

# Development of Methods to Assess Puff Topography of Heated Tobacco Stick Products Used with the Ploom® Heated Tobacco Device Among US Adults who Smoke Combustible Cigarettes

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## Introduction

Puff topography (PT) methodologies are established for combustible cigarettes (CC) but not heated tobacco sticks (HTS). For market authorization, the FDA requires manufacturers to submit data on product use patterns, which includes assessing user topography. We conducted a pilot study to develop methods for assessing the PT of menthol- and tobacco-flavored HTS used with the Ploom® device among adults (aged 21-64) who smoke cigarettes.

## Methods

PT data were collected during a single-blind, randomized study across seven visits. Prior to conducting the study, we identified the need to support the SODIM SPA/M PT measurement device mouthpiece with a bespoke brace designed not to affect flow rate or resistance to draw.

- Participants (n=61) were randomized to one of four HTS varieties (two menthol-flavored, two tobacco-flavored), matched on CC preference for menthol (n=33) or non-menthol (n=28).
- Participants used their assigned HTS during Topography Visits 1-5, switching to the alternate in their flavor category for visit 6 (Figure 1).
- Topography visits included four product use periods - 5 minutes of ad libitum use, followed by 55 minutes of rest (Figure 2).
- PT measurements occurred during the final product use period only.
- PT outcomes included the number of puffs, puff duration, and per puff volume.
- Descriptive statistics of puffing behavior by HTS and visit are presented in Figures 3-5.
- Product use experience Consumer Reported Outcome Measures (CROM) are presented in Figures 6-7 (select items from the modified cigarette evaluation questionnaire (mCEQ, adapted for HTS)).
- Intraclass correlations (ICC) assessed PT reliability overall and by HTS variant (Tables 1-4).



Figure 1. Study Design

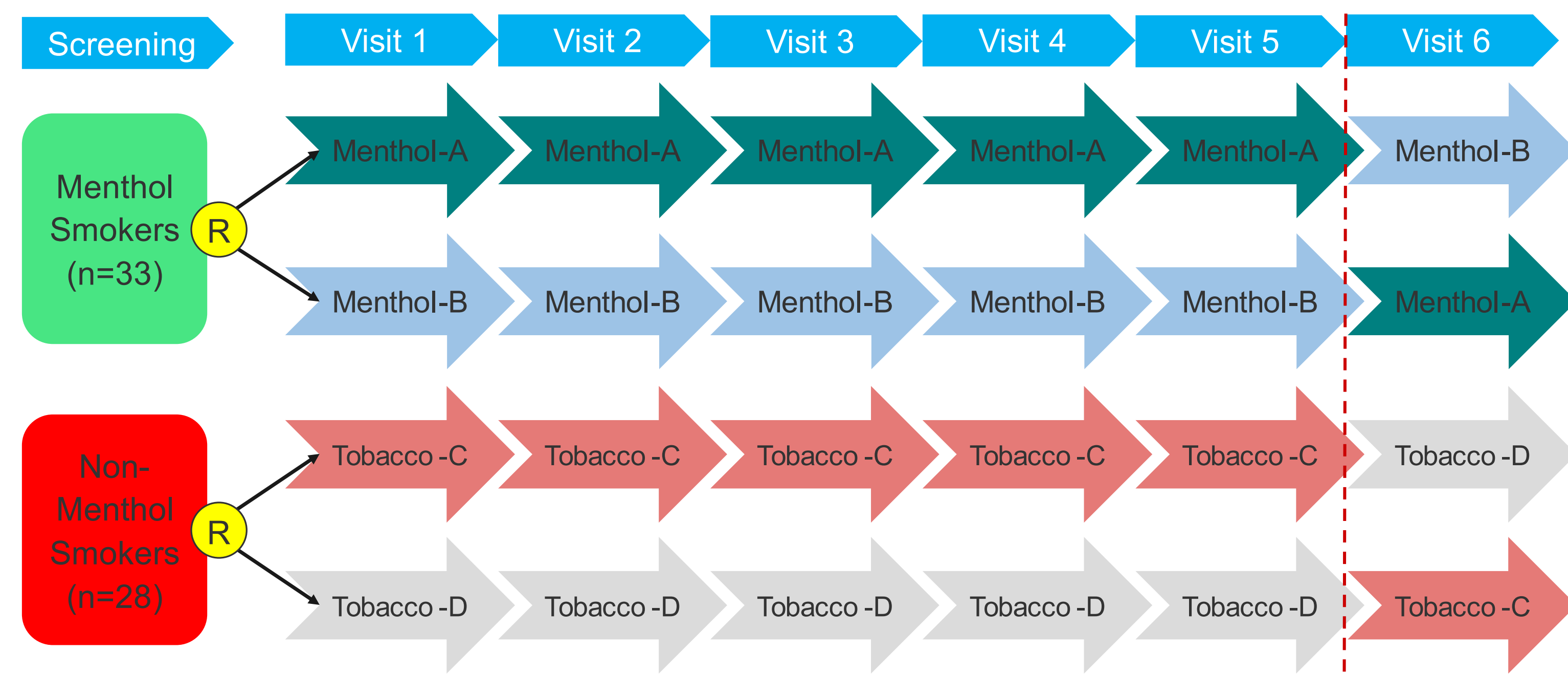
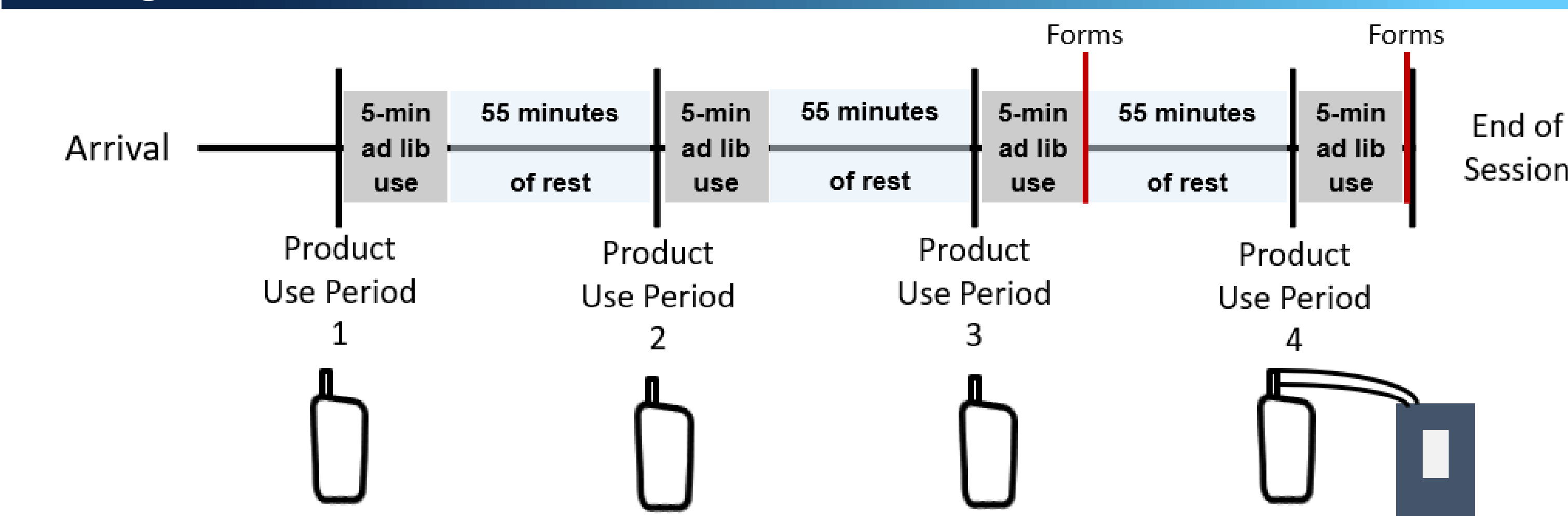


Figure 2. Visit Procedures



## References

1. Terry K. Koo, Mae Y. Li, A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research, Journal of Chiropractic Medicine, Volume 15, Issue 2, 2016, Pages 155-163, ISSN 1556-3707, <https://doi.org/10.1016/j.jcm.2016.02.012>.

## Results

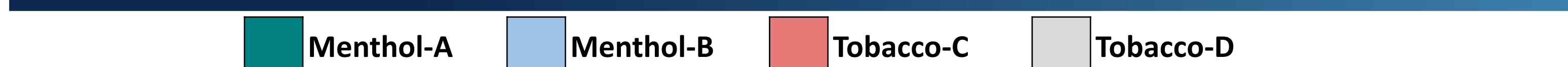


Figure 3. Mean Number of Puffs (95%CI) by Visit & HTS Variety

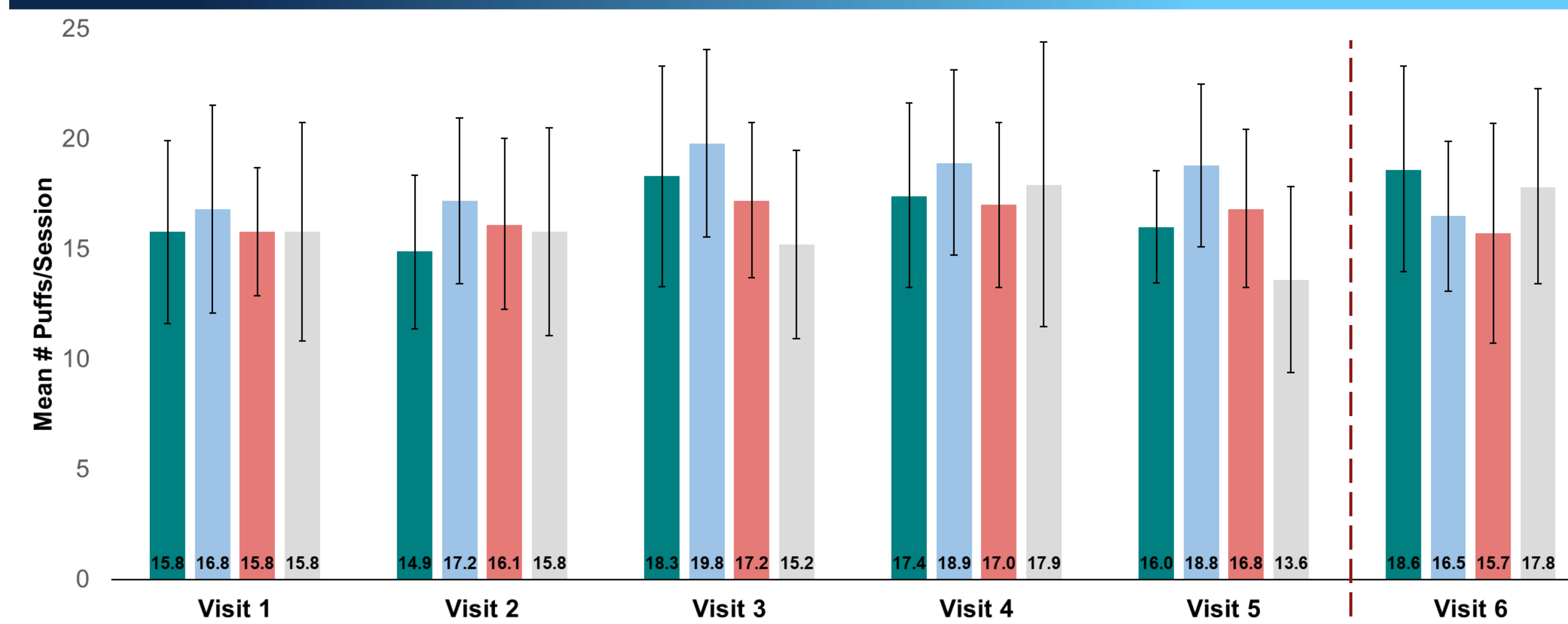


Figure 4. Mean per Puff Duration (95%CI) by Visit & HTS Variety

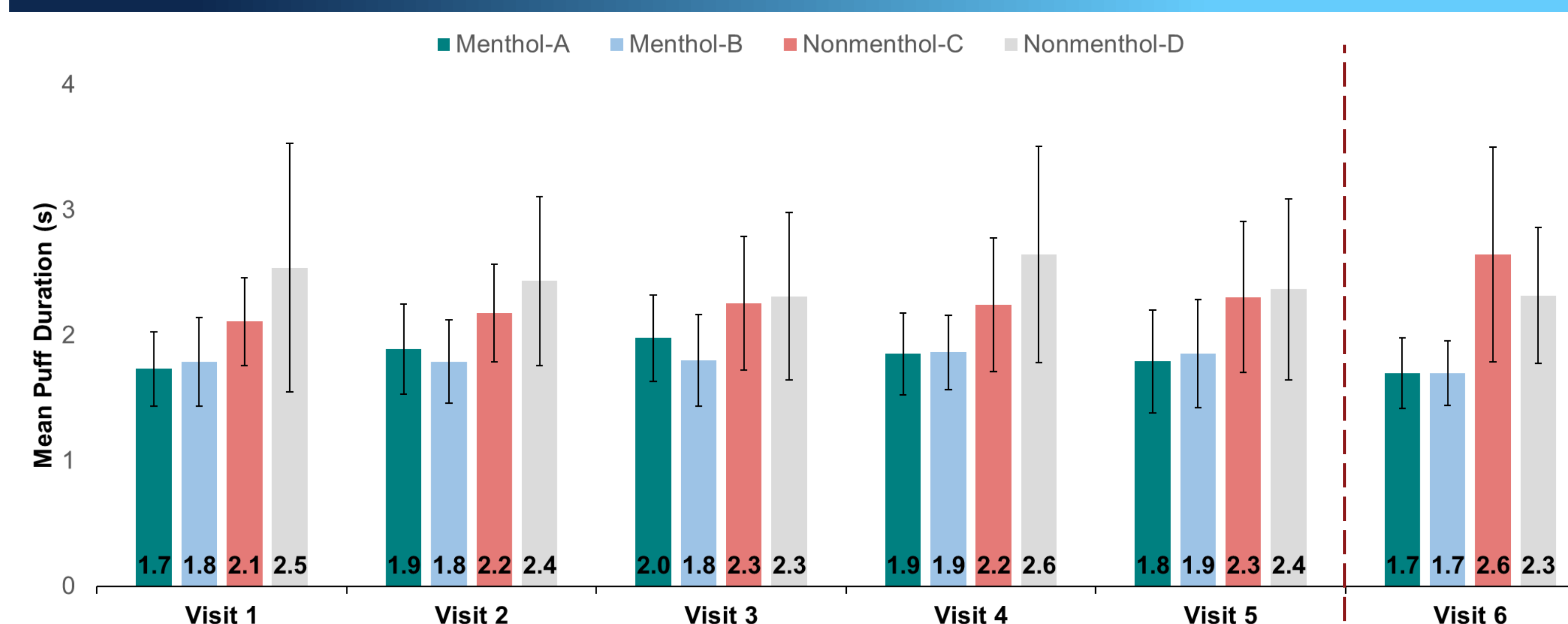


Figure 5. Mean per Puff Volume (95%CI) by Visit & HTS Variety

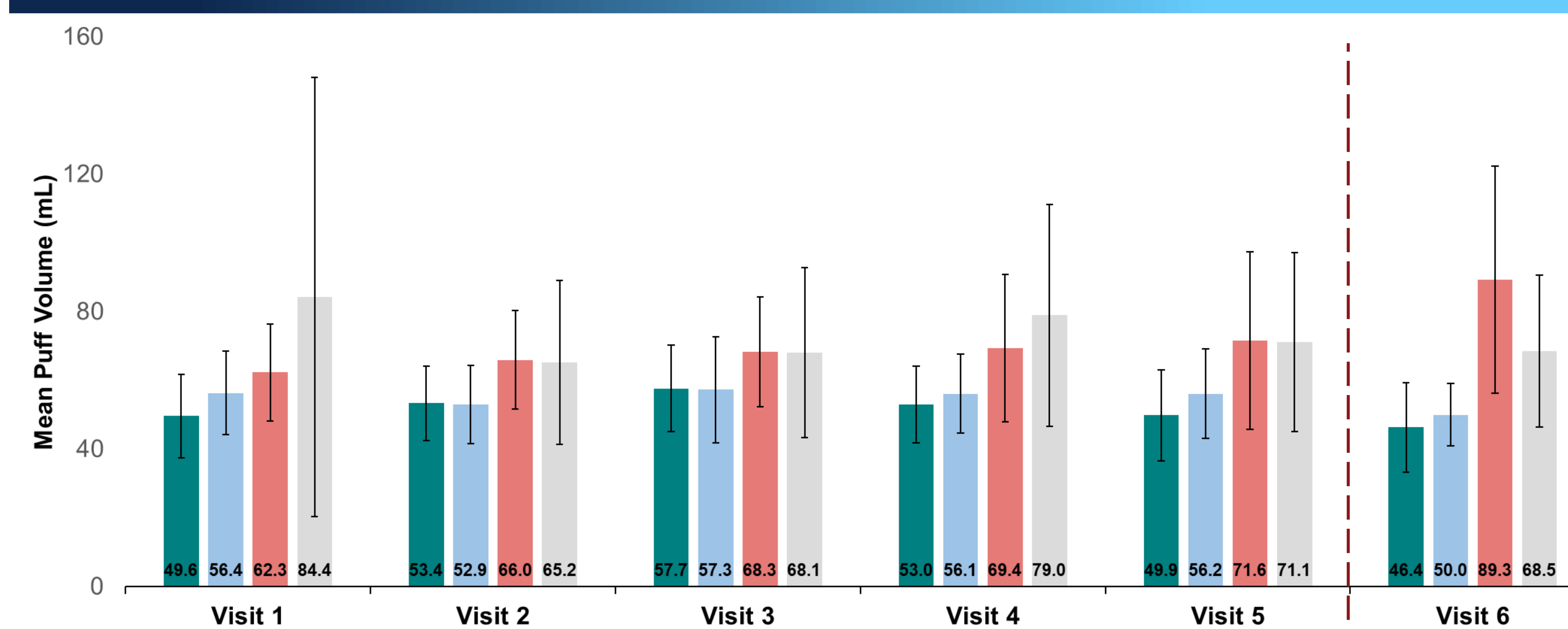


Figure 6. Mean mCEQ Product Use Satisfaction (95%CI) by Visit & HTS Variety

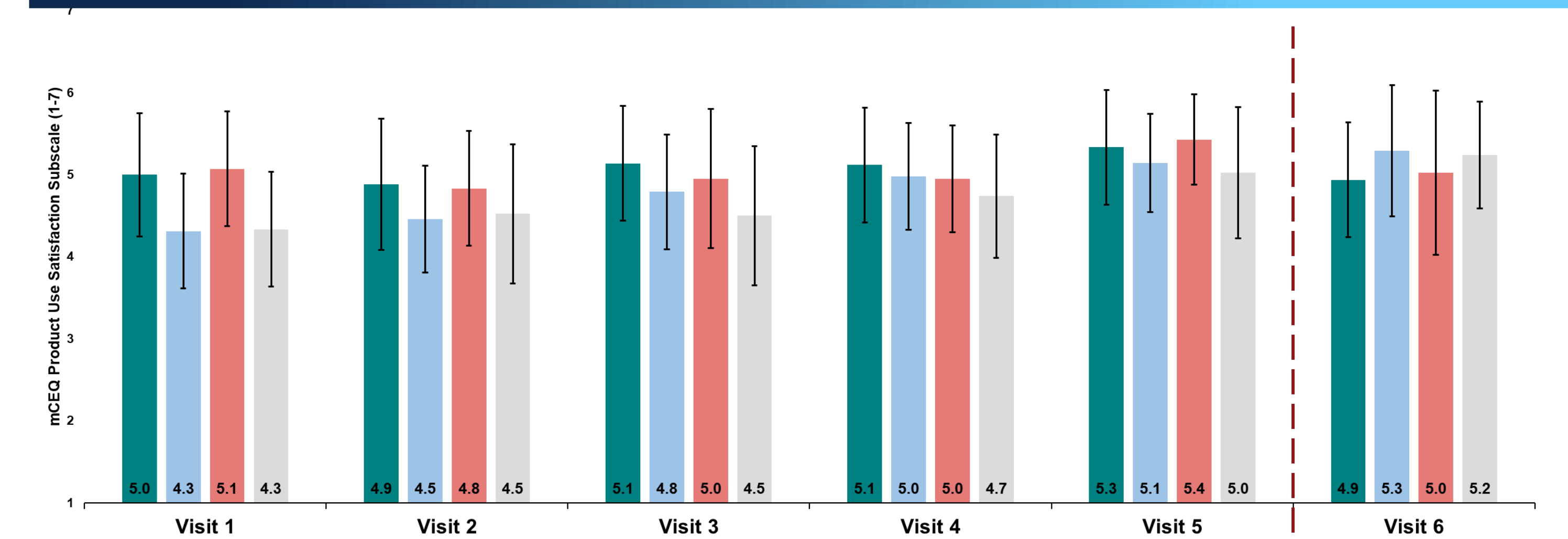


Figure 7. Mean mCEQ Cigarette Craving Reduction (95%CI) by Visit & HTS Variety

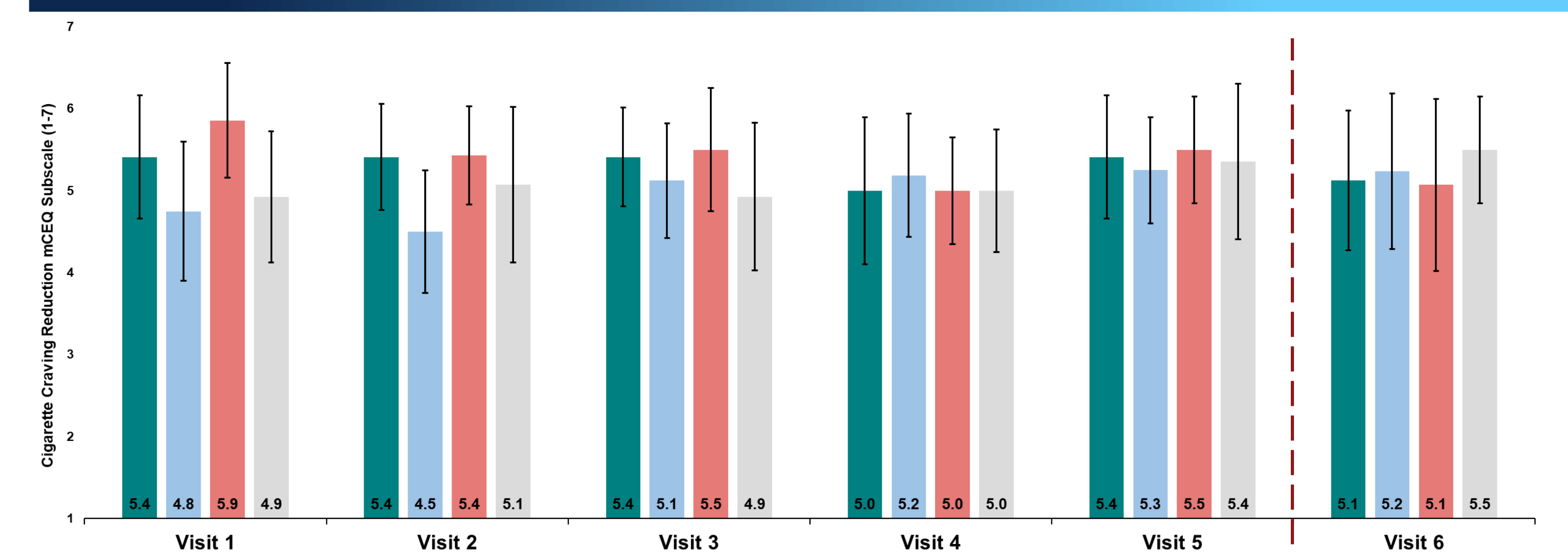


Table 1. ICC Descriptive Qualifiers based on Koo & Li (2016)<sup>1</sup>

ICC Descriptive Qualifier	Range of ICC ± 95% CI
Poor	< 0.50
Moderate	0.50 to 0.75
Good	0.75 to 0.90
Excellent	> 0.90

Table 2. ICC Visits 1-5: Number of Puffs

	n	ICC	95% CI
Overall	56	0.95	0.92 0.97
Flavor Groups			
Menthol	30	0.92	0.87 0.96
Tobacco	26	0.97	0.94 0.98

Table 3. ICC Visits 1-5: Per Puff Duration

	n	ICC	95% CI
Overall	56	0.96	0.94 0.97
Flavor Groups			
Menthol	30	0.96	0.92 0.98
Tobacco	26	0.96	0.92 0.98

Table 4. ICC Visits 1-5: Per Puff Volume

	n	ICC	95% CI
Overall	56	0.93	0.90 0.96
Flavor Groups			
Menthol	30	0.97	0.95 0.98
Tobacco	26	0.92	0.85 0.96

## Conclusions

Overall, adults who smoke menthol or non-menthol cigarettes acclimated to the HTS product over the course of the study, as indicated by the consistency in their puff behavior.

- The Ploom® System combined with the SODIM SPA/M PT measuring system and a custom brace provided fit-for-purpose PT data.
- A limited trial period of 20 or less product use periods may be sufficient for adults who smoke to form reliably consistent puffing behaviors as indicated by Good (ICC = 0.75 to 0.90) to Excellent (ICC > 0.90) ICC values.
- Participants consistently rated the HTS products high on positive subjective measures, suggesting high levels of satisfaction and product acceptance.

