Development and Validation of a Portable Puffing Topography Analyser

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Southampton, UK
Outline

Background & Objective

Design & Development

Laboratory Validation

Field Study

Findings & Next Steps

Conclusions
Measurement of puffing topography provides data to support product stewardship and development activities.

- SA7\(^1\) successfully used in numerous studies
  - Puff volumes
  - Puff durations
  - Optical tar (Estimate of NFDPM)

Requires a central location and a trained operator which can be costly and may affect behaviour.

Objective

To develop a simple to use topography measurement system that allows for capture of a smoker’s puffing behaviour in their every day environment.

Portable topography devices are commercially available but the option to design and develop a bespoke device was chosen:

• Hand held unit
• Simple interface
• Puff volumes/durations
• Optical tar
• Store raw data subsequent duplication
Objective

To develop a simple to use topography measurement system that allows for capture of a smoker’s puffing behaviour in their every day environment.

- Promotes more natural behaviour
- Consumers’ own environment
- Output data is a better representation of consumer behaviour
- Less costly field studies
PSA Design

- Based on the SA7 device
- Portable, lightweight handheld unit
- Measures pressure differential across an orifice when flow reaches set threshold
- Measurements taken at 25 Hz
- Puff by puff calculation of puff volume and duration
- LED and detector allows for a measurement of optical obscuration allowing estimate of tar delivery on a puff by puff basis
PSA Design - Use

Awakens on movement and performs background measurement

Green LED informs subject of status

Cigarette is inserted into the holder and lit

Puff through the mouthpiece as a regular cigarette

Flows over set threshold will be measured and recorded onto SD card with a date & time stamp

Device remains active until 2 minutes after last puff

Data can be downloaded via USB cable and software
Laboratory Validation

- PSA devices were calibrated on receipt for pressure and flow rates
- 6 devices underwent full in-house laboratory validation
  - Puff volume – to be within ±1.0 mL burette
  - Puff duration – to be within ±0.1 s of SA7
  - Optical tar – 2 products -1mg ISO tar and 10 mg ISO tar
Laboratory Validation

Test regimes

Volumes
- were within ± 1mL of the burette across the 25-100 mL range.
- Only 11 of the 864 measurements greater than tolerance, greatest error ±1.3 mL

Durations
- Greater than SA7 measured durations,
- Majority of measurements fell within ±0.2 s, greatest error ±0.3 s
- Longer durations explained by firmware recording an additional 5 records at the end of each puff
Six PSA Devices – All Puff Volume measurements (n = 864)

$R^2 > 0.9997$
Optical Sensitivity

All units underwent an optical sensitivity check with 2 products

- 1 mg product at low intensity regime (volume 20 mL, duration 1.5 s, interval 30 s)
- 10 mg product at high intensity regime (volume 80 mL, duration 2.5 s, 30 s)

All devices gave a response greater than 0% light obscuration at the low intensity regime and below 99% light obscuration at the high intensity regime

- The optical range of the device is suitable for a range of products.

Full Optical calibration to NFDPM was carried out for 6 devices

- Both 1 mg and 10 mg products were smoked for 10 regimes
Field Study Validation

UK field study with SA7 benchmark at central location
1 mg and 10 mg smokers using commercial product both at a central location and in own environment

Visit 1
- Free smoke, PSA and SA7 sessions
- Collection of single tips for part-filter analysis
- Sensory questionnaires
- Issue of PSA device and cigarettes to be used ad libitum in own environment

Visit 2
- PSA and SA7 sessions
- Sensory questionnaires
- Collection of single tips for part-filter analysis
- Return of PSA unit
## Topography Data (n=20)¹

<table>
<thead>
<tr>
<th>Device</th>
<th>Visit</th>
<th>Total Volume (ml)</th>
<th>Mean Volume (ml)</th>
<th>Mean Duration (s)</th>
<th>Puff Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA</td>
<td>1</td>
<td>938 (547) a</td>
<td>62.0 (25.0)a</td>
<td>2.5 (0.9)a</td>
<td>14.9 (6.4)a</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>900 (521) a</td>
<td>61.2 (24.4)a</td>
<td>2.3 (0.7)ab</td>
<td>15.9 (9.6)a</td>
</tr>
<tr>
<td>SA7</td>
<td>1</td>
<td>977 (540) a</td>
<td>59.4 (22.7)a</td>
<td>2.0 (0.7)bc</td>
<td>16.3 (7.2)a</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1053 (635) a</td>
<td>58.9 (27.3)a</td>
<td>1.9 (0.6)bc</td>
<td>18.3 (9.2)a</td>
</tr>
</tbody>
</table>

²ANOVA (GLM) α= 0.05, presented as mean values and associated standard deviation

- There are no statistically significant differences in subjects’ total volumes, mean volumes and puff numbers between devices or visit to central location.
- Mean durations were longer for the PSA compared with the SA7, this difference was statistically significant for PSA usage on the first visit when compared with SA7 usage.
Mouth Level Exposure (n=20)

<table>
<thead>
<tr>
<th>Visit 1</th>
<th>Estimated Nicotine (mg/cig)</th>
<th>Estimated NFDPM by UV (mg/cig)</th>
<th>Estimated NFDPM by Solanesol (mg/cig)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA</td>
<td>1.6 (0.6)</td>
<td>16.9 (7.5)</td>
<td>16.3 (6.8)</td>
</tr>
<tr>
<td>SA7</td>
<td>1.4 (0.6)</td>
<td>15.1 (5.9)</td>
<td>15.0 (6.8)</td>
</tr>
<tr>
<td>Free Smoke</td>
<td>1.4 (0.3)</td>
<td>14.4 (3.6)</td>
<td>14.0 (3.9)</td>
</tr>
<tr>
<td>p value¹</td>
<td>0.054</td>
<td>0.097</td>
<td>0.107</td>
</tr>
</tbody>
</table>

¹ANOVA (GLM) α= 0.05, presented as mean values and associated standard deviation

There were no statistically significant differences between the estimates for mouth level exposure to nicotine and NFDPM by UV or solanesol methodology between the smoke sessions in the first central location visit.
### Mouth Level Exposure (n=20)

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Visit</th>
<th>Estimated Nicotine (mg/cig)</th>
<th>Estimated NFDPM by UV (mg/cig)</th>
<th>Estimated NFDPM by Solanesol (mg/cig)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA</td>
<td>1</td>
<td>1.6 (0.6)</td>
<td>16.9 (7.5)</td>
<td>16.3 (6.8)</td>
</tr>
<tr>
<td>PSA</td>
<td>2</td>
<td>1.6 (0.6)</td>
<td>17.0 (6.5)</td>
<td>16.9 (7.1)</td>
</tr>
<tr>
<td>SA7</td>
<td>1</td>
<td>1.4 (0.6)</td>
<td>15.1 (5.9)</td>
<td>15.0 (6.8)</td>
</tr>
<tr>
<td>SA7</td>
<td>2</td>
<td>1.5 (0.5)</td>
<td>15.2 (5.2)</td>
<td>14.9 (5.8)</td>
</tr>
<tr>
<td><em>p value</em> 1</td>
<td></td>
<td>0.148</td>
<td>0.150</td>
<td>0.137</td>
</tr>
</tbody>
</table>

1 ANOVA (GLM) α= 0.05, presented as mean values and associated standard deviation

There were no statistically significant differences between the estimates for mouth level exposure to nicotine or NFDPM between device type or visit to the central location.
Findings & Next Steps

- PSA measured durations are longer than SA7 durations
- ‘Awake’ state uses battery life e.g. movement during shipping
- Battery life in the field varies widely dependent upon user behaviour and charging
  - Low battery impacts upon data collection and recording

Simple updates to the device hardware and firmware are required to improve battery life and data collection.
Findings & Next Steps

- Less control over subjects following protocol outside of the central location
- Home use generates a large amount of data
  - Topography and optical obscuration data to be analysed
  - Software and data management strategy needs to be refined
- To adapt the PSA design for use with next generation products
Conclusions

BAT have developed a portable topography unit that is comparable to the SA7 in terms of data capture but offers more flexibility:

- Accurately records volumes and durations on a puff by puff basis
- Estimates of optical tar
- Simple subject interface
- Data captured is more representative of natural behaviour
- Portable
- Allows for storage of data for subsequent duplication
Thank you for your time.

Are there any questions?
### PSA recorded puffing regimes
- **Puff volume and puff duration**

<table>
<thead>
<tr>
<th>Puff Flow Profile Shape</th>
<th>Puffing Regime</th>
<th>Set Puff Volume (mL)</th>
<th>Set Puff Duration (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bell (Sine Wave)</td>
<td>1</td>
<td>25</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>50</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>75</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>100</td>
<td>2.5</td>
</tr>
<tr>
<td>Square Wave</td>
<td>5</td>
<td>25</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>50</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>75</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>100</td>
<td>2.5</td>
</tr>
<tr>
<td>Triangle</td>
<td>9</td>
<td>25</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>50</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>75</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>100</td>
<td>2.5</td>
</tr>
<tr>
<td>Early Triangle</td>
<td>13</td>
<td>25</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>50</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>75</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>100</td>
<td>2.5</td>
</tr>
</tbody>
</table>
## Mouth Level Exposure - 1 mg Product

<table>
<thead>
<tr>
<th>1 mg (Visit 1)</th>
<th>Estimated Nicotine (mg/cig)</th>
<th>Estimated NFDPM by UV (mg/cig)</th>
<th>Estimated NFDPM by Solanesol (mg/cig)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA</td>
<td>1.3 (0.3)</td>
<td>13.7 (2.3)</td>
<td>12.7 (2.1)</td>
</tr>
<tr>
<td>SA7</td>
<td>1.2 (0.2)</td>
<td>11.8 (2.1)</td>
<td>11.1 (2.7)</td>
</tr>
<tr>
<td>Free Smoke</td>
<td>1.2 (0.1)</td>
<td>12.2 (1.9)</td>
<td>12.0 (2.4)</td>
</tr>
<tr>
<td>p value¹</td>
<td>0.022</td>
<td>0.001</td>
<td>0.107</td>
</tr>
</tbody>
</table>

¹General Linear Model ANOVA, α= 0.05, presented as mean values and associated standard deviation
# Mouth Level Exposure - 10 mg Product

<table>
<thead>
<tr>
<th>10 mg (Visit 1)</th>
<th>Estimated Nicotine (mg/cig)</th>
<th>Estimated NFDPM by UV (mg/cig)</th>
<th>Estimated NFDPM by Solanesol (mg/cig)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA</td>
<td>1.9 (0.8)</td>
<td>20.0 (9.6)</td>
<td>19.9 (8.2)</td>
</tr>
<tr>
<td>SA7</td>
<td>1.7 (0.6)</td>
<td>18.5 (6.7)</td>
<td>18.9 (7.4)</td>
</tr>
<tr>
<td>Free Smoke</td>
<td>1.6 (0.4)</td>
<td>16.7 (3.5)</td>
<td>16.1 (4.2)</td>
</tr>
<tr>
<td>$p$ value$^1$</td>
<td>0.210</td>
<td>0.360</td>
<td>0.141</td>
</tr>
</tbody>
</table>

$^1$General Linear Model ANOVA, $\alpha = 0.05$, presented as mean values and associated standard deviation
Sensory

Sensory questionnaires were administered after each smoke session. Responses to 9 sensory attributes and overall acceptability of the product were collected using a scale of magnitude of 1-5 (1 being the lowest and 5 the highest).

- Pleasantness of flavour
- Effort for satisfactory puff
- Mouthfill
- Satisfactory smoke delivery
- Hotness/tingling/prickling in mouth/upper throat
- Kick sensation in lower throat
- Amount of flavour
- Natural tobacco flavour
- Mouth drying
- Acceptability

No statistically significant differences\(^1\) across all smoke sessions for any of the sensory attributes with the exception of ‘hotness/tingling/prickling in the mouth/upper throat’.

Tukey’s ranking

- SA7 \(^1\)\(^a\)
- SA7 \(^1\)\(^b\)
- PSA \(^1\)\(^ab\)
- PSA \(^1\)\(^b\)
- Free smoke\(^b\)

\(^1\)General linear model ANOVA, \(\alpha=0.05\), \(p\) value = 0.009
Sensory Responses

Comparison of sensory responses across all smoke sessions presented as mean values (s.d.)

<table>
<thead>
<tr>
<th>n=20</th>
<th>Free Smoke</th>
<th>PSA 1</th>
<th>PSA 2</th>
<th>SA7 1</th>
<th>SA7 2</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pleasantness</td>
<td>3.7 (0.9)</td>
<td>3.8 (0.7)</td>
<td>3.5 (0.9)</td>
<td>3.3 (0.9)</td>
<td>3.3 (0.7)</td>
<td>0.108</td>
</tr>
<tr>
<td>Draw effort</td>
<td>2.5 (1.1)</td>
<td>2.8 (1.2)</td>
<td>2.7 (1.1)</td>
<td>2.8 (1.3)</td>
<td>2.8 (1.1)</td>
<td>0.682</td>
</tr>
<tr>
<td>Mouth fill</td>
<td>3.1 (1.2)</td>
<td>3.4 (0.9)</td>
<td>3.4 (0.9)</td>
<td>3.2 (1.0)</td>
<td>3.3 (1.0)</td>
<td>0.577</td>
</tr>
<tr>
<td>Satisfactory smoke delivery</td>
<td>3.1 (1.3)</td>
<td>3.5 (0.8)</td>
<td>3.4 (0.9)</td>
<td>3.3 (0.9)</td>
<td>3.3 (0.9)</td>
<td>0.698</td>
</tr>
<tr>
<td>Tingling sensation</td>
<td>2.1 (1.1)</td>
<td>2.6 (1.1)</td>
<td>2.4 (0.9)</td>
<td>3.0 (1.3)</td>
<td>2.8 (1.0)</td>
<td>0.009</td>
</tr>
<tr>
<td>Kick/Hit</td>
<td>2.5 (1.2)</td>
<td>3.0 (0.9)</td>
<td>3.0 (1.1)</td>
<td>3.1 (1.4)</td>
<td>3.1 (1.0)</td>
<td>0.139</td>
</tr>
<tr>
<td>Amount of flavour</td>
<td>3.6 (0.9)</td>
<td>3.7 (0.9)</td>
<td>3.5 (0.9)</td>
<td>3.7 (0.9)</td>
<td>3.6 (0.9)</td>
<td>0.600</td>
</tr>
<tr>
<td>Natural tobacco Flavour</td>
<td>3.4 (0.9)</td>
<td>3.6 (0.7)</td>
<td>3.4 (0.8)</td>
<td>3.4 (0.7)</td>
<td>3.6 (0.6)</td>
<td>0.708</td>
</tr>
<tr>
<td>Mouth drying</td>
<td>3.0 (1.3)</td>
<td>2.9 (1.3)</td>
<td>3.2 (1.5)</td>
<td>3.4 (1.3)</td>
<td>3.2 (1.3)</td>
<td>0.252</td>
</tr>
<tr>
<td>Acceptability</td>
<td>4.2 (0.9)</td>
<td>4.0 (1.0)</td>
<td>3.7 (0.9)</td>
<td>4.0 (1.1)</td>
<td>3.8 (0.9)</td>
<td>0.288</td>
</tr>
</tbody>
</table>

1 General linear model ANOVA, \( \alpha=0.05 \), paired for subject