

Laboratory Evaluation of the Acapella Device: Pressure Characteristics Under Different Conditions, and a Software Tool to Optimize Its Practical Use

Carlos Eduardo Alves Silva PT MSc, Josiel G Santos Eng, José M Jansen MD PhD, and Pedro Lopes de Melo Eng PhD

BACKGROUND: The Acapella is a respiratory rehabilitation device designed to aid sputum clearance. When the patient exhales through this device, continuous and oscillatory pressure levels are produced. The adequate practical use of the Acapella is critically dependent on the characteristics of the produced pressure, which include the production of a mean pressure ≥ 10 cm H₂O and a matching of the oscillation frequency with the respiratory-system resonance frequency, and/or with the frequency of ciliary movement (approximately 13 Hz). The development of a dedicated software tool would contribute to optimize the clinical application of this device. Thus, the aim of this study was 2-fold: to characterize the mechanical behavior of the Acapella, and to develop a software tool to ease the practical use of this device. **METHODS:** An experimental setup was assembled in order to study mean pressure, oscillation frequency, and the oscillation amplitudes produced by 3 Acapella devices (model green) in the whole range of instrument adjustments and under air flow rates ranging from 200 mL/s to 800 mL/s. In order to increase flexibility, allowing the fast integration of further information obtained in future studies, the software was developed in a graphical environment. **RESULTS:** The device characterization showed an oscillation frequency varying from 8 Hz to 21 Hz, mean pressure ranging from 3 cm H₂O to 23 cm H₂O, and oscillation amplitude from 4 cm H₂O to 9 cm H₂O. These parameters increased with flow and instrument adjustment. A user-friendly software was developed, incorporating the current knowledge concerning secretion removal. After the introduction of the desired frequency and the patient air flow by the user, the software automatically calculates the necessary instrument adjustment, as well as mean pressure and oscillation amplitude. **CONCLUSIONS:** The Acapella device may produce clinically adequate values of mean pressure and oscillation frequency. However, it depends on its use at optimized conditions. The user-friendly software proposed in this study could help the user to achieve these conditions. *Key words:* high-frequency oscillation, positive expiratory pressure, bronchial hygiene, chest physiotherapy, Acapella, software, secretion clearance, oscillatory positive expiratory pressure. [Respir Care 2009;54(11):1480–1487. © 2009 Daedalus Enterprises]

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Introduction

Some diseases affecting the respiratory system, such as bronchiectasis, chronic obstructive respiratory disease, and cystic fibrosis, result in excessive production of sputum in the respiratory tract.¹ Airway obstruction results from secretion retention. In order to facilitate the secretion removal during respiratory rehabilitation procedures, oscillatory positive expiratory pressure (PEP) devices were developed.²

These devices have resistance elements and also produce short and successive disruptions to the air flow, resulting in the production of positive pressure combined with vibration during expiration. These factors increase the bronchial mucus mobilization, avoid alveolus collapse during expiration, and increase the probability of expectoration. There are 2 commonly used types of oscillatory PEP device, which can be classified by the method used to produce vibrations. The first type is the Flutter VRP1 (Vari-oraw, Aubonne, Switzerland), which contains a steel ball in the air flow way. The exhaled air passing through the device makes the ball vibrate, creating the oscillations. Since in this case the vibration depends on the gravity force, the used angle of the oscillatory PEP device affects the frequency and the oscillation amplitude produced.³⁻⁶ The second type, called Acapella (DHD Healthcare, Wampsville, New York), combines the principles of high-frequency oscillation and PEP by employing a counter-weighted lever and a magnet. The oscillations are produced when the exhaled air is intermittently occluded by the magnetic attraction effect. This device allows changing the frequency, oscillation amplitude, and mean pressure⁷ through 5 main levels, which are adjusted with a dial localized at the distal end of the device (Fig. 1). At level 1 the 2 magnets are far from each other, providing less resistance; in opposition, they are closer at level 5, increasing the resistance.

Although the mechanisms related to sputum removal by applying vibration in the airway entrance are not completely explained,⁸ it is suggested that the expectoration can be optimized when the applied pressure frequency coincides with the ciliary movement range, approximately 13 Hz,⁹ or with the respiratory-system resonance frequency.¹⁰ Darbee et al¹¹ recently suggested that PEP values in the range of 10–20 cm H₂O improve gas mixing in individuals with cystic fibrosis.

It is important to point out that the adequate performance of the Acapella is critically dependent on the characteristics of the produced pressure. Nonetheless, only one study was found in the literature describing the changes in these characteristics with different air flows and levels of instrument adjustment.³ Manufacturers' instructions for using oscillatory PEP devices may be vague, and often lack the specifications respiratory therapists (RTs) need to un-

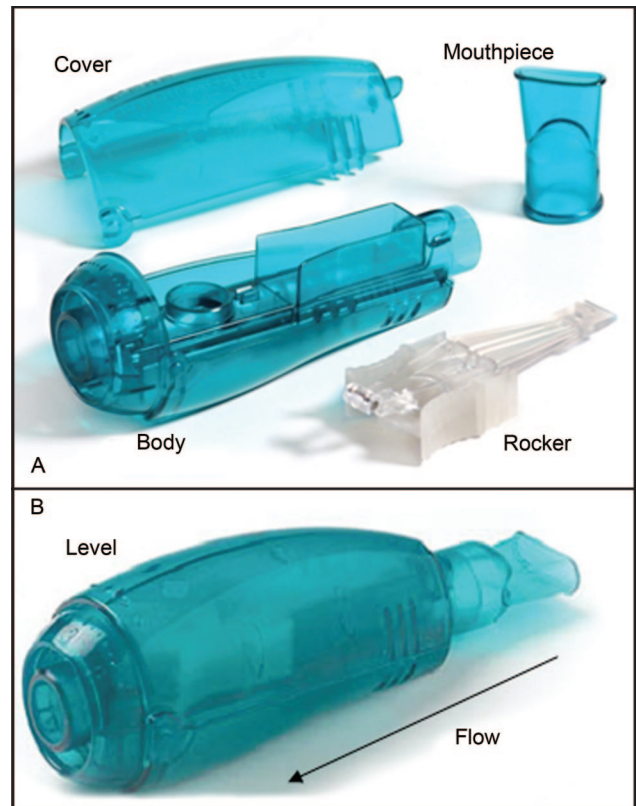


Fig. 1. Picture describing the Acapella device.

derstand the effects of the devices.⁴ There is a general agreement in the literature that it is necessary to develop new studies on the mechanical evaluation of oscillatory PEP devices.^{3-5,10,12} In a recent editorial, laboratory experiments that investigate the performance characteristics of airway-clearance devices were encouraged.⁴

Medical software is a valuable tool to help healthcare professionals in data interpretation, increasing their productivity and ability to control many aspects of treatment procedures. A detailed characterization of the Acapella device results in several types of information, which may not be easy to use in practice. Thus, software describing the mechanical behavior of the Acapella would be an interesting tool, contributing to ease the practical use of this device. This software could also help RTs to optimize the device operation according to the features of each patient. To the best of our knowledge there is no description in the literature of any software with these characteristics.

The purpose of this study is, therefore, 2-fold: to evaluate the mechanical characteristics of the Acapella device in the flow range that the patients clinically exhibit, and, based on these data, to develop a small program for helping RTs to optimize using the device.

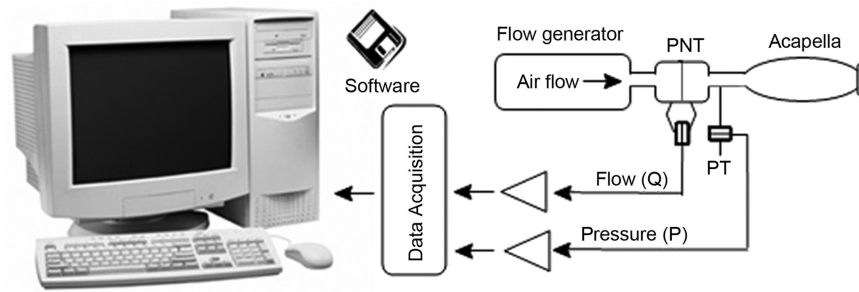


Fig. 2. Simplified block diagram of the measurement system. Q = flow. PNT = pneumotachograph. PT = pressure transducer.

Methods

The study was performed in the Biomedical Instrumentation Laboratory, State University of Rio de Janeiro, Rio de Janeiro, Brazil.

Measurements

To minimize the effects of the constructive differences among the devices, 3 not-previously-used Acapella (model green) were analyzed within the flow range 200–800 mL/s, which includes the values normally found in practice.³ The parameters were evaluated with all 5 adjustment levels of the device, at intervals of 50 mL/s, resulting in 65 trials with each device. In each of the studied conditions we first waited for 60 s to stabilize the system, then conducted an 80-s measurement. All measurements were carried out with the device horizontal.

Equipment Setup and Data Acquisition

Figure 2 describes the setup. The flow generator was an air compressor whose input voltage was controlled by a variac (ATV215M, Sociedade Técnica Paulista, Brazil). The flow was monitored by a screen-type pneumotachograph (PT-36, Jaeger-Tonnie, Hoechberg, Germany) connected to a differential pressure transducer (176PC, Honeywell Microswitch, Boston, Massachusetts).

The pressure-measurement system includes a similar pressure transducer, and presents flat frequency response up to 60 Hz. The frequency response of this system was evaluated in detail via spectrum analysis,¹³ a mathematical method widely used to study the dynamic properties of physical systems. Briefly, a signal with a wide frequency range (1–100 Hz in the present study) is applied to the entrance of the device under test (the pressure-measurement system, in this work). The amplitude and frequency content of the time-varying signal at the output of the device under test is evaluated, allowing the determination of its frequency response.

Signals from the pressure transducer were amplified, low-pass filtered (cutoff frequency = 60 Hz, Butterworth, 8th order) and further adapted to a data-acquisition board with 16 channels and 12-bit resolution (6024E, National Instruments, Austin, Texas). The signals generated by the pressure system were measured at a sampling frequency of 256 Hz and stored by a program developed in graphical programming software (LabView version 5.1, National Instruments, Austin, Texas).

Analysis

Initially, a program developed using the fast Fourier transform routines available in LabView version 5.1 was used in order to accurately obtain the following variables of the pressure signal:

- Pressure oscillation frequencies: number of oscillations per second
- Positive pressure mean values: mean pressure resulting from flow production (ie, PEP)
- Pressure oscillations amplitude: difference between lower and higher (peak-to-peak) pressure values

Then these results were described as a function of flow and adjustment level in plain graphics.

The variability of the amplitude, frequency, and mean pressure measurements was evaluated by using the coefficient of variation, (coefficient of variation = $100 \times \text{SD}/\text{mean}$) of 5 results obtained in the same day from 10:00 AM to 6:00 PM, in intervals of 2 hours. These measurements were conducted in a condition very common in practice: air flow of 300 mL/s and an Acapella adjustment of level 3.

The effects of flow and adjustment level on oscillation frequency, mean pressure, and pressure-oscillation amplitudes were evaluated via one-way analysis of variance. A *P* value of less than .05 was considered statistically significant. These analyses were performed with a commercial software package (Origin 6.0, OriginLab, Northampton, Massachusetts).

Software for Helping Users

Based on the results of the preceding section, a user-friendly program was also developed in LabView 5.1 environment. The graphical G programming used in LabView allows the synthesis in icons of subroutines or complex algorithms, which can be interfaced by means of simple connections with other icons, composing a main program. This feature makes the modification or inclusion of new subroutines easier, allowing the fast integration of new knowledge concerning the pathophysiologic mechanisms involved in sputum clearance, without changing the structure of the main program.

Results

The effects of the flow and the adjustment levels are presented in Figure 3. The oscillation frequency increased significantly with flow ($P < .001$). On the other hand, the oscillation frequency increased with the adjustment level in the flow range 200–500 mL/s ($P < .001$), but this increase was not significant in the flow range 500–800 mL/s (see Fig. 3A). To reach a minimum oscillation frequency of 12 Hz, the lower flow values at the 5 dial adjustment levels were 500 mL/s, 500 mL/s, 450 mL/s, 450 mL/s, and 200 mL/s, respectively, from levels 1 to 5. The variability of the frequency measurements was very low (coefficient of variation 0.4%).

The effects of flow and adjustment level on mean pressure are shown in Figure 3B. Mean pressure increased with flow ($P < .001$), while changes in the adjustment level did not result in significant modifications in this parameter. In order to reach a minimum mean pressure of 10 cm H₂O, the lower flow rates at the 5 dial adjustment levels were 500 mL/s, 500 mL/s, 500 mL/s, 500 mL/s, and 450 mL/s, respectively, from levels 1 to 5. We also observed very low variability in the mean pressure measurements (coefficient of variation 1.5%).

The peak-to-peak pressure amplitude increased with flow ($P < .001$), and was almost constant when the adjustment level increased (see Fig. 3C). The Acapella device produced peak-to-peak pressures ranging from 4 cm H₂O (at 200 mL/s) to 9 cm H₂O (at 800 mL/s). Similar to frequency and mean pressure, the peak-to-peak amplitude measurements presented low variability (coefficient of variation 4.6%).

Figure 4A describes the frontal panel of the program. Its use is described in the flow diagram presented in Figure 4B.

Initially, the user may describe the characteristics of the patient, including name, biometric characteristics, address, and disease. The characteristics of the procedure may also be saved for further analysis and to evaluate the evolution

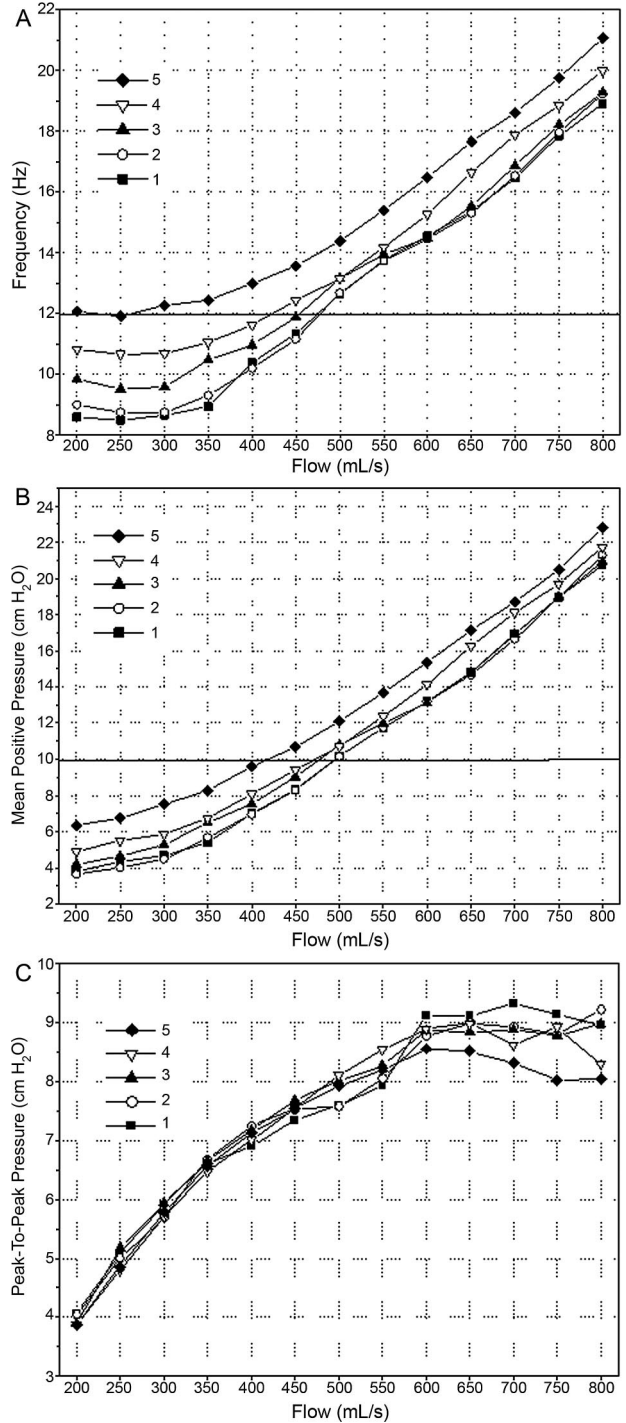


Fig. 3. Mean values of frequency (A), positive pressure level (B), and amplitude of pressure oscillation (C) obtained across the range of flows and adjustment levels tested.

of the treatment. The input of the software simply consists of the controls for adjustment of the flow produced by the patient and for the desired frequency, as defined by the user. These controls are positioned in the field “Input parameters.” After the first selection of the option “Calcu-

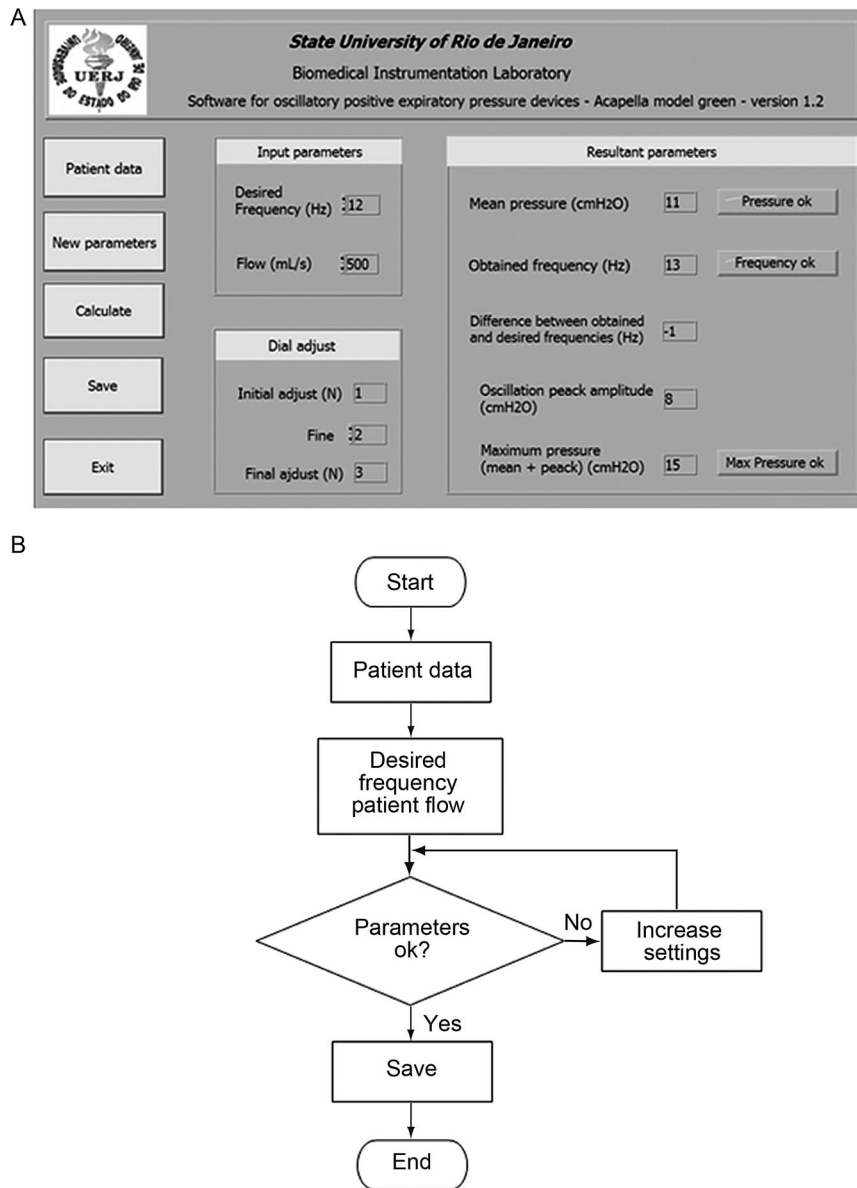


Fig. 4. Frontal panel (A) and the flow diagram (B) of the program elaborated to help Acapella adjustments.

late,” an initial report with the results of the calculations is given in indicators, which correspond to the following (see Fig. 4A):

1. The initial adjustment (N) to the desired frequency attainment, which is shown by an indicator located approximately in the middle of the screen, in the field “Dial adjust.”

2. The mean pressure, the frequency, and the effectively produced amplitude are described at the field “Resultant parameters,” at the right side of the screen.

3. The difference between the desired frequency and the obtained frequency, as well as the maximal pressure value.

4. Indicators comparing the obtained values with those suggested in the literature are also shown.

In the first calculation the program will find the lowest adjustment able to reach the desired frequency. It is possible that the mean pressure becomes smaller than the limit of 10 cm H₂O in this first calculation (see Fig. 4B).¹¹ In this case the user may optimize the pressure, increasing the adjustment “Fine” in the field “Dial adjustment,” pressing “New parameters,” and re-calculating (see Fig. 4A). When all parameters become adequate, the user may save all the obtained information using the “Save” option at the left side of the front panel. The saved file format is compatible

with popular programs such as Excel and Word (Microsoft, Redmond, Washington).

Discussion

Although the appropriate use of the Acapella device is critically dependent on the frequency and amplitudes of the oscillations, as well as on the mean pressure produced, it is uncommon to find such information in the user literature. Moreover, there are few data in the literature concerning the influence of the flows and the several levels of the device adjustment in the pressure produced by the Acapella. In fact, only one study has addressed this question.³ This first study, however, does not investigate all device-adjustment levels and does not use the results to develop tools for helping the users in the device operation.

Figure 3A shows that the frequency increases as flow and adjustment level increase. These behaviors, obtained as a mean of 3 devices measurements, are consistent with previous results obtained from only one Acapella device,⁷ and can be explained by the increasing speed of the vane/counterweight set movement with the increase of flow, and by the magnetic set approximation. The frequency increasing with the difficulty level is consistent with the results obtained by Volsko et al.³ In contrast to the present study, however, the cited work did not find frequency changes with flow. We can speculate that this difference is related to the use of 2 types of Acapella in the study conducted by Volsko et al.³ (green and blue), in contrast with the present study, which used only the Acapella model green.

In the present work the device characterization has shown frequencies varying from 8.5 Hz to 21 Hz, which includes those observed at ciliary beats (12–15 Hz)⁹ and it is also in accordance with the suggested ciliary movement range that makes the expectoration easier.¹⁴ In vitro studies have shown that increasing oscillating air flow frequency seemed to reduce viscoelasticity of mucus gel simulants.¹⁵ On the other hand, peaks of intermittent expiratory flow seem to be responsible for promoting micro-movements of the mucus in the direction of the upper airways.^{3,16} Therefore, the higher the flow amplitude, the higher the effectiveness of the therapy.⁵ It is known that the highest flow amplitude occurs in the respiratory-system resonance frequency. The respiratory system presents properties related to the energy storage capacity, which are determined by the elastic properties, dominant at low oscillation frequencies, in combination with the inertive properties, which become progressively more important with the increasing of frequency. At the respiratory-system resonance frequency, the elastic and inertial forces are equal in magnitude, resulting in the cancellation of the effect of these 2 properties and in the increase of the air flow. As a physiologic result, this in-

crease in air flow may, theoretically, improve mucus transport.¹⁰ Considering that the expectoration is optimized when the applied pressure frequency coincides with the respiratory-system resonance frequency,¹⁰ it is important to point out that the frequencies produced by the Acapella device (8.5–21 Hz) are in agreement with the resonance frequency of the respiratory system of patients with asthma (10–35 Hz)¹⁷ and chronic obstructive pulmonary disease (10–32 Hz).¹⁸ Recently we found that the resonance of patients with cystic fibrosis is also in this frequency range (14–30 Hz) (unpublished data). However, it is interesting to point out that the resonance frequency increases with airway obstruction.^{17,18} Therefore, patients with very high obstruction may present resonance frequencies higher than that of the frequencies produced by the Acapella device.

In practice, the ideal behavior would be that a frequency value of 12 Hz or higher may be obtained by the patients with the least possible effort. According to Figure 3A, the adjustment of the Acapella device in higher levels would favor the achievement of this frequency because it allows the obtaining of adequate frequencies with lower flows. More specifically, by adjusting the Acapella device to its highest level (5), it was possible to obtain the minimum frequency of 12 Hz with a flow of 200 mL/s, which is an interesting feature, since it would favor patients with air-flow limitation.

In agreement with the results obtained by Volsko et al.,³ the mean pressure increases as flow and level adjustment increase (see Fig. 3B). This can be explained by the resistance elevation produced by the vane/counterweight set approximation. In these tests the device produced pressures ranging from 3 cm H₂O to 23 cm H₂O. The application of pressures higher than the atmospheric in the airways during expiration helps to keep the alveoli open during expiration. Darbee et al.¹¹ recently suggested that PEP values in the range 10–20 cm H₂O improve gas mixing in individuals with cystic fibrosis. The results presented in Figure 3B show that, when adequately adjusted, the Acapella device is able to provide PEP values in this range. The lowest expiratory flow to achieve this pressure range is 400 mL/s. The necessity of such intermediate flows may hinder the effectiveness of the device when used by subjects with air flow limitation.

Brooks et al.¹² pointed out that there are no effective studies regarding the ideal pressure for mucociliary clearance, and suggested that pressures above 20 cm H₂O are not clinically recommended, because they can represent a risk for the patient. Figure 3B shows that mean pressure higher than 20 cm H₂O may be produced by the Acapella device in conditions of air flow higher than 750 mL/s.

The amplitude of pressure oscillation increases as flow and adjustment level increase (see Fig. 3C), showing values ranging from 3.8 cm H₂O to 9.3 cm H₂O. These results are similar to those reported by Volsko et al.³ in low flows.

However, at flows near 500 mL/s and higher, the amplitude continues to increase, contrasting with the results described by Volsko et al,³ who reported lower amplitudes. This may be associated with the differences in the dynamic features of the instrumentation used.

The evaluation of the variability of the amplitude, frequency, and mean pressure measurements resulted in very low coefficients of variation. These experimental results were in close agreement with our expectations, which may in part be due to the fact that our flow generator is a very robust and stable electrical pump, which is exclusively dedicated to this study. Another important point is that we are studying a mechanical device (Acapella), and a high stability is a usual characteristic of this class of devices.

Manually operated adjustment procedures based on graphics are time-consuming and may not be sufficiently accurate. Based on the results presented in Figure 3, a program with high potential for clinical use was developed. This program may help, for example, in the adjustments that may be carried out in the Acapella device due to the clinical evolution of the patient. In order to make clinical applications easier for non-technical personal, a dedicated user-friendly front panel was developed. This interface is shown in Figure 4(A).

Initially, the user adjusts the desired frequency (Hz) and the air flow produced by the patient (mL/s) during a slow-vital-capacity maneuver. By pressing the "Calculate" button, the oscillation frequency, the mean pressure, and the peak-to-peak amplitude of the oscillation pressure are provided for the clinicians (see Fig. 4B). These parameters are automatically calculated, preventing manual procedures. The final version of the program is small (695 kb) and may be easily used in a palmtop computer, a portable, relatively inexpensive, and popular tool that is now experiencing widespread acceptance in the field of medicine.¹⁹ The software was considered of easy use by the RTs of our laboratory. In order to further ease the use of the program, online description was provided for each control and indicator.

Another important point for discussion concerns the characteristics of the Acapella device. It must be pointed out that there are ranges of frequencies and flows in which it is not possible to find an adequate adjustment. Since there is a defined relationship between flow and oscillatory frequency (see Fig. 3A), the range of adjustment is limited. When the desired frequency and the flows are not compatible, a red indicator is turned on in the software, calling the user to attention (see Fig. 4A). A similar graphical indicator, showing the maximum pressure produced, is also included in the software. It was pointed out that pressure above 20 cm H₂O can represent a risk for the patient.¹² In order to prevent the use of such dangerous high pressure, the developed software includes a routine that calculates the maximum pressure (mean pressure plus peak

oscillation amplitude). If its maximum pressure reaches values higher than 20 cm H₂O, a red indicator will be turned on, calling the user to attention and allowing the user to know if the produced pressure could be higher than that clinically recommended,¹² before the beginning of the rehabilitation procedure.

Previous studies in laboratory^{15,16} and animal models²⁰ showed the relevance of the oscillatory pressure characteristics on the efficiency of mucus-clearance procedures. One of the main motivations of the present study was to contribute to the transference of this knowledge to the clinical setting. To this end, it is critically important that the frequency, amplitude, and pressure offered to the patient by the Acapella must be precisely controlled. Although the optimal combination of these variables is still under discussion, there is evidence that the expectoration can be optimized when the applied pressure frequency coincides with the ciliary movement range⁹ or with the respiratory-system resonance frequency.¹⁰ In order to test these 2 hypotheses it is necessary to adjust the applied pressure frequency. The graphics and the software presented in this work may help in this task. After these more basic studies the results of the present work may also be useful in the practical use of the Acapella, allowing the optimized adjustment of this device as a function of the characteristics of the patient.

There are a few potential drawbacks to this study. The first relates to the analysis of 3 not-previously-used Acapella devices. In practice, old devices may present small mechanical modifications due to the cleaning and disinfectant procedures, which may slightly change the characteristics of the produced pressures. The second possible limitation might be related to the fact that all measurements were conducted with the device at horizontal position. Although the Acapella principle of operation is magnetic, if the device is used in other positions, the results might change slightly due to possible small gravitational effects on the counterweighted lever.

Conclusions

The Acapella device may produce adequate oscillation frequencies, which are in the ranges of ciliary movements and respiratory-system resonance frequency of patients with respiratory diseases. This device may also produce values of mean pressure that are probably high enough to keep the alveoli open during expiration. However, the achievement of these adequate parameters depends on the optimized adjustment of the device. The graphics and the user-friendly software proposed in this study could help the user to achieve these conditions. Further studies are needed to establish the actual clinical utility of the prescription of the Acapella device, taking into consideration the procedures described in this work. We hope that it may increase

our ability to facilitate the secretion removal during respiratory rehabilitation procedures.

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