

Performance Comparison of Two Oscillating Positive Expiratory Pressure Devices: Acapella Versus Flutter

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BACKGROUND: Oscillatory positive expiratory pressure (PEP) with the Flutter device facilitates secretion removal. In the Flutter a steel ball vibrates inside a cone, causing air flow vibration. A new device, the Acapella, uses a counterweighted plug and magnet to create air flow oscillation. The Acapella comes in 2 models: one for patients with expiratory flow ≥ 15 L/min and one for ≤ 15 L/min. We hypothesized that the Acapella and Flutter would produce similar mean PEP, oscillatory pressure amplitude, and frequency over a clinically relevant range of flows. **METHODS:** We measured oscillatory amplitude, PEP, and frequency. Values for frequency, peak, trough, and mean pressure were recorded automatically every 3 seconds at flows of 5, 10, 15, 20, 25, and 30 L/min. The pressure waveform for 1 second was also graphically displayed and recorded. The devices were adjusted to give low, medium, and high mean expiratory pressure (Flutter angle at 0, 20, and 40°; Acapella by dial setting). Data were analyzed by 2-way repeated measures analysis of variance, and differences were considered significant when p was < 0.05 . **RESULTS:** There were statistically significant differences between the devices for mean pressure, pressure amplitude, and frequency, for all experimental conditions. However, the differences were relatively small and may not be clinically important. Both devices produced similar pressure waveforms at the medium flows. At 5 L/min the Acapella produced a more stable waveform, with a lower frequency, higher amplitude, and a slightly wider range of PEP than the Flutter. **CONCLUSIONS:** Acapella and Flutter have similar performance characteristics. Acapella's performance is not gravity-dependent (ie, dependent on device orientation) and may be easier to use for some patients, particularly at low expiratory flows. *Key words:* oscillatory, oscillation, positive expiratory pressure, PEP, Acapella, Flutter, secretion clearance. [Respir Care 2003;48(2):124–130]

Introduction

Many disease processes interfere with normal mucociliary clearance and require airway clearance techniques to facili-

tate secretion removal. Several types of airway clearance adjuncts are commercially available to aid in mucus mobilization and expectoration. We conducted a laboratory evaluation of 2 airway clearance devices that combine high-frequency air flow oscillations with positive expiratory pressure (PEP).

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The Flutter (Scandipharm, Birmingham, Alabama) has been evaluated clinically and found to aid in mucus production and have similar effects on oxygen saturation, pulmonary function, hospital length of stay, arterial blood gas values, and symptom scores, compared with other conventional forms of airway clearance such as chest physiotherapy, autogenic drainage, and active cycle of breathing technique.^{1–4} The Flutter has a perforated cap that contains an inner cone and a steel ball. As exhaled gas passes through the device, the steel ball vibrates vertically within its casing, causing air flow vibrations or oscillations. The angle at which the device is held by the patient affects the amount of effort needed to cause the steel ball to vibrate, which affects the expiratory flow and thus controls the frequency and amplitude of the oscillations and PEP.⁵

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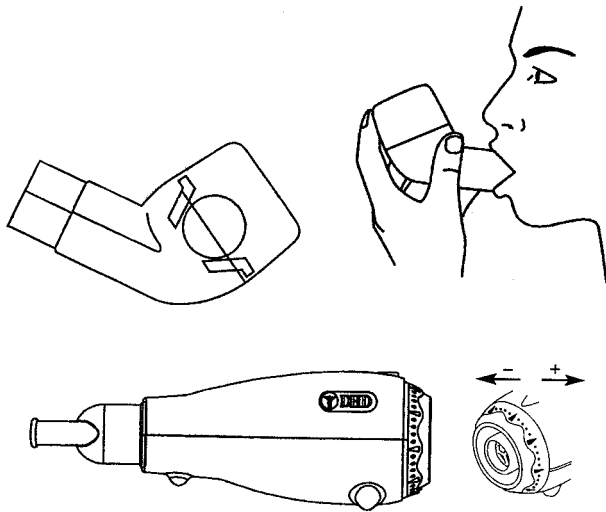


Fig. 1. The Flutter (top) and the Acapella (bottom). The Acapella's positive expiratory pressure (PEP) level is adjusted with a dial on the distal end of the device (bottom right).

The Acapella (DHD Healthcare, Wampsville, New York) combines the principles of high-frequency oscillation and PEP by employing a counterweighted lever and magnet. Exhaled gas passes through a cone, which is intermittently occluded by a plug attached to the lever, producing air flow oscillations. A knob located at the distal end of the device adjusts the proximity of the magnet and counterweighted plug, thereby adjusting the frequency, amplitude, and mean pressure. The Acapella is available in 2 models: a green device for patients who can sustain at least 3 seconds of expiratory flow ≥ 15 L/min, and a blue device for patients with expiratory flow ≤ 15 L/min.

Both the Flutter and the Acapella generate PEP and oscillations by the opposition to flow produced by an obturator acting with a metered force. The Flutter uses the force of gravity. The Acapella uses the force of magnetic attraction.

The objective of our laboratory evaluation was to compare the pressure waveforms generated by the Flutter and the Acapella. We hypothesized that the Acapella and Flutter would produce similar mean expiratory pressure (PEP), oscillatory pressure amplitude, and frequency over a range of flow and PEP settings.

Methods

Equipment Set-up

Figure 1 shows the 2 devices. They were evaluated at discrete, constant flows from a compressed oxygen source connected to 2 standard medical oxygen flow meters (in parallel, to achieve the desired flow range). One end of a 0.95-cm (inner diameter) \times 2.5 cm piece of tygon tubing

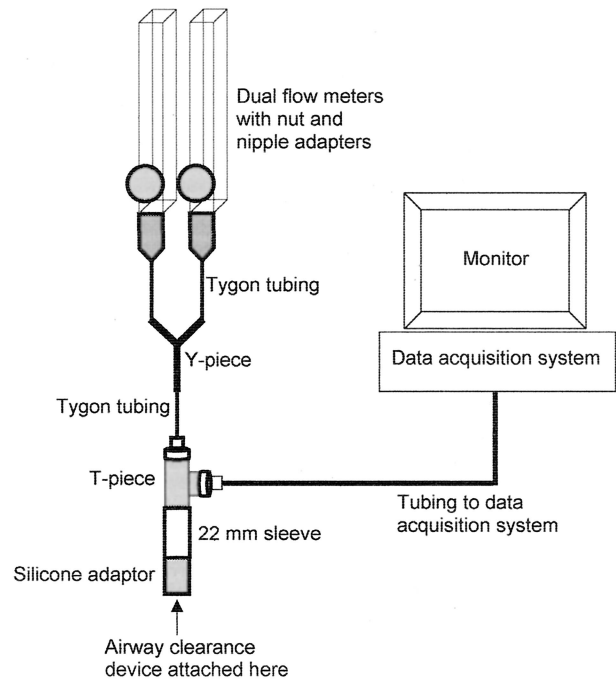


Fig. 2. Experimental setup.

was attached to the nut and nipple adapter on each flow meter and the other end to a 0.95-cm (inner diameter) Y-piece. A 0.95-cm (inner diameter) \times 7.6 cm piece of tygon tubing was attached to the distal end of the Y-piece and connected the flow sources together. Rubber flex adapters were used to connect the flow source to the data acquisition system and airway clearance device in series (Fig. 2).

Positive Expiratory Pressure and Flow Settings

The devices were adjusted to give low, medium, and high range PEP (Table 1). The Flutter, which is available in only one model, was tested across the full range of flows (5–30 L/min). A flow range of 5–15 L/min was used with the blue Acapella. A range of 20–30 L/min was used with the green Acapella. Flows of 5, 10, 15, 20, 25, and 30 L/min were tested with each of the PEP settings. The angle at which the Flutter was secured (0, 20, and 40°) corresponded to PEP settings of low, medium, and high, respectively. The PEP level of the Acapella was varied by setting the dial. A ring stand with a claw clamp was used to set and maintain the angle at which the Flutter was held throughout the experiment. The Flutter PEP level was varied by altering the angle of the device relative to the laboratory countertop (0° was parallel with the countertop). A protractor was used to set the angle at which the Flutter was secured. Both Acapella devices were studied with the long axis parallel to the counter.

Indicator marks on the Acapella were used as reference points for PEP settings. The middle mark designated me-

PERFORMANCE COMPARISON OF TWO OSCILLATING POSITIVE EXPIRATORY PRESSURE DEVICES

Table 1. Experimental Conditions Used to Evaluate Oscillatory PEP Devices

	Device	Flows (L/min)	PEP Setting
Low PEP	Flutter	5, 10, 15, 20, 25, 30	0°
	Acapella (blue)	5, 10, 15	Fully counterclockwise
	Acapella (green)	20, 25, 30	Fully counterclockwise
Medium PEP	Flutter	5, 10, 15, 20, 25, 30	20°
	Acapella (blue)	5, 10, 15	Middle mark
	Acapella (green)	20, 25, 30	Middle mark
High PEP	Flutter	5, 10, 15, 20, 25, 30	40°
	Acapella (blue)	5, 10, 15	Fully clockwise
	Acapella (green)	20, 25, 30	Fully clockwise

PEP = positive expiratory pressure

dium PEP. The marks furthest clockwise and counterclockwise designated high and low PEP, respectively.

Data Acquisition

Oscillation amplitude, mean pressure (PEP), and frequency were measured with data acquisition software designed for blood pressure measurement (Biosystems XA, Buxco Electronics, Sharon, Connecticut). The sample rate was 200 Hz. Digital values for frequency, peak, trough, and mean pressure were recorded automatically every 3 seconds, yielding a table of 13 data points for each variable. The first 3 data points for each experimental condition were used for the statistical analysis. The pressure waveform for 1 second was also graphically displayed and recorded.

Statistical Analysis

Data were analyzed using commercially available software (Excel, Microsoft, Redmond, Washington, and Sigma-Stat, SPSS, Chicago, Illinois). Mean values for frequency, mean pressure, and amplitude were calculated from 3 data points for each experimental condition of flow and PEP setting. Two-way analysis of variance for repeated measures was used to compare the outputs of the 2 devices across the range of flows. Differences were considered statistically significant when $p < 0.05$.

Results

Figure 3 shows the mean values for frequency, amplitude, and mean pressure across the range of flows and PEP settings. The standard deviations for all measurements were negligible and thus are not included. The p values in Fig-

ure 3 are for the interaction effect from the analysis of variance. Table 2 summarizes the data from Figure 3.

Relation Between Mean Expiratory Pressure and Flow

Though there was a significant difference between the 2 devices in terms of mean pressure, the differences appear to be clinically unimportant. Both devices showed a significant effect ($p < 0.001$) of flow on mean expiratory pressure (ie, PEP). Mean pressure increased as flow increased, but the effect was rather small. In fact, the devices act more like threshold resistors than flow resistor positive end-expiratory pressure valves.⁶ The Acapella produced slightly higher pressures than the Flutter at the high setting.

Relation Between Pressure Amplitude and Flow

Acapella produced higher amplitudes at the medium and high settings but not at the low setting. The differences were several centimeters of water pressure at some flow levels, which may be clinically important.

Relation Between Oscillatory Frequency and Flow

Though there was a significant difference in frequency, the effect was small for most experimental conditions. However, the Flutter produced frequencies from 1–5 Hz higher than the Acapella at the medium setting. Five Hz represents 17% of the maximum frequency of these devices (see Table 2), which may be large enough to produce a clinical effect when coupled with the Flutter's tendency to produce lower amplitudes. The effect of flow level on frequency was only significant at the high setting, but, again, there would seem to be little clinical importance.

The graphical representation of each airway clearance device's amplitude and frequency during the 1-second sampling period for each flow and PEP setting was randomly selected and printed. We selected representative waveforms for Figures 4 and 5. From visual inspection, the Acapella and the Flutter produce similar waveforms at the medium flows (see Fig. 4). The Acapella, however, produced a more regular waveform (ie, more like a simple sine wave) at the high flows (see Fig. 5).

Discussion

Oscillating PEP (OPEP) is designed to be used with a steady expiratory maneuver. In the clinical setting patients are instructed to take a slightly larger than normal tidal volume breath but not to completely fill the lungs, then to maintain a steady exhalation for at least 4 seconds but not to exhale all the way down to functional residual capacity. Thus, the OPEP maneuver is different from the forced

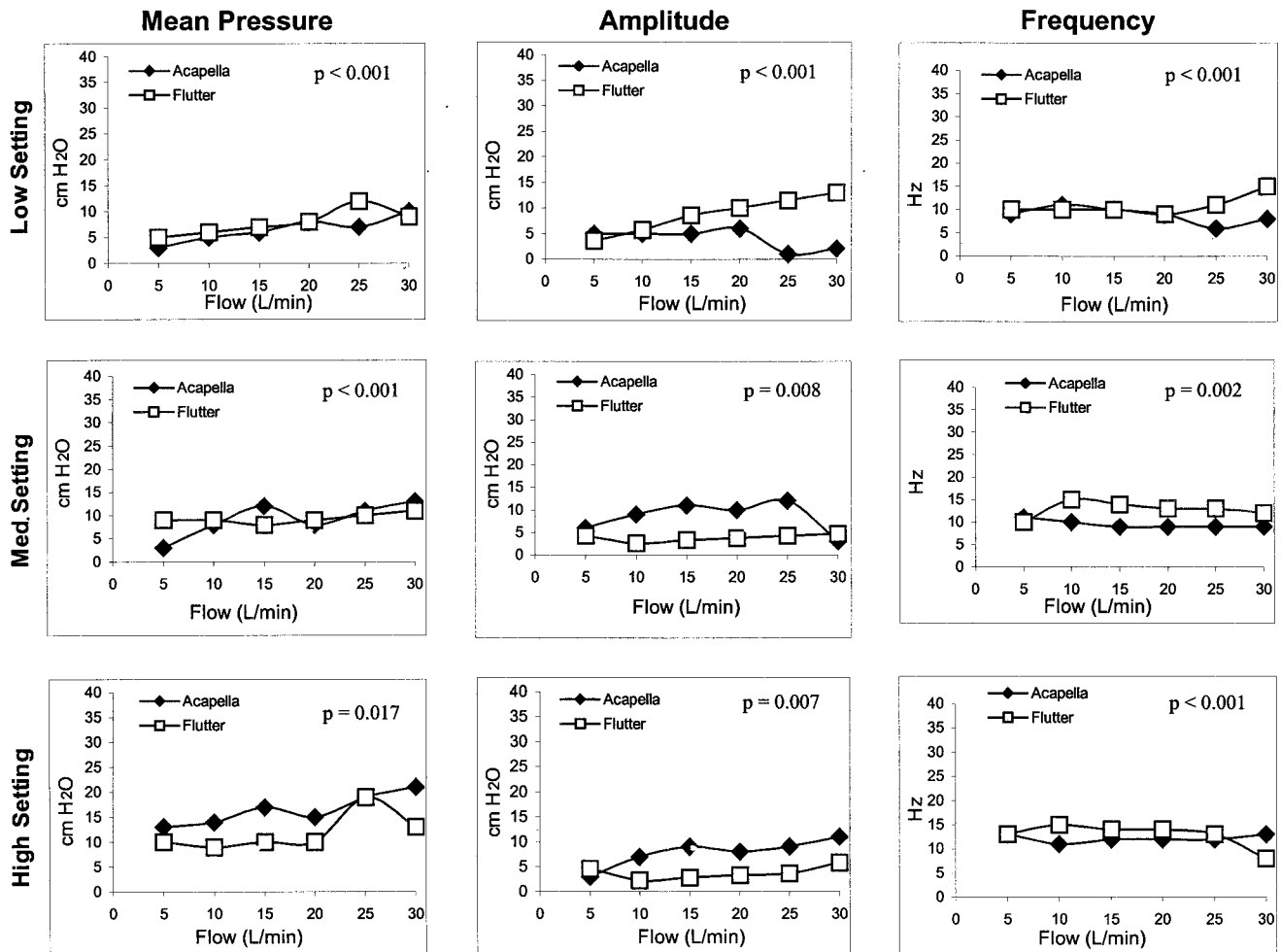


Fig. 3. Mean values for frequency, pressure, and amplitude displayed across the range of flows and positive expiratory pressure (PEP) settings tested. The standard deviations were negligible. The p values are for the interaction effects from analysis of variance.

expiratory maneuver performed during pulmonary function testing. However, a consideration of pulmonary function results from sick patients guided our selection of flows for the bench study. We reasoned that exhaled volume would be somewhere between a large tidal volume (eg, 10

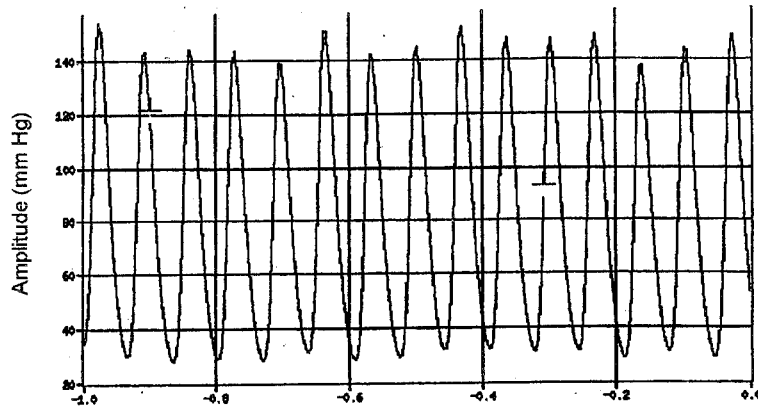
mL/kg) and a forced vital capacity available in patient charts. We have observed very sick cystic fibrosis patients who have forced vital capacity of < 1.0 L but are still able to perform OPEP. On the other extreme, we have seen cystic fibrosis patients who use OPEP and have forced vital capacity around 2.0 L. Thus, a low value for expiratory flow would be approximately 10 mL/kg × 40 kg = 400 mL over 4 seconds or about 6 L/min. A high value would be 2.0 L exhaled in 4 seconds = 30 L/min. We selected a flow range of 5–30 L/min for the study. We validated this selection by measuring the mean expiratory flow during simulated OPEP maneuvers with 3 pediatric patients with cystic fibrosis ranging from mild to severe. The average flow ranged from 13 to 24 L/min. On a normal adult volunteer we observed a mean expiratory flow of 18–37 L/min. Actual expiratory maneuvers would result in an exponential decay flow waveform within these flow limits, with much of the expiratory time at lower than

Table 2. Data Summary

Variable	Device	Range
Mean expiratory pressure (cm H ₂ O)	Acapella (blue)	3–24
	Acapella (green)	6–21
	Flutter	5–19
Pressure amplitude (cm H ₂ O)	Acapella (blue)	3–11
	Acapella (green)	1–12
	Flutter	2–10
Oscillatory frequency (Hz)	Acapella (blue)	8–25
	Acapella (green)	13–30
	Flutter	15–29

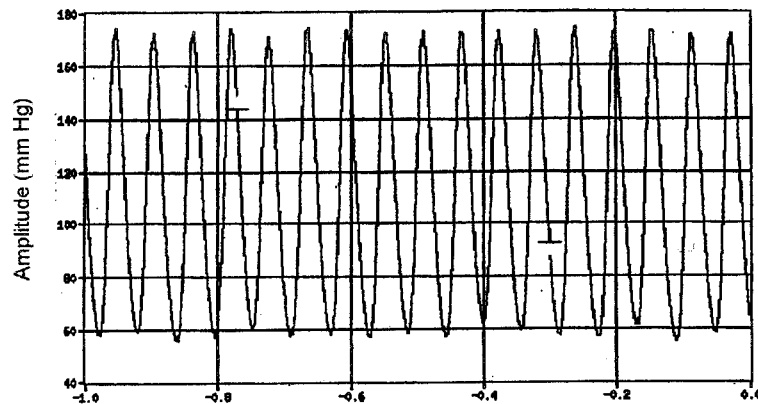
Flutter

Flow = 25 L/min
Frequency = 15 Hz
Amplitude = 115 mm Hg



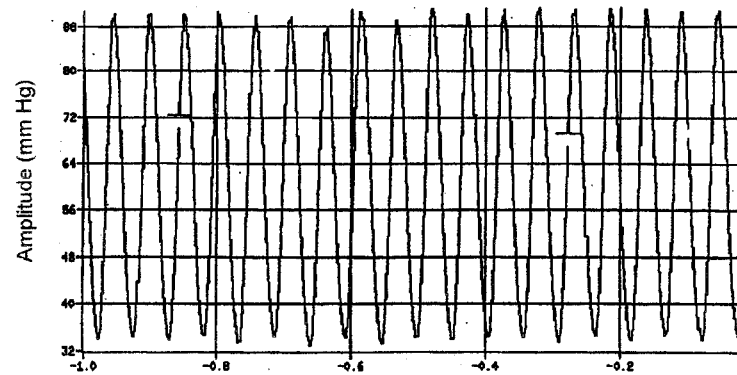
Acapella (green)

Flow = 25 L/min
Frequency = 17 Hz
Amplitude = 120 mm Hg



Flutter

Flow = 10 L/min
Frequency = 19 Hz
Amplitude = 55 mm Hg



Acapella (blue)

Flow = 10 L/min
Frequency = 15 Hz
Amplitude = 85 mm Hg

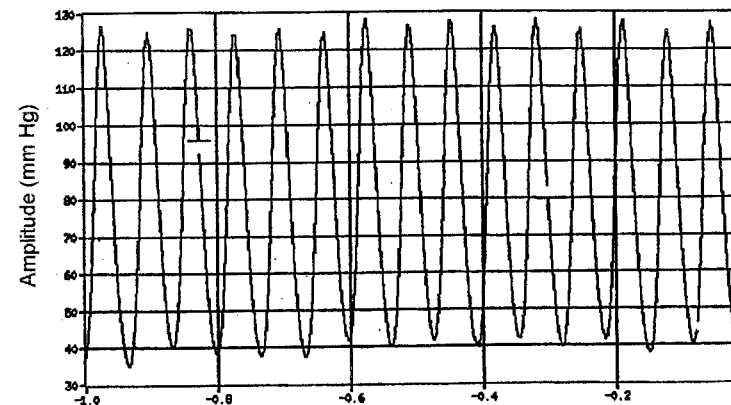
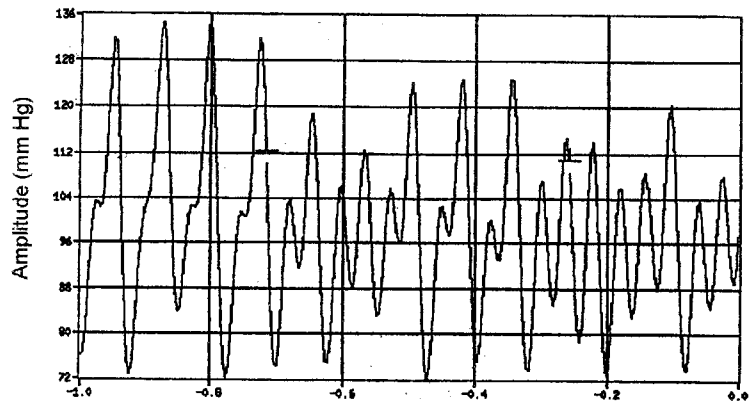


Fig. 4. Representative pressure waveforms for Flutter and Acapella at the medium flows (10 and 25 L/min). The waveforms are comparable for amplitude and frequency.

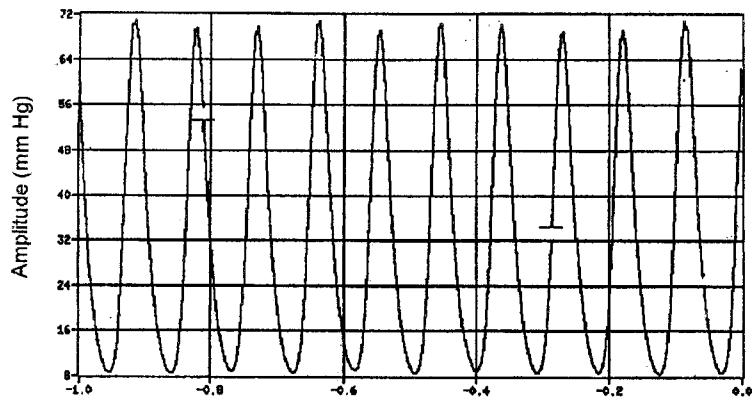
Flutter

Flow = 5 L/min
 Frequency = 20 Hz
 Amplitude = 35 mm Hg



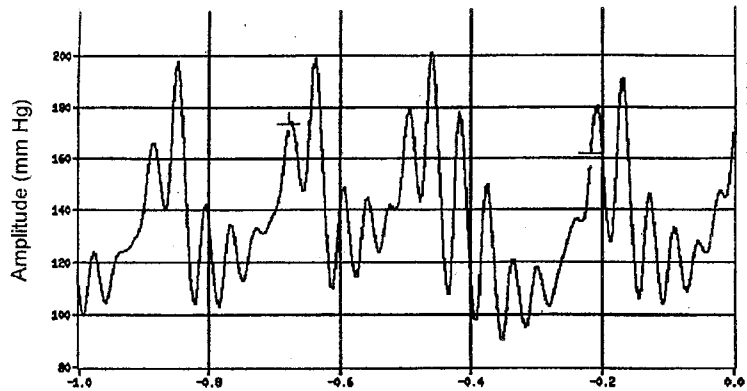
Acapella (green)

Flow = 5 L/min
 Frequency = 10 Hz
 Amplitude = 60 mm Hg



Flutter

Flow = 30 L/min
 Frequency = 20-30 Hz
 Amplitude = 20-100 mm Hg



Acapella (blue)

Flow = 30 L/min
 Frequency = 25 Hz
 Amplitude = 100 mm Hg

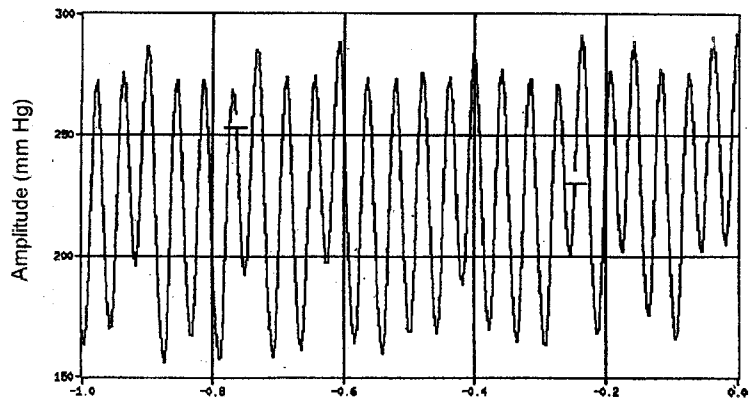


Fig. 5. Representative pressure waveforms for Flutter and Acapella at the low and high flows (5 and 30 L/min). The Acapella produced a more stable waveform, with a higher amplitude and lower frequency.

average flow. Observing the devices' behavior at constant flows describes the performance envelope for exponential flows.

Both Flutter and Acapella can be thought of as simply "black boxes" that take a flow input and deliver a pressure waveform output. Hence, the relation between flow and pressure waveform characteristics (mean, amplitude, and frequency) was the basis of our comparison. We can only speculate about the relative clinical effects of these devices. However, such speculation can be founded on both clinical and bench data.⁷ Specifically, the patient supplies the flow, which is periodically occluded (partially or completely) so that the flow approaches zero in the device. Consequently, the flow energy is transformed to stagnation pressure, causing pressure to increase and expiratory flow to decrease. We speculate that enhanced mucus clearance has a lot to do with the increased acceleration and short bursts of high flows that result when the pressure that builds up behind the occlusion is released; the higher the pressure build-up, the higher the subsequent flow burst. This pressure builds up because of the tension in the elastic components of the lungs, relaxation of inspiratory muscles, and contraction of expiratory muscles. During the short bursts of expiratory flow caused by the OPEP devices, high flow spikes of turbulence may exist farther down in the lungs, as well as in the upper airways, causing increased drag on the mucus on the airway walls. The OPEP devices produce this increased drag only during expiration, so there would tend to be a net mucus movement out of the lungs. We may think of the phenomenon as akin to a rapid series of short coughs.

Figures 4 and 5 show that the Acapella and the Flutter produce similar pressure waveforms at medium flows (10–25 L/min). At extremes of the flow ranges tested (5 and 30 L/min), our evaluation produced interesting results. The Acapella created more stable air flow oscillations (less variation in amplitude and frequency). Furthermore, compared to the Flutter, the Acapella consistently generated higher-amplitude oscillations with the lowest flow tested (5 L/min). That higher pressure build-up during occlusion results in a higher subsequent flow burst and presumably a greater mucus transport effect.

Our clinical experience indicates that the ability of the Acapella to produce effective oscillations at low flows (5 L/min) allows the use of OPEP with a broader spectrum of

patients. Patients with low expiratory flow due to severe air flow obstruction, age, and/or size may now be included among those who are able to perform and perhaps benefit from OPEP. Because the Acapella is not gravity-dependent, it may be used while positioning the patient for postural drainage.

One subject that remains to be explored is how to determine at the bedside whether a patient can perform OPEP therapy and, if so, which device to select. The Acapella is labeled as a single-patient-use item and retails for about \$45 (comparable to the Flutter). It is wasteful of time and money to open a package (or 2) only to find the patient cannot perform the maneuver.

Conclusions

The Acapella has pressure-flow characteristics similar to the Flutter. This confirms the Food and Drug Administration's consent to manufacture the Acapella, under section 510(k) of the Food, Drug, and Cosmetics Act, with Flutter as the predicate device. We expect the Acapella to be an appropriate choice of devices when applying OPEP. The Acapella may offer advantages to some patients by virtue of its ability to generate OPEP at any angle (eg, with the patient supine) and at very low expiratory flows (eg, in children with severe obstructive lung disease).

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