Number of Subjects	62	63	48	58	48
Highest Mean Scores for Subjective Responses [Mean (SD)]:					
Satisfaction	5.1 (1.65)	4.7 (1.73)	5.4 (1.30)	4.5 (1.43)	5.2 (1.46)
Easy to Use	6.6 (1.22)	6.6 (1.24)	6.0 (1.64)	5.6 (1.56)	6.0 (1.57)
Comfortable Using the Product in Public	6.4 (1.30)	6.4 (1.06)	6.1 (1.58)	5.6 (1.71)	6.3 (1.26)
Lowest Mean Scores for Subjective Responses [Mean (SD)]:					
Aversion	1.6 (1.34)	1.9 (1.66)	1.3 (0.53)	2.2 (1.33)	1.3 (0.45)
Concerned about Dependence	2.5 (1.77)	2.2 (1.60)	2.0 (1.59)	2.6 (1.89)	2.1 (1.58)

References

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