

Characterization of Nicotine Pharmacokinetics and Subjective Effects of NJOY ACE® Products Relative to Usual Brand Combustible Cigarettes Among Adults Who Smoke

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Taken together, the nicotine PK and subjective effects suggest that NJOY ACE products may be a suitable substitute for combustible cigarettes

INTRODUCTION

- Public health authorities, including the Food and Drug Administration (FDA), acknowledge a continuum of risk, with combustible cigarettes (CC) at the highest end and non-combustible (smoke-free) products, such as e-cigarettes, on the lower end of this continuum
- NJOY ACE tobacco and menthol-flavored e-cigarettes have substantially lower levels of toxicants compared to cigarettes. Additionally, exposure to select toxicants was observed to be substantially reduced in a longitudinal cohort study
- Therefore, adults who smoke (AS), may benefit by switching completely from cigarettes to e-cigarettes. Assessing the abuse liability of e-cigarettes can inform the switching potential of these products

AIMS

- The aims of this study were to characterize nicotine pharmacokinetics (PK) and subjective effects following *ad libitum* use of NJOY ACE® products relative to the subject's usual brand combustible cigarettes (UBC) among adults who smoke cigarettes (AS) to inform the abuse liability and switching potential

METHODS

- Healthy AS (n=24) were assigned to use NJOY ACE products *ad libitum* (10 minutes) in this randomized, open-label, crossover study. Nicotine PK and subjective responses were assessed periodically
- Baseline-adjusted plasma nicotine PK parameters included maximum measured plasma concentration (C_{max}) and time to achieve C_{max} (T_{max})
- The Urge to Smoke/Use Study Product Questionnaires were administered and scored on a visual analog scale from 0 to 100 mm. Subjective responses were evaluated based on mean maximum change from baseline (E_{max})
- Additional subjective effects were measured including satisfaction, psychological reward, relief, aversion, ease of use, comfortable using in public, dependence concern, and product liking

Study Sample	
Total	24
Female	12
Male	12
Race, n (%)	
Black or African American	5 (20.8%)
White	18 (75.0%)
White, Black, or African American	1 (4.2%)
Ethnicity, n (%)	
Hispanic or Latino	0 (0.0%)
Age (years)	
Mean	41.2
SD	10.84
# of CC Smoked per Day	
Mean	15.4
Range	10-25
CC flavor, n (%)	
Menthol CC	11 (45.8%)
Non-menthol CC	13 (54.2%)

The majority of subjects had been using combustible cigarettes for more than 20 years (13 subjects [54.2%]).

Product Name	Flavor	Nicotine Strength
Usual Brand Cigarette	Menthol and Non-menthol	NA
NJOY ACE	Menthol	5%
NJOY ACE	Classic Tobacco	5%

Results will focus on data for NJOY ACE Menthol 5% and Classic Tobacco 5%; which were authorized by the FDA to be appropriate for the protection of public health

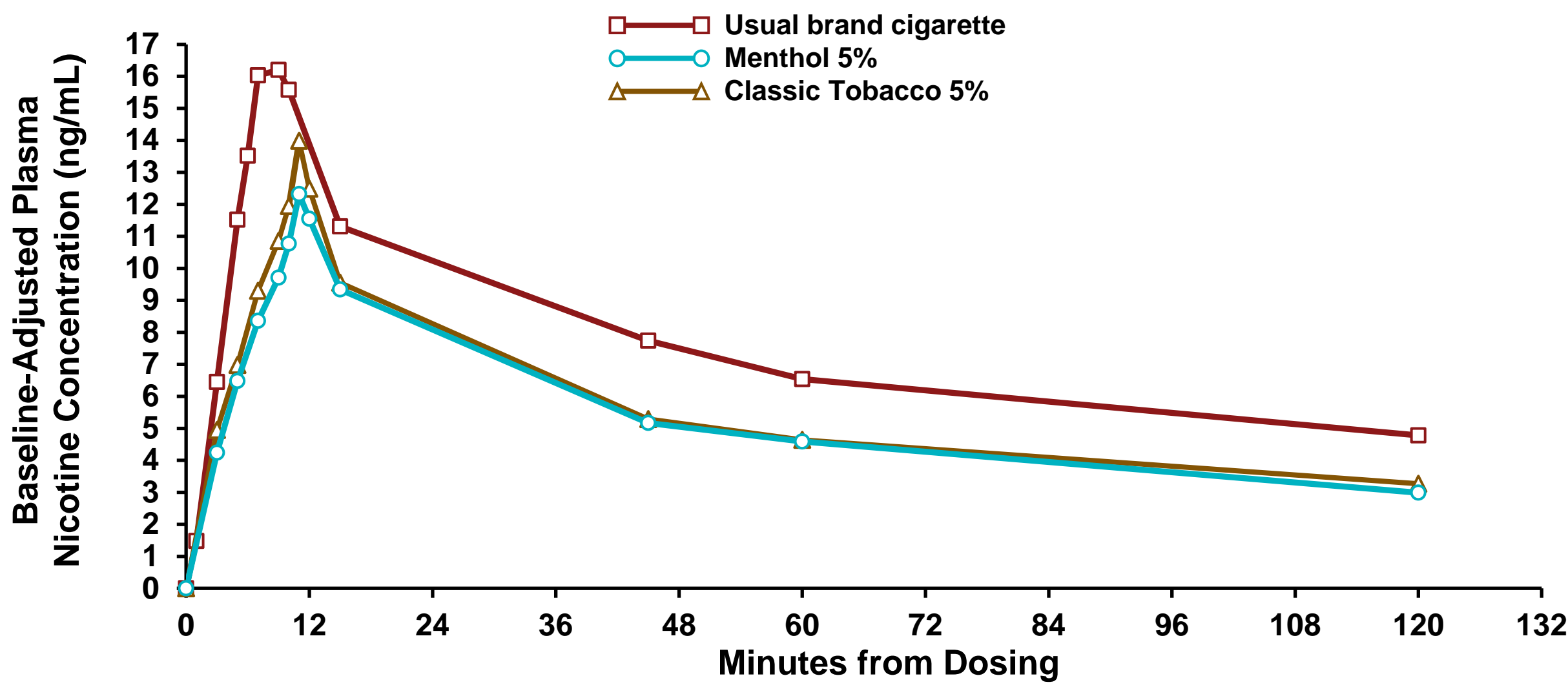
CONCLUSIONS

- Nicotine PK Parameters: Geometric mean C_{max} was significantly lower for NJOY ACE compared to UBC while T_{max} for NJOY ACE was similar to UBC
- Subjective Responses: The Urge to Smoke/Use Product E_{max} was lower for NJOY ACE products ($p<0.05$). While subjects rated satisfaction, psychological reward, and relief greater for their UBC, they rated NJOY ACE products lower for aversion and dependency concerns

RESULTS

NJOY ACE Nicotine PK Was Lower than but Similar to UBC

- The C_{max} values for NJOY ACE Menthol and Classic Tobacco were significantly lower than UBC ($p=0.001$)
- Importantly, the T_{max} values for the NJOY ACE products were similar (~12-13 mins) compared to UBC

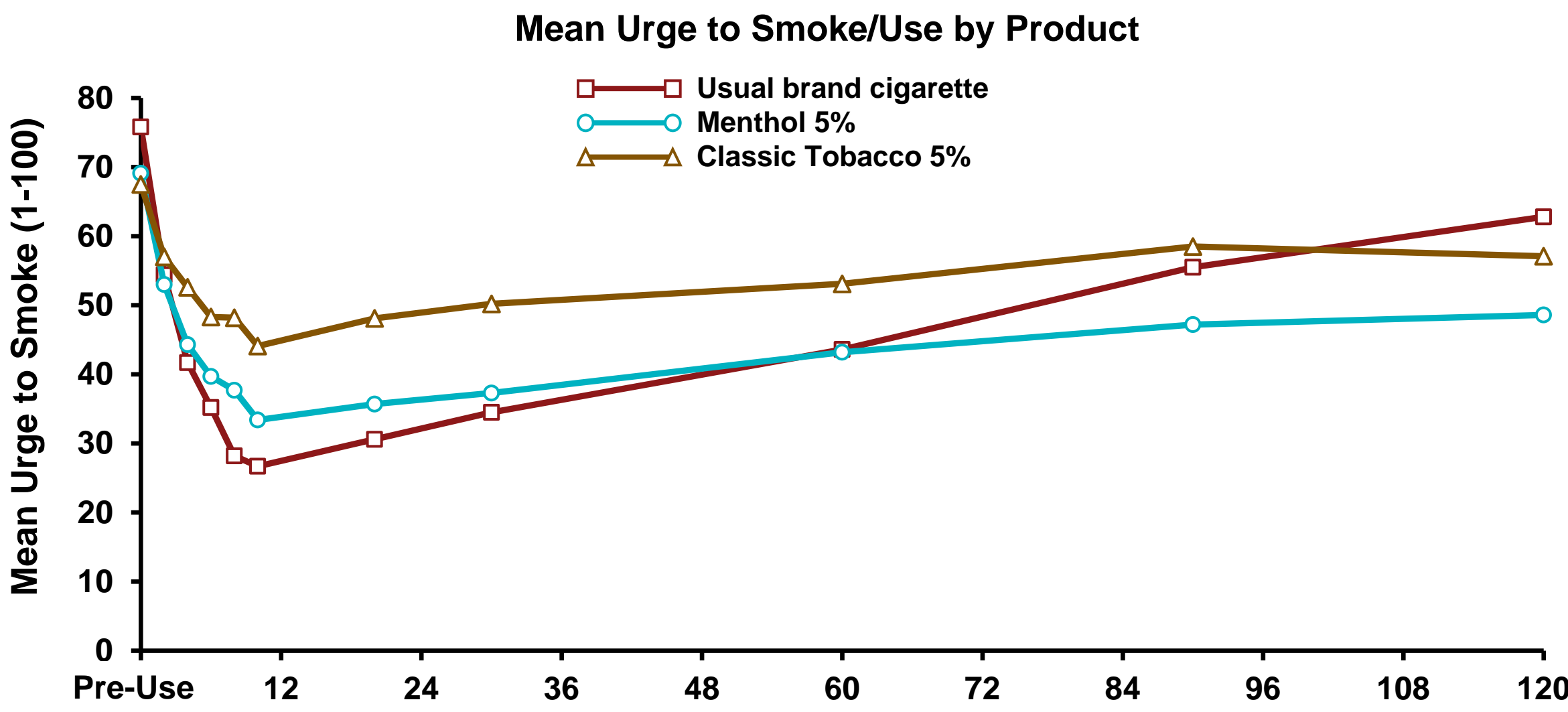


Overall Baseline-Adjusted Plasma Nicotine Pharmacokinetic Parameters

Descriptive Statistics	AUC ₀₋₁₂₀ (ng*min/mL) Geometric Mean	C_{max} (ng/mL) Geometric Mean	T_{max} (min) Median
Usual Brand Cigarette (n=24)			
Geometric Mean	832.4	15.60	8.29
Minimum-Maximum	352-1760	4.40-50.2	4.95-15.00
NJOY ACE Classic Tobacco 5% (n=21)			
Geometric Mean	476.0	9.52	12.75
Minimum-Maximum	68.6-1520	0.80-41.2	8.93-119.95
Following Use of NJOY ACE Menthol 5% (n=22)			
Geometric Mean	434.0	8.13	12.13
Minimum-Maximum	28.0-1860	0.28-43.30	4.67-45.10

Reduction for Urge to Use NJOY ACE Was Similar to the Reduction for UBC

The Urge to Smoke/Use Product E_{max} for both Menthol 5% (42.56) and Classic Tobacco 5% (28.01) was statistically significantly lower compared to UBC (59.15)



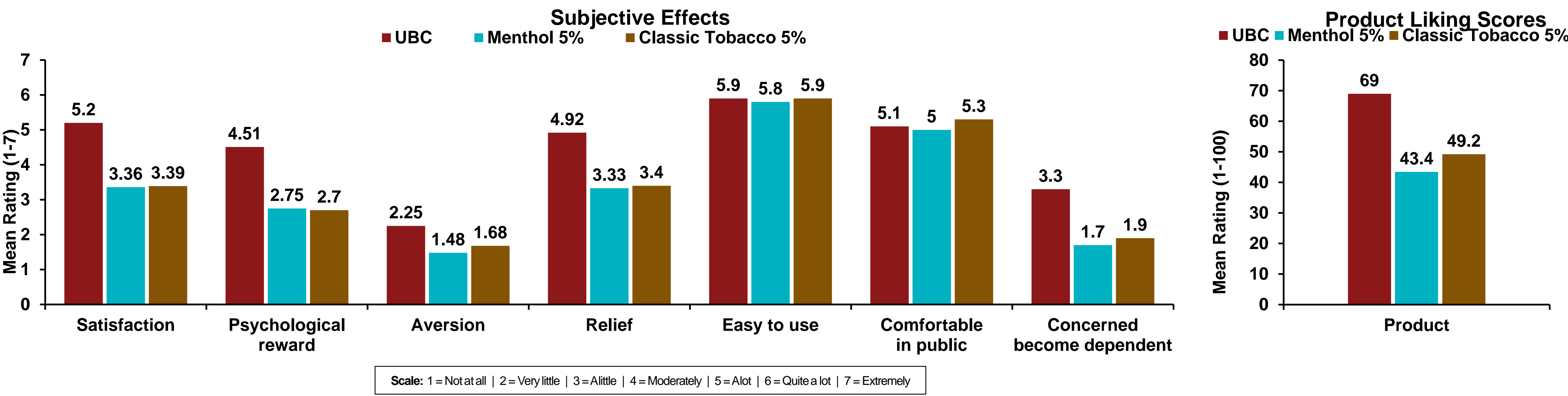
Urge to smoke questionnaire used for UBC and Urge to use product questionnaire used for NJOY ACE Menthol 5% and Classic Tobacco 5%.

Scale for Original Score: 0=Not at all | 100=A great deal

Statistical Comparison of Urge to Smoke/Use Product VAS Parameters (E_{max} and AUEC₀₋₁₂₀)

Comparison	Parameter	Test	LS Mean		LS Mean Difference		95% CI	P-value
			(n)	UBC Reference	(n)	(Test-Reference)		
Menthol 5% vs UBC	E_{max}	42.56	22	59.15	24	-16.59	-27.47, -5.71	0.0031
	AUEC ₀₋₁₂₀	3263.52	22	3680.61	24	-471.09	-1666.81, 832.63	0.5097
Classic Tobacco 5% vs UBC	E_{max}	28.01	22	59.15	24	-31.14	-42.02, -20.26	<.0001
	AUEC ₀₋₁₂₀	1761.06	22	3680.61	24	-1919.55	-3169.27, -669.83	0.0029

Subjective Effects Support NJOY ACE as a Suitable Substitute for UBC



DEFINITIONS

AUC₀₋₁₂₀ = Area under the concentration-time curve from time 0 to the 120-minute time point; C_{max} = Maximum measured plasma concentration over the duration of the measurement interval; E_{max} = Maximum change from baseline visual analog scale score; LS = Least square; PK = Pharmacokinetic(s); TE_{max} = Time of the maximum change from baseline visual analog scale score; T_{max} = Time of the maximum measured plasma concentration over the duration of the measurement interval; UBC = Usual brand cigarette; VAS = Visual analog scale.

REFERENCES

FDA TPL PMTA Summary for NJOY ACE Menthol Products.



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