Original investigation

Design and Validation of a Research-Grade Waterpipe Equipped With Puff Topography Analyzer

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Abstract

Introduction: Worldwide, commercially available waterpipes vary widely in design and durability, including differences in fabrication materials, degree of leak-tight fit, and flow path diameter. Little is known about how the components of the waterpipe may influence puffing behavior and user's exposure to toxins. To systematically evaluate exposure, it is necessary to use a standardized research-grade waterpipe (RWP) when conducting clinical and laboratory-based trials.

Methods: We developed a RWP that is configured with an in-line topography system which allows real-time measurement and recording of the smoke volume drawn through the RWP. The RWP was calibrated across the flow rate range expected for waterpipe tobacco smoking and the calibration was verified for known puff volumes using a smoking machine. Operation of the RWP was qualified in a cohort of experienced waterpipe smokers, each smoker using the RWP *ad libitum* in a laboratory setting while smoker topography and subjective effects data were collected.

Results: RWP machine smoking was highly reproducible and yielded puff volumes that agreed well with true values. User acceptance was comparable, and puffing behavior was similar in pattern, with more frequent puffing in the beginning of the session, but significantly different in intensity from that used to estimate the majority of toxicant exposure reported in the literature.

Conclusions: The RWP operates with known precision and accuracy and is well accepted by experienced smokers. This tool can be used to determine the extent to which puffing behaviors are affected by the waterpipe design, components, and/or accessories, tobacco nicotine content, sweet flavorings and/or additives known to increase addictiveness.

Implications: This study describes a standardized RWP, equipped with a puffing topography analyzer, which can operate with known precision and accuracy, and is well-accepted by experienced smokers in terms of satisfaction and reward. The RWP is an important tool for determining if puffing behaviors, and thus estimated toxin exposures, are affected by the waterpipe design, components, and/or accessories, tobacco nicotine content, sweet flavorings, and/or additives that are known to increase addictiveness.

Introduction

Just within the past 11 years, the global evolution of the waterpipe tobacco smoking habit has exceeded worst predictions.^{1,2} This worldwide epidemic has increasingly spread among youth, primarily in the Middle East and North Africa, and the popularity of waterpipe use in Europe and North America is increasing rapidly among adolescents 13–15 years old.^{3–5} The most recent data (2010–2012) in the United States reported that 18% of high school seniors used a waterpipe in the past year.⁶ Recent reviews indicate prevalence of tobacco/waterpipe (excluding cigarettes) use as high as 35%–40% in Lebanon, and 4%–17% in the United States.^{1,7} The introduction of flavored waterpipe tobacco (“ma’assel”) in the 1990s,^{2,8} the rising popularity of waterpipe cafes that permit indoor smoking,^{1,9} the perception that it is a safer alternative to cigarette smoking,⁷ and internet marketing are all thought to be important factors contributing to the rise in popularity of waterpipe tobacco smoking among youth.¹

The US Food and Drug Administration (FDA), through the Family Smoking Prevention and Tobacco Control Act,¹⁰ has classified harm from tobacco products in terms of the chemical constituents that can be inhaled, ingested or absorbed into the bodies of users.¹¹ These harmful and potentially harmful constituents (HPHCs) have been measured in waterpipe tobacco smoke, and thus have the potential to cause direct harm via delivery of carcinogens, toxicants and addictive chemicals to the body, or indirect harm by facilitating tobacco initiation,¹² increasing progression to cigarette smoking,¹³ impeding cessation of cigarette smoking,^{14,15} and/or increasing the intensity of tobacco product use.

The ability to measure puffing behavior is important in estimating the indirect and direct harm associated with waterpipe tobacco smoking. Ma’assel waterpipe tobacco contains sweet, candy- and fruit-like flavorings, such as chocolate, apple, and mango. Similar characterizing flavors have been banned as constituents and additives in cigarettes in the United States,¹⁰ but not in waterpipes, because they serve to enhance the consumer appeal of these products, especially for youth.^{16–19} It has not been definitively proven whether candy-like or sweet flavorings have the potential to cause indirect harm by affecting the intensity of puffing and/or overall exposures from waterpipe tobacco smoking.

As has been previously done with cigarette smoking,^{20,21} direct harm can be estimated by collecting human waterpipe tobacco smoking topography data (puff volume, duration, flow, and inter-puff interval), using these data to machine smoke a waterpipe, and measuring the resulting mainstream HPHCs.²² Combining this approach with exhaled breath measurements allows estimates of volatile and semivolatile HPHC body burden, as has been demonstrated in cigarette smokers.²³ Several studies^{22,24,25} have used behavioral data and machine smoking to characterize the chemical composition, toxicity, and carcinogenicity of waterpipe tobacco smoking; the results from these studies were recently reviewed.²⁶ These studies, which generally show higher concentrations of mainstream and sidestream HPHCs for a waterpipe tobacco versus cigarette smoking session, have been further substantiated by reports of actual uptake and body burden of waterpipe-related smoke constituents.^{27–32}

Direct harm also includes chemicals that increase a tobacco product’s addictiveness, such as nicotine, and can cause smokers to use a product more intensely. Compensation, or smoking low-yield cigarettes with greater intensity to achieve a specific nicotine intake, has been well documented.³³ The evidence regarding whether or not waterpipe smokers engage in compensation to obtain more nicotine is not clear. One study of young adult, occasional waterpipe-only

smokers used topography to show that puff volume and duration, and number of puffs were significantly affected by whether or not the products smoked contained nicotine.³⁴ However, a similar cohort and cross-over study design showed no significant differences in any of these parameters.³⁵ These two studies used the same topography collection device,³⁶ but it is not clear whether the waterpipe itself was standardized across the two studies. To examine how puffing behavior might be affected by a reduced nicotine, that is, less addictive, waterpipe tobacco requires the use of a standardized research-grade waterpipe (RWP) that can be operated under carefully controlled and reproducible conditions.

Efforts to characterize waterpipe tobacco smoking behavior have been sparse. One study of patron’s in a Lebanese waterpipe café used direct observation of the bubbling water in the bowl and a stopwatch, together with a portable puff topography instrument specially designed for use in the field to measure naturalistic waterpipe tobacco smoking behaviors.³⁷ Data collected with the portable topography device used commercially available waterpipes that were not characterized with respect to their materials, design, or nicotine delivery. These data were reduced to yield the so-called Beirut method,^{36,37} a machine smoking regimen that has been adopted and used by all researchers to characterize and report estimated mainstream exposures,³⁶ with one exception.³⁸

In comparison with cigarette smoking, waterpipe tobacco smoking presents a much greater variety of equipment, component, and accessory options to the smoker. All waterpipes have five major components: the bowl, stem, head, hose, and mouthpiece.³⁹ These are made of various materials including bronze, brass, and copper for stems; glass, ceramics, and Plexiglas for bases; glass and ceramics for bowls; and wrapped foil, leather, and rubber for hoses. There is also great variability regarding the design of the joint connections between the bowl, stem, and head, and the degree to which the connection forms a leak-tight seal. The diameter of the flow path, which is directly related to the resistance to draw (or pressure drop) experienced by the smoker, can also vary significantly, even from the same supplier.

It is not known which design features or components of the waterpipe have the greatest effect on the toxin exposure experienced by the user.⁴⁰ This lack of consistency in commercially available waterpipes makes it very difficult to methodically examine the role of waterpipe design, specific components, accessories, and operating conditions on the resulting emissions. In order to systematically evaluate exposure, it is necessary to use a standardized RWP when conducting clinical and laboratory-based research. The purpose of this study was to design, fabricate, validate through machine smoking, and qualify the human use of a RWP for the collection of waterpipe tobacco-smoking puffing behaviors in a laboratory setting.

Materials and Methods

Waterpipe

We constructed the RWP from commercially available and specially fabricated components, as pictured in [Figure 1](#). To reduce contamination and memory effects, guard against degradation over time from the corrosive nature and high humidity of mainstream waterpipe tobacco smoke, and facilitate easy cleaning, all wetted materials have inert surfaces. The specific components are made of the following: the bowl (Erlenmeyer flask, Kimax, Kimble, 2L) and head (hand-blown, The Ohio State University Glassblowing Laboratory, 43 mm i.d., 37.8 cm³ available for holding tobacco) are of Pyrex,

Figure 1. Photo showing the main components of the research-grade waterpipe; signal amplifier and data acquisition hardware not shown.

the stem is of stainless steel (316) sealed to the base with a rubber O-ring (Buna-N, 0.5 cm thick, 0.25 cm i.d., Grainger), the pneumotachometer is of polycarbonate (Adult flow sensor, RSS100, Hans Rudolph, Shawnee, KS), and the pneumotachometer tubing adaptor is of Delrin. The tubing itself is made of a corrosive-resistant plastic (Saint Gobain Tygon Formula 2075, 9.5 mm i.d., 12.7 mm o.d.) with a smooth inner surface that is designed to minimize particle adsorption, and the mouthpiece is of Teflon tubing (9.5 mm o.d., 7.8 mm i.d., Fisher Scientific, 7.6 cm long) that is disposable. The length of the stem (15.9 mm o.d., 9.8 mm i.d.) from the head to the mouth of the bowl is 28.6 cm, and the length of the down stem (9.5 mm o.d., 7.3 mm i.d.) is 21.0 cm. A portion (6.8 cm) of the down stem is submerged in the water (ASTM Type II, 1.5 L), which was added using an Erlenmeyer flask (2 L) at the beginning of each experiment. Special consideration was given to make the RWP leak-tight, and give minimal resistance to flow (minimum diameter of the smoke path ≥ 5.8 mm).

Pneumotachometer

The RWP is equipped with an in-line topography system, attached between the bowl and hose, which allows real-time measurement and recording of the flow rate of smoke drawn through the RWP during a smoking session. The topography system is based on an in-line fixed orifice differential pressure pneumotachometer, commercially

designed for continuous pulmonary monitoring of patients in critical care environments. This device introduces minimal draw resistance to the waterpipe ($<5\%$ at 27 L/min), and performs reliably when measuring flows of the sugary, high humidity aerosol that is characteristic of mainstream waterpipe tobacco smoke. These disposable pneumotachometers have no moving parts but must be replaced over time due to wear. Calibration data collected during the study period for the four pneumotachometers used were reproducible and applied to yield a single curve to describe the relationship between flow through the pneumotachometers and voltage response. Flexible tubing (1.2 mm i.d., 3.0 mm o.d.) was attached to either side of the linear flow restriction inside the polycarbonate tube and connected to an amplifier (Amplifier 1, Series 1110, Hans Rudolph, Shawnee, KS) that incorporates pressure transducers to convert pressure drop (0–2 cm H_2O) across the restriction to an electrical response (0–1 Vdc). Data were monitored graphically in real time (ChromPerfect LSi, Justice Laboratory Software, Denville, NJ) and recorded continuously (5 Hz) using a 24-bit serial analog-to-digital data logger (Tigre III, Justice Laboratory Software, Denville, NJ). Data files were processed manually using a graphical interface (ChromPerfect Analysis module), or in batches using an automatic algorithm (MatLab, MathWorks, Natick, MA) to produce a spreadsheet report describing the volume, duration, average and peak flow rates for each puff, and interpuff intervals.

Automated Data Processing

Automated data processing is achieved using a MatLab macro that can process all of the individually recorded pneumotachometer files with a single command. Stepping through the algorithm for a single file containing the RWP pneumotachometer output from a smoking session, the voltages are corrected for bias. This is achieved by subtracting the average voltage of all the values before the first puff and all the values after the last puff. The bias-corrected voltages are then converted to a flow rate using the empirically derived calibration curves. The start and end of each puff is determined by a threshold flow rate, which was set to 1 L/min, the lowest quantifiable flow rate. The start/stop of the puff is recorded as the point at which the flow rate increases/decreases above/below the threshold. At lower flow rates (1–3 L/min), because the smoke matrix is bubbled through the bowl, pressure drop perturbations result in a puffing flow rate pattern that is observed as numerous peaks with no interpuff interval. To ensure that this type of low-flow puff was properly assigned as a single puff, individual puffs were combined into a single puff when the end and start of consecutive puffs were less than 1 second apart, the approximate time period between pressure drop spikes corresponding to the bubbling at low flow. Each puff is then integrated using trapezoidal numerical integration. Puffs resulting in a total volume of less than 0.05 L are ignored. For each puff, the volume, duration, average and peak flow rates, and interpuff intervals are recorded.

Statistical Analysis

Paired *t* tests were used to test the differences between pre- and post-smoking subjective effects measures. To examine topography measures across tertiles, mixed models analysis and the coefficient of variation were used.

Supplementary Methods

Details on the pneumotachometer calibration, machine smoking, and participant recruitment and processing can be found in the [Supplementary Methods](#) section.

Results

Pneumotachometer Calibration

The relationship between pneumotachometer response and flow through the RWP was best described using a quadratic curve fit ($R^2 = 0.999$), as shown in [Figure 2](#). The measured pressure drop introduced by the pneumotachometer at specific puffing flow rates (0–27 L/min), is shown in [Supplementary Figure S-1](#). The highest added pressure drop (1 inch H₂O) was less than 5% of the pressure drop (23 inches H₂O) measured at the highest flow rate that a smoker is likely to draw. This added resistance is similar to the pressure drop associated with the water bubbling in the bowl and thus is very likely imperceptible to smokers.

RWP Accuracy and Precision

Calibration verification was performed for known puff volumes using a smoking machine equipped with syringe pumps. Sham (unlit charcoal) machine smoking of the RWP over the expected puff volume range, 0–0.75 L,³⁶ was accurate and reproducible as shown in [Supplementary Figure S-2](#). Results yielded average puff volumes with less than 4% error from the true value, and replicate puff volume measurements varied by less than 9%, except for the lowest level which varied by less than 15%. Testing the RWP performance over time under more challenging conditions, that is, with the sticky waterpipe tobacco smoke matrix, yielded excellent precision and accuracy (cf. [Supplementary Figure S-3](#)). Replicate puffs based on the Beirut Method Waterpipe Smoking regimen, 0.50 L puff volume, 3-second duration, 20-second interpuff interval, were measured during a 1-hour machine smoking session; [Supplementary Figure S-3](#) shows the resulting integrated puff volumes. The average error of the measured puff volumes (2.0%), durations (1.6%), and interpuff intervals (–0.6%) for 158 puffs did not exceed 2%, and the relative standard deviation for these metrics was less than 4%.

Reproducibility of RWP Machine Smoking Sessions

Replicate machine smoking sessions were conducted to determine the minimum variability associated with RWP smoking. Replicate 1-hour sessions ($n = 24$) were conducted using the same machine

Figure 2. Relationship between flow rate through the research-grade waterpipe and the topography measurement device response.

smoking conditions and regimen mentioned above, and before and after charcoal and tobacco weights were obtained separately. Percent consumption of these materials was calculated as the fraction of material lost during the smoking session. Results are shown graphically in Figure 3. The average percent of tobacco consumed, $18.8 \pm 1.7\%$ (mean $\pm$ SD), varied by 9.2%, and the average percent of charcoal consumed, $55.8 \pm 2.6\%$, by 4.7%.

Participant Smoking

We recruited 36 experienced waterpipe users and obtained human topography data from 35 of these participants while smoking the RWP. One participant's topography data was not stored due to a technical error, and hence this participant was excluded from analysis. Participant average age was 24.3 ± 5.5 years (range 18–40 years), they were 71.4% male and 77.1% white, and 57.1% also smoked combustible cigarettes. Almost two-thirds (60%) of the participants self-reported smoking waterpipe tobacco at least once a month but not weekly, and one-third (34%) reported at least once a week but not daily. Only two participants reported smoking waterpipe tobacco at least once a year but not monthly, and none reported daily use. In the past 30 days, participants reported smoking waterpipe tobacco an average of 3.0 ± 3.0 days, 1.3 ± 0.8 times per day, and 70.4 ± 44.3 minutes per session; smoking an average of 4.2 ± 4.0 “bowls” or heads of tobacco. Participant responses to a smoking history questionnaire revealed that for those that smoked combustible cigarettes, they smoked an average of 7.7 ± 7.0 (mean $\pm$ SD) cigarettes per day and they had smoked cigarettes regularly on average for 6.9 ± 7.7 years (~ 2.7 pack years). On average, over the past 30 days, participants had used a waterpipe for tobacco smoking for 3.0 ± 3.0 sessions, with 4.2 ± 4.0 heads of tobacco smoked/session, over a 70.3 ± 44.3 minutes smoking session.

For the purpose of testing inter-individual variability, and to evaluate whether waterpipe smoking typically involves more frequent and intense puffing in the beginning of the smoking session, we divided the time the subjects took to complete their smoking sessions into thirds, and analyzed each tertile separately, in addition to evaluating each subject's entire smoking session as a whole. The

resulting smoker-averaged topography data by tertile period and entire smoking period are shown in Table 1.

Subjective Effects Measures

To evaluate user-acceptance of the RWP smoking experience, we summarized participants' responses to selected items from two subjective effects questionnaires, the Hughes-Hatsukami Withdrawal Scale and the Direct Effects of Tobacco Scale. Supplementary Table S-1 reports summary responses of participants on two items of the Hughes-Hatsukami Withdrawal Scale and four items of the Direct Effects of Tobacco Scale. For the items, “Urges to smoke a waterpipe” and “Craving a waterpipe/nicotine,” the mean scores after smoking decreased significantly compared to the pre-smoking scores (by 18.6 and 17.5, respectively; $P < .0001$ based on the paired t tests for each item). For post-smoking Direct Effects of Tobacco Scale items, participants rated 59.2 ± 21.7 (mean $\pm$ SD) for “satisfying”; 62.3 ± 18.3 for “pleasant”; 60.5 ± 23.3 for “taste good”; and 17.2 ± 17.3 for “taste bad.”

Discussion

We designed and fabricated a research grade waterpipe that includes a data-logging pneumotachometer device for use as an important tool in the empirical testing needed to determine how the components of the waterpipe, including purported harm reduction devices and the chemical and physical properties of the tobacco smoked, influence user's puffing behavior and exposure to toxins. Capturing the puffing behavior associated with different waterpipe configurations and tobacco additives is critical to understanding user's exposures, as history has shown that constituent yields based on machine smoking of cigarettes do not reflect smoker compensation,³³ and thus are not well correlated with mortality and morbidity.⁴¹ The RWP can generate the objective evidence needed³⁹ to provide a more thorough understanding of the health effects associated with specific waterpipe designs and tobacco, and inform policy and decision-making for regulatory agencies, tobacco smoking prevention and cessation programs, and consumers.

Figure 3. Reproducibility of charcoal and tobacco consumption resulting from machine smoking of the research-grade waterpipe.

Table 1. Smoker-Averaged Topography Measures by Tertile and for Entire Smoking Period Among Established Waterpipe Smokers (*n* = 35)

	Tertile 1 ^a			Tertile 2			Tertile 3			All		
	Mean	Range	95% CI	Mean	Range	95% CI	Mean	Range	95% CI	Mean	Range	95% CI
Puff duration (s)												
Mean	5.3	2.7–13.9	4.5–6.0	4.3	1.5–13.5	3.5–5.0	3.8	1.8–11.0	3.1–4.5	4.5	2.1–12.8	3.8–5.2
Minimum	2.6	1.0–6.4	2.1–3.0	2.6	1.0–10.7	2.0–3.2	2.0	1.0–4.1	1.7–2.3	1.7	1.0–3.7	1.5–2.0
Maximum	9.1	4.7–23.2	7.6–10.7	6.9	2.2–23.4	5.5–8.3	6.2	2.5–26.1	4.8–7.7	9.8	4.9–26.1	7.9–11.7
SD	1.5	0.7–4.7	1.2–1.8	1.2	0.3–4.8	0.9–1.5	1.2	0.4–6.3	0.8–1.6	1.6	0.6–4.6	1.3–1.9
Puff volume (L)												
Mean	0.86	0.28–1.62	0.75–0.97	0.55	0.18–1.28	0.46–0.64	0.46	0.11–1.18	0.37–0.55	0.64	0.20–1.34	0.55–0.74
Minimum	0.33	0.05–1.09	0.25–0.42	0.3	0.05–0.82	0.22–0.38	0.22	0.05–0.53	0.16–0.27	0.16	0.05–0.45	0.12–0.20
Maximum	1.61	0.79–3.00	1.44–1.78	0.86	0.28–1.97	0.74–0.99	0.8	0.19–1.83	0.65–0.95	1.61	0.87–3.00	1.45–1.78
SD	0.32	0.11–0.58	0.28–0.36	0.16	0.06–0.43	0.13–0.19	0.16	0.03–0.41	0.13–0.19	0.31	0.11–0.51	0.27–0.35
Interpuff interval (s)												
Mean	19.5	4.5–46.9	16.1–22.9	33.7	5.0–111.0	26.5–40.8	33.8	4.9–129.8	25.0–42.6	26.2	4.8–74.0	21.3–31.0
Minimum	3.3	0.8–25.7	1.8–4.9	8.9	0.8–36.4	6.4–11.5	5.8	0.8–22.0	3.9–7.7	3.0	0.8–22.0	1.7–4.4
Maximum	52.5	9.1–124.1	41.7–63.2	82.1	13.4–262.3	64.6–99.5	109.3	14.8–578.4	71.9–146.8	119.8	14.8–578.4	83.4–156.2
SD	13.1	2.0–36.6	10.1–16.1	21.2	2.2–88.9	15.2–27.2	31.0	3.2–202.6	17.6–44.4	22.4	2.9–109.0	15.6–29.2
Mean flow (L/min)												
Mean	11.2	5.0–20.4	9.8–12.6	9.5	3.3–20.4	8.1–10.9	8.9	3.5–18.4	7.6–10.2	10.0	4.5–18.7	8.7–11.3
Minimum	6.0	1.8–14.5	5.0–6.9	5.8	1.3–17.8	4.7–7.0	5.3	1.0–12.7	4.4–6.2	4.6	1.0–12.7	3.7–5.5
Maximum	17.7	5.9–25.5	16.0–19.4	13.2	5.7–22.0	11.5–14.9	13.6	5.5–23.6	11.9–15.4	18.3	6.3–25.5	16.7–19.9
SD	3.0	0.5–5.4	2.6–3.4	2.1	0.5–7.7	1.6–2.6	2.2	0.7–5.1	1.9–2.6	3.0	0.9–6.4	2.6–3.4
Peak flow (L/min)												
Mean	17.0	7.9–25.4	15.3–18.6	14.9	6.4–27.8	13.1–16.7	14.4	6.5–26.5	12.6–16.1	15.6	7.7–26.2	13.9–17.2
Minimum	10.0	4.2–20.3	8.7–11.3	9.5	1.9–26.2	7.8–11.1	8.9	1.0–19.0	7.4–10.3	7.8	1.0–19.0	6.5–9.2
Maximum	25.1	15.3–28.2	23.9–26.4	20.5	9.8–28.1	18.6–22.5	21.2	10.0–28.2	19.2–23.2	25.8	15.3–28.2	24.6–27.0
SD	4.0	2.1–6.6	3.7–4.4	3.1	0.7–8.3	2.5–3.6	3.4	1.4–6.8	2.9–3.9	4.1	1.8–7.1	3.7–4.5
Number of puffs ^b	27.4 (12.0) ^b	10–62	23.2–31.5	20.7 (12.8)	6–58	16.3–25.1	22.9 (14.2)	7–61	18.0–27.8	70.9 (37.3)	29–177	58.1–83.7
Smoking period (min) for tertile and for entire session ^b	10.57 (4.76)	3.78–22.16	8.94–12.21	—	—	—	—	—	—	31.72 (14.29)	11.34–66.48	26.81–36.63

CI = confidence interval.

^aTertile 1 = first third, Tertile 2 = next third, and Tertile 3 = final third of the smoking session duration.^bNumber in parentheses are standard deviations.

For this study, the relationship between pneumotachometer response and flow through the RWP was empirically derived and used to quantify the topography parameters of puff duration, puff volume, interpuff interval, and mean and peak flow rate. Unlike mainstream combustible cigarette yields, where rod-to-rod variability is generally less than 5%,⁴² waterpipe tobacco smoking is inherently more variable due to the tobacco product and the equipment used.⁴³ The RWP was designed to reduce the variability associated with the required equipment, that is, waterpipe components, as much as possible, and the precision and accuracy of the RWP were quantified to provide the basis for evaluating the effect of these components and harm reduction accessories on puffing behavior. In addition, the inter-individual variability and homogeneity of puffing behavior across a given participant's smoking period was evaluated in a group of experienced waterpipe tobacco smokers, over half of whom also smoked combustible cigarettes. Finally, user-acceptance in terms of urges, craving, and reward associated with the RWP smoking experience was evaluated among the same waterpipe tobacco smokers.

Both sham (unlit charcoal) and machine smoking showed that the RWP was able to measure puff volumes accurately and reproducibly over a 1-hour period using a topography similar to the Beirut waterpipe smoking regimen, viz., puff volume (0.50 vs. 0.53 L), duration (3.0 vs. 2.6 seconds) and interval (20 vs. 17 seconds), and coal usage (1.0 vs. 1.5 coals).³⁷ Although the RWP topography data measurement and collection is based on essentially the same principles as those employed in the mobile topography device described by Shihadeh et al.,³⁷ the RWP does not use a buffer volume to dampen pressure perturbations caused by bubbling. A second notable difference between the two devices is that the RWP was validated and machine-smoked using syringe pumps that mimic the smooth inhalation of a human diaphragm and do not exhibit the pulsation normally associated with the mechanical pump used by Shihadeh et al.³⁶ In general, the accuracy and precision of the topography parameters measured using the RWP are similar to those reported for the portable puff topography instrument developed by Shihadeh et al.³⁶

Tobacco consumption resulting from machine smoking of the RWP over a 1-hour period varied by 9.7% across the 24 replicate sessions. This is higher than that reported by Saleh and Shihadeh,⁴³ using a commercially available waterpipe equipped with a plastic hose, 1.0% for 30 sessions, but comparable to that reported by Schubert et al.,⁴⁴ using a commercially available laboratory waterpipe, 9.3% for 15 sessions. The latter was also equipped with a plastic hose and utilized a similar plunger-based smooth puffing method (Sisha Smoker, Borgwaldt KC). Comparing our results to those generated with waterpipes that have plastic hose material is important, as Saleh and Shihadeh⁴³ have shown that due to air infiltration through leather hoses, average tobacco consumption increases by 42% in commercially available waterpipes equipped with plastic versus the more traditional leather hose. RWP average tobacco consumption, 2.84 ± 0.26 g, is significantly lower: 56% of that reported by Saleh and Shihadeh,⁴³ and 27% lower than that reported by Schubert et al.⁴⁴ These differences may be due to differences between the RWP and the waterpipes used by other researchers and/or the machine-smoking puffing regimens used. The puffing regimen used by Saleh and Shihadeh⁴³ and Schubert et al.,⁴⁴ had more puffs (171 vs. 158) of shorter duration (2.6 vs. 3.0 seconds) that were spaced closer together (17 vs. 20 seconds) than used for the RWP, which resulted in a larger total puffing volume (91 L vs. 79 L). A larger puffing volume means more hot air is drawn across the tobacco and the additional half-piece of charcoal could result in a greater percentage

of the tobacco being burned/consumed. Other important differences include the addition of half a coal after the first two-thirds of the machine smoking session, the material separating the charcoal and tobacco (9 × 9 cm foil sheet vs. 43 mm i.d. metal screen), and perforation geometry (18 vs. 30 holes) in the case of Saleh and Shihadeh;⁴³ only one coal was used by Schubert et al.,⁴⁴ but the foil and perforation geometry matched that of Saleh and Shihadeh.⁴³ The percentage of coal consumed with the RWP varied by 4.7%, roughly twice as much as that reported by Schubert et al.⁴⁴ However, the variance measured can be accounted for by the pre-smoking weight of the coals themselves, which averaged 11.98 ± 0.55 g (4.6% relative standard deviation). Overall, RWP topography and tobacco and coal consumption variability were comparable to those reported for machine smoking using similar topographies and commercially available consumer and laboratory-based waterpipes.

We also qualified the RWP for human use in a group of established waterpipe users. We examined human waterpipe puffing behavior by tertile period using within-subjects analysis of variance approach (ie, mixed models). The results showed that smoker-averaged puff duration, volume, and mean and peak flow decreased, while interpuff interval increased uniformly across the three tertile periods; and all of the differences between tertiles were statistically significant ($P < .01$; with two exceptions for the differences between tertile 2 and tertile 3 in peak flow [$P = .075$] and interpuff interval [$P = .185$]). In general, the variability in tertile 1 was the smallest (mean coefficient of variation = 39.0) whereas the variability in tertile 3 was the largest (mean coefficient of variation = 52.5). Thus smokers took larger, more frequent and more intense puffs at the beginning of a smoking session. This indicates that human waterpipe puffing behavior is not homogenous throughout a single smoking session. These results are similar to those found by other researchers in cohorts of dependent⁴⁵ and occasional³⁵ dual users (combustible cigarettes and waterpipe). The most widely varying parameters across all subjects were the smoking period, number of puffs, and interpuff interval, which varied by as much as 92% within a given tertile period. These data suggest that the actual puff that smokers took when smoking the RWP was fairly consistent, but that the number, puffing rate, and smoking session period varied much more widely across all participants.

A comparison of our overall smoker-averaged results to the reported data recorded in naturalistic and laboratory environments is shown in [Supplementary Table S-2](#). Comparing the RWP to the results obtained by Shihadeh et al.,³⁷ the puff duration and interpuff interval are longer (~70%), puff volume is larger (21%), and average puffing flow is smaller (20%). Generally, our participants took bigger and less intense puffs less frequently when using the RWP. It is not clear whether the larger, less intense, and rapid puffing rate associated with the RWP are a real difference in puffing behavior between the participants sampled in the two studies, or are a difference in the algorithm used to detect and distinguish one puff from another. The RWP's plastic hose may play a role, in that the lack of air infiltration⁴³ makes the smoke sample more concentrated in nicotine, and thus smoker's do not feel the need to take as intense or frequent puffs as those using leather hoses in a café setting.³⁷

Naturalistic puffing topography has also been measured using a compact spirometer³⁸ for a smaller sample of smokers ($n = 11$) in a waterpipe café in Switzerland. The results obtained there are more comparable with those measured for the RWP in the laboratory, with an average puff volume of 1.0 ± 0.47 L, 5-second duration, and interval of 25 seconds (cf. [Supplementary Table S-2](#)). Comparing the RWP results to those obtained in a laboratory environment using

a similar size cohort ($n = 33$),³⁵ on average our participants took longer puffs of smaller volume more frequently (cf. [Supplementary Table S-2](#)), and roughly the same number of puffs (70.9 ± 37.3 vs. 66.3 ± 42.2 for Blank³⁵) for a similar total volume of smoke inhaled (41.8 ± 25.4 L vs. 57.0 ± 45.6 L for Blank³⁵). The inter-subject variability in puff duration, puff volume, and interpuff interval was very comparable between the two studies, but Blank et al.³⁵ found much higher variability in the total volume of smoke inhaled.

Based on selected items from the Hughes-Hatsukami Withdrawal Scale and Direct Effects of Tobacco Scale, subjective effects of the RWP smoking were comparable to those effects reported in other waterpipe studies (cf. [Supplementary Table S-1](#)).^{35,46,47} After smoking the RWP, participant-reported urges to smoke a waterpipe and craving of a waterpipe/nicotine decreased significantly. This, in addition to participants' ratings for "satisfying," "pleasant," "taste good," and "taste bad" show that their smoking experiences using the RWP were equivalent to experiences reported in other studies by experienced users of commercially available waterpipes. These data provide evidence that use of the RWP to collect clinical research laboratory data does not compromise user acceptance of waterpipe smoking experience.

Limitations

We wish to point out the following limitations to the data collected for this study. For simplicity, all of the participant smoking and subsequent topography data collection was conducted solo in a laboratory environment. The puffing behavior recorded here may not be representative of what occurs when sharing a waterpipe among friends in a typical social setting. In addition, the use of a plastic hose has been shown to deliver higher levels of nicotine and other toxicants to the user,⁴³ and thus puffing behavior for the RWP may actually be less intense than what might occur with a waterpipe equipped with a leather hose. Also, all participants began each smoking session with a fresh plastic hose. Re-used leather and washed plastic hoses can build up smoke residues and become less palatable over time, which also may affect puffing behavior. The RWP is a laboratory-based, not a real-world, device that is designed to give reproducible results so that waterpipe tobacco, components and accessories, and their effect on puffing behaviors, can be systematically evaluated. While the RWP is an important tool for rigorously analyzing how exposures from waterpipe tobacco smoking may be affected by additives, nicotine delivery, components, and purported harm reduction accessories, it is not meant to be a device that accurately mimics naturalistic smoking conditions. To determine whether participants find the RWP similar to a more traditional, commercially available waterpipe, a study that uses a cross-over design and a single tobacco to examine both devices is needed, so that users' resulting subjective effects and topography can be compared.

Conclusions

This study describes a standardized RWP, equipped with a puffing topography analyzer, which can operate with known precision and accuracy, and is well-accepted by experienced smokers in terms of satisfaction and reward. A rigorous analysis of waterpipe tobacco smoking behaviors (ie, topography) shows that they are not homogeneous throughout a session; smoking is more intense, that is, larger, with more frequent puffs, in the beginning of laboratory smoking sessions. The RWP is an important tool for determining if puffing behaviors, and thus estimated toxin exposures, are affected by the

waterpipe design, components, and/or accessories, tobacco nicotine content, sweet flavorings, and/or additives that are known to increase addictiveness.

Supplementary Material

[Supplementary Methods, Tables S-1 and S-2 and Figures S-1–S-3](#) can be found online at <http://www.ntr.oxfordjournals.org>

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Declaration of Interests

None declared.

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