## smiths medical

bringing technology to life

### WHITE PAPER

# **Bronchial Hygiene Therapy**

#### **OBJECTIVES**

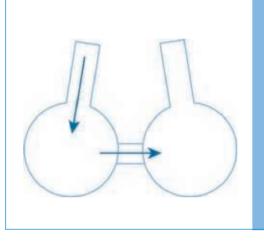
At the conclusion of this paper the reader should have an understanding of the following:

- A background of chest physiotherapy, and rational for use of Positive Expiratory Pressure (PEP) and oscillatory positive expiratory pressure (OPEP).
- Benefits of using OPEP in various disease states Cystic Fibrosis (CF), Chronic Obstructive Pulmonary Disease (COPD/Bronchiectasis) and post-operative care.
- Clinical perspectives on and protocols used for the acapella<sup>®</sup> choice vibratory PEP therapy system.

#### INTRODUCTION

Chest physiotherapy (CPT) is a form of bronchial hygiene which includes, but is not limited to: postural and autogenic drainage, deep breathing exercises, manual chest percussion, and active cycle breathing techniques. Patients undergoing CPT may complain the treatment is uncomfortable, time-consuming and may require the assistance of a second person<sup>1</sup>. Due to these concerns, there may be decreased patient compliance to CPT at home. Additionally, some CPT treatments address only symptoms of bronchial hygiene such as secretion stasis, rather than the underlying defect, collapsed airways. Therefore, due to patient compliance issues and a potential gap in the way bronchial hygiene is administered, different therapies are needed.

PEP is generated by exhaling against a resistance, and this results in an increase in airway pressure. PEP therapy is therapeutic when the elevated airway pressure is in the range of 10-20 cmH20. During treatment with PEP, the patient maintains tidal breathing, with a slightly active expiration all while breathing against the resistance of the PEP device. Breathing against resistance over a period of time will increase Functional Residual Capacity (FRC) in patients with atelectasis or reduce



residual volume in patient with air trapping as seen in patients with CF. The retained gas within the lungs can, through collateral ventilation, localize distal to a mucous block and improve mucous clearance in patients with CF<sup>2</sup>. Similarly increasing airway pressure by PEP can improve the dilation of the airways, or stenting, thereby improving lung function and mucus clearance in patients with CF<sup>3</sup>. These actions have been described in relation to a ketchup bottle, whereby ketchup is easier to remove from a bottle if air is behind the ketchup<sup>4</sup>. Therefore, PEP is effective by localizing air behind mucus blocks through stenting and collateral ventilation.

Oscillatory Positive Expiratory Pressure (OPEP) combines the properties of PEP with airway vibrations, or oscillations. OPEP induces airway vibrations due to the oscillatory nature of the therapy and, therefore, OPEP and vibratory PEP are used interchangeably. These oscillations decrease the viscoelastic properties of the mucus, easing removal from the airway. The applied vibration frequency by an OPEP device is most effective for secretion mobilization when it matches the frequency of ciliary movement, which is ~12-15 Hz<sup>5</sup>. The expectoration of sputum can be further improved if the applied pressure frequency coincides with the respiratory-system

#### Figure 1:

Gollateral Ventilation. Gas is diffused between alveolar sacs via the Pores of Kohn and Canals of Lambet. The localization of gas in alveolar sacs behind collapsed airways may aid in the recruitment of lung tissue.

resonance frequency<sup>6</sup>. Work with various disease states has shown the optimal respiratory system resonance frequency to be 10-35 Hz for asthma<sup>7</sup>, and 10-32 Hz for COPD<sup>8</sup>.

The acapella<sup>®</sup> choice vibratory PEP therapy system combines high-frequency oscillations and PEP into a single treatment. Exhaled air is opposed as it passes through the device resulting in positive expiratory pressure. Additionally, this expired flow is intermittently occluded by a moving magnetic counterweight, producing air flow oscillations. The use of a magnetic counterweight allows for usage of the device independent of position (sitting or lying supine, prone or lateral) and still allows for a patient specific therapy by adjustment of the magnet positioning. There are 5 levels on the acapella<sup>®</sup> allowing for optimization of frequency, oscillation amplitude, and mean pressure. The acapella® family of products (Blue, Green, and Choice) have a range of PEP (3-23 cm H20) <sup>9,10,11,12,13</sup> and frequency of oscillation (8-21 Hz) <sup>8-12</sup>. This range of oscillatory frequency is within the range of ciliary beating<sup>4</sup> and coincides with the resonant frequency of the respiratory tract of patients with COPD, 10-32 Hz<sup>7</sup>.

#### **CYSTIC FIBROSIS (CF)**

The clinical use of OPEP has been studied in a variety of disease states. A common feature of these disease states is abnormal mucus secretion in the airway leading to mucus plugs and airway obstruction. These obstructions can lead to infections in the lung causing increased mucus secretion. Therefore, the removal of respiratory secretions is of great importance. In a disease such as CF, the increased levels of mucus is due to a mutation in the Cystic Fibrosis Transmembrane conductance Regulator (CFTR) gene. The mutation to the CFTR gene causes a thick viscous secretion which is difficult for patients to expectorate from their lungs. There are several methods of secretion management for CF patients including physical manipulations

of the body, airway clearance devices such as PEP devices, high frequency chest wall compression, mechanical percussion devices and OPEP devices. All of these devices and manipulations aim to aid in the expectoration of mucus.

The clinical usefulness of OPEP devices in CF patients has been studied since the mid-1990s. Studies have demonstrated that the use of OPEP may improve sputum expectoration<sup>14,15</sup>. No difference in sputum production between OPEP and the control group<sup>16,17</sup> has also been noted in studies. OPEP has shown at least similar efficacy to active breathing techniques<sup>13</sup>, postural drainage<sup>14,18</sup> and autogenic drainage<sup>16</sup>, PEP therapy<sup>19,20,21,22,23</sup> and manual percussion<sup>24</sup>. Transient lung function and blood gas concentrations were noted with the use of Flutter® compared to PEP<sup>25</sup>. McCarren studied 18 CF patients comparing the physiologic effects of vibration to other physiotherapy interventions. This study demonstrated that clinically acapella® can produce vibrations at 13.5 Hz (±1.7)<sup>26</sup>. This clinical and bench work indicates that the acapella® is capable of producing effective oscillations (13.5 Hz) at low flows (5 L/min). These parameters make the use of acapella® especially attractive to those patients with low expiratory flow due to severe air flow obstruction, and of a low age<sup>13</sup>.

First author	Institution	Population	n	Study design	Outcome variables measured	Major findings
Pryor	Royal Brompton Hospital, London UK	Cystic Fibrosis	24	Randomized crossover trial of: ACBT, Flutter® +ACBT	Sputum production, Spirometry, SpO <sub>2</sub>	Greater sputum production with ACBT (p<0.001). No difference in spirometry of SpO <sub>2</sub> values.
Konstan	Rainbow Babies and Children's Hospital, Cleveland, USA	Cystic Fibrosis	18	Randomized crossover trial of: postural drainage and percussion, Flutter®	Sputum production	Significantly more sputum production with Flutter® (p<0.001)
Newhouse	Michigan State University, USA	Cystic Fibrosis	11	Randomized crossover trial of: postural drainage and percussion, Flutter <sup>®</sup> , IPV	Sputum production, Spirometry, SpO <sub>2</sub>	No difference in sputum production, significant improvements in flow with both IPV and Flutter®. Transient decrease in SpO <sub>2</sub> with postural drainage and percussion.
Homnick	Michigan State University, Michigan, USA	Cystic Fibrosis	33	Prospective randomized trial of: postural drainage and percussion, Flutter®	Spirometry, Hospital stay, Number of treatments, Clinical score	No difference in any measured outcome
Gondor	All Children's Hospital, St. Petersburg, Florida, USA	Cystic Fibrosis	23	Prospective randomized trial of: postural drainage and percussion, Flutter®	Spirometry, 6 min walk, SpO <sub>2</sub> , Hospital Stay, Sputum cultures	Similar significant Spirometry and 6 minute walk improvements with postural drainage and percussion and Flutter <sup>®</sup> . No difference in SpO <sub>2</sub> , hospital stay or sputum cultures. Significant improvements in FVC and FEV <sub>1</sub> at 7 days with Flutter <sup>®</sup> .
Арр	Albert-Ludwigs- University Freiburg, Germany	Cystic Fibrosis	17	Prospective randomized crossover trial of: Autogenic drainage, Flutter®	Sputum production, Spirometry, Sputum viscoelasticity	No difference in spirometry or sputum production. Significant decrease in sputum viscoelasticity with Flutter® (p<0.01).
Oermann	Texas Children's Hospital	Cystic Fibrosis	29	Prospective randomized crossover trial of: Postural drainage and Percussion, HFCWC, Flutter®	Pulmonary function, modified National Institute of Health score, Petty Score, Patient satisfaction score	No difference in pulmonary function, Modified NIH score, Petty score. HFCWC had significantly higher patient efficacy score than Flutter <sup>®</sup> . Flutter <sup>®</sup> had significantly higher convenience score than HFCWC or postural drainage and percussion.

First author	Institution	Population	n	Study design	Outcome variables measured	Major findings
West	The Childrens Hospital at Westmead. Westmead, New South Wales, Australia	Cystic Fibrosis	23	Prospective Randomized trial of: PEP mask or acapella®	Lung function (FEV <sup>1</sup> , FVC, FEF (25-75) and PEF) and exercise performance. Total sputum production and patient satisfaction	No statistically significant differences noted with any of the outcomes
McCarren	School of Physiotherapy, University of Sydney, New South Wales, Australia	Cystic Fibrosis	18	Cross over trial of acapella®, Flutter®, PEP and percussion	Expiratory flow rates and Frequencies of airflow oscillation of vibration	acapella® had the highest airflow vibration 13.5+/-1.7Hz of the group and low peak expiratory flow rate
Newbold	St. Michaels Hospital, Toronto, Canada	Cystic Fibrosis	42	Prospective randomized trial of: PEP, Flutter®	Pulmonary function, Quality of life, Symptoms scores	No difference in any measured outcomes
Lagerkvist	Department of Pediatrics Goteborg University, Goteborg, Sweden	Cystic Fibrosis	15	Prospective randomized trial of: PEP, Flutter®	Pulmonary function, transcutaneous blood gas values	Significant decrease in $PtcCO_2$ (p<0.05) with Flutter <sup>®</sup> during and immediately after sessions. Immediate transcutaneous results after oscillating PEP demonstrated significantly higher $PtcO_2$ (p<0.05) and significantly lower $PtcCO_2$ (p<0.001) compared to PEP. All differences between methods disappeared after therapy.
McIlwaine	University of British Columbia, Vancouver, British Columbia, Canada	Cystic Fibrosis	40	Prospective randomized trial of: PEP, Flutter®	Pulmonary function, hospitalization rates, Huang Score, Schwachman score, Chest Radiograph, Sputum Culture, Patient adherence rate	No difference in Schwachmann scores, chest radiographs, or changes in sputum bacteriologic cultures. Significant difference in FVC (p<0.05), hospitalization rate (p=0.03), Huang scores (p<0.05) in favor of PEP. No difference in patient adherence.
van Winden	Erasmus University and Children's Hospital, Rotterdam, Netherlands	Cystic Fibrosis	22	Prospective randomized trial of: PEP, Flutter®	Pulmonary function, SpO <sub>2</sub> , Symptoms score, Cough frequency, Sputum production, Shortness of breath	No difference in any measure outcome

#### CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) AND BRONCHIECTASIS

COPD is characterized by poor air flow through the lung. This is due to obstructions caused by damaged or chronically inflamed lung tissue, hyper secretion of mucus may be the result of the inflammatory state. Patients with COPD will often suffer acute exacerbations with increased dyspnea (shortness of breath), worsening fatigue and a decline in lung function.

Bronchiectasis is a result of a chronic and excessive inflammatory response causing a dilation of the bronchioles. In this disease state, there is also excessive production of secretions and impaired mucus clearance. Patterson et al. demonstrated equivalence comparing acapella® to normal airway clearance techniques in a 20 patient randomized cross-over trial<sup>27</sup>. This result was also seen comparing Flutter® with ACBT by Thompson et al<sup>28</sup>. Additionally, Murray et al., demonstrated that the use of acapella® improved the health-related quality of life (HRQoL) when compared to no physiotherapy in a 20 patient, 3 month cross over trial<sup>29</sup>. A study by Naraparaju et al. that compared acapella<sup>®</sup> and inspiratory muscle trainer (IMT), revealed that patients preferred the use of acapella<sup>30</sup>. In a study of acute exacerbation of COPD at New York Methodist hospital, the use of acapella<sup>®</sup> has indicated there may be a decrease in hospital length of stay<sup>31</sup>. This constellation of human clinical studies demonstrate the efficacy of OPEP in the treatment of COPD and bronchiectasis.

Patterson University of Ulster Belfast City Bronchiectasis 20 Prospective Self-reported duration The selfast   Hospital. Belfast over trial of: sputum and perception for	Major findings There were no statistically different observations noted for any of the ends points. The acapella® did not increased sputum expectorated.
Ulster Belfast City randomized cross of treatment, volume of di Hospital. Belfast over trial of: sputum and perception fo	different observations noted for any of the ends points. The acapella® did not increased
Medical College,randomized trial of:Patient preferencemHyderabad, Indiaacapella® and IMTar	acapella® had significantly more sputum expectorated and the acapella® was preferred by patients.
North Bristol NHS Randomized Spirometry, therapy w   Trust, Bristol, UK crossover trial of: duration, symptoms spirometry   Flutter®, ACBT scores, patient duration duration	Significant improvement in FEV <sub>1</sub> with Flutter <sup>®</sup> . No difference in sputum production, therapy duration, or symptoms scores. 11 of 17 patients preferred Flutter <sup>®</sup> .
Methodist Hospital randomized trial of: Daily sputum volumes, su PEP and acapella® dyspnea, BORG, 6MWT, st	Treatment with acapella® suggests reduced length of stay in patients with a COPD acute exacerbation

#### **POST-OPERATIVE CARE**

The post-operative care of patients following thoracic procedures includes airway clearance. The removal of secretions and lung recruitment is important to avoid atelectasis, pneumonia and increased mortality. However, due to thoracic incisions, post-operative pain can interfere with therapies aimed at the removal of secretions. The standard of care for post-operative patients is manual physiotherapy, including percussion and this may be contraindicated due to incisional pain in post-operative patients. Therefore, the use of alternative therapies to remove secretions in this patient population has been studied. Chu et al. conducted a 78-patient study that compared the use of acapella® with incentive spirometry (IS) in post-operative lung resection patients. They demonstrated equivalent lung function and secretion clearance between the acapella® and IS groups<sup>32</sup>. Significantly, patients preferred the use of acapella® to IS, which should lead to increased compliance. Harbrect et al. demonstrated that post-operative care with a standardized clinical protocol including PEP and OPEP devices can decrease ICU and hospital length of stay and lower total hospital costs<sup>33</sup>.

#### CONCLUSION

The use of OPEP devices has been studied with various disease states and has been shown to be at least equivalent to various physiotherapies. Specifically, acapella<sup>®</sup> has been shown to be capable of producing clinically relevant vibrations and producing sufficient PEP pressures. The use of OPEP should be part of a larger standardized clinical protocol which should include PEP, IS and OPEP. This patient customized therapy may result in improved patient outcomes.

#### References

- 1 Bregnballe V, et al. Barriers to adherence in adolescents and young adults with cystic fibrosis: a questionnaire study in young patients and their parents. Patient Prefer Adherence. 2011;5:507-15
- 2 Groth S, et al. Positive expiratory pressure (PEP-mask) physiotherapy improves ventilation and reduces volume of trapped gas in cystic fibrosis. Bull Eur Physiopathol Respir. 1985;21(4):339-43
- 3 Oberwaldner B, et al. Forced expirations against a variable resistance: a new chest physiotherapy method in cystic fibrosis. Pediatr Pulmonol. 1986;2(6):358-67
- 4 Falk M, et al. Improving the ketchup bottle method with positive expiratory pressure, PEP, in cystic fibrosis. Eur J Respir Dis 1984 65(6):423-32.
- 5 Patterson JE, et al. acapella versus "usual airway clearance" during acute exacerbation in bronchiectasis: a randomized crossover trial. Chron Respir Dis. 2007;4(2):67-74.
- 6 Lima L, et al. Mechanical evaluation of a respiratory device. Med Eng Phys 2005; 27(2):181-187
- 7 Cavalcanti JV et al. Detection of changes in respiratory mechanics due to increasing degrees of airway obstruction in asthma by the forced oscillation technique. Respir Med 2006;100(12):2207-2219, 2006
- 8 DiMango AMGT, et al. Changes in respiratory mechanics with increasing degrees of airway obstruction in COPD: detection by forced oscillation technique. Respir Med 2006;100:399-410
- 9 Alves CE, Nunes LGMQ, Melo PL. Mechanical analysis of an oscillatory positive expiratory pressure device used in respiratory rehabilitation. Conf Proc IEEE Eng Med Biol Soc. 2010;2010:2477-80
- 10 Silva CEA, Santos JG, Jansen JM, de Melo PL. Laboratory evaluation of the acapella device: pressure characteristics under different conditions, and a software tool to optimize its practical use. Respir Care 2009;54(11):1480-1487
- 11 Mueller G et al. Laboratory evaluation of four different devices for secretion mobilization: acapella Choice, Green, Blue versus water bottle. Respir Care 2014;59(5):673-677
- 12 Dos Santos AP, Guimaraes RC, de Carvalho EM, Gastaldi AC. Mechanical behaviors of Flutter VRP1, shaker, and acapella devices. Respir Care 2013 Feb;58(2):298-304
- 13 Volsko TA, DiFiore J, Chatburn RL. Performance comparison of two oscillating positive expiratory pressure devices: acapella versus Flutter. Respir Care. 2003 Feb;48(2):124-30
- 14 Pryor JA, et al. The Flutter VRP1 as an adjunct to chest physiotherapy in cystic fibrosis. Respir Med 1994;88(9):677-681
- 15 Konstan, MW et al. Efficacy of the flutter device for airway mucus clearance in patients with cystic fibrosis. J Pediatr 1994;124(5 Pt 1):689-693.
- 16 Newhouse PA, et al. The intrapulmonary percussive ventilator and flutter device compared to standard chest physiotherapy in patients with cystic fibrosis. Clin Pediatr (phila) 1998;37(7):427-432.
- 17 App et al. Sputum rheology changes in cystic fibrosis lung disease following two different types of physiotherapy: flutter vs autogenic drainage. Chest 1998;114(1):171-177.
- 18 Homnick DN et al. Comparison of the flutter device to standard chest physiotherapy in hospitalized patients with cystic fibrosis, a pilot study. Chest 1998;114(4):993-997.
- 19 Oermann CM, et al. Comparison of high-frequency chest wall oscillation and oscillating positive expiratory pressure in the home management of cystic fibrosis: a pilot study. Pediatr Pulomonol 2001;32(5):372-377.
- 20 West K, et al. Acapella vs PEP mask therapy; a randomized trial in children with cystic fibrosis during respiratory exacerbation. Physiother Theory Pract. 2010 Apr;26(3):143-9.
- 21 McIlwaine, PM et al. Long-term comparative trial of positive expiratory pressure versus oscillating positive expiratory pressure (flutter) physiotherapy in the treatment of cystic fibrosis. J Pediatr 2001;138(6):845-850.
- 22 Van Winden, CM et al. Effects of flutter and PEP mask physiotherapy on symptoms and lung function in children with cystic fibrosis. Eur Respir J. 1998;12(1):143-147
- 23 Newbold ME, et al. The flutter device versus the PEP mask in the treatment of adults with cystic fibrosis. Physiother Can 2005;57(3):199-207,
- 24 Gondor et al. Comparison of flutterdevice and chest physical therapy in the treatment of cystic fibrosis pulmonary exacerbation. Pediatr Pulmonol 1999; 28(4):255-260
- 25 Lagerkvist AL, et al. Immediate changes in blood gas tensions during chest physiotherapy with positive expiratory pressure in patients with cystic fibrosis. Respir Care 2006;51(10):1154-1161
- 26 McCarren B, et al. Physiological effects of vibration in subjects with cystic fibrosis. Eur Respri J 2006;27:1204-1209
- 27 Patterson JE, et al. acapella versus 'usual airway clearance' during acute exacerbation in bronchiectasis: a randomized crossover trial. Chronic Respir Disease. 2007;4:67-74

- 28 Thompson CS, et al. Randomized crossover study of the Flutter device and the active cycle of breathing technique in non-cystic fibrosis bronchiectasis. Throax 2002;57(5):446-448.
- 29 Murray MP, et al. A randomized crossover trial of chest physiotherapy in non-cystic fibrosis bronchiectasis. Eur Respir J 2009; 34:1086-1092
- 30 Naraparaju S et al. A comparison of the acapella and a threshold inspiratory muscle trainer for sputum clearance in bronchiectasisa pilot study. Physiotherapy Theory and Practice 2010;26(6):353-357
- 31 Bondalapati P et al. Vibratory/positive expiratory pressure device (PEP-FV) and hospital length of stay for acute exacerbation of chronic obstructive pulmonary disease. Am J Respir Crit Care Med 189 2014:AS196
- 32 Cho, YJ et al. A randomized controlled trial comparing incentive spirometry with the acapella device for physiotherapy after thoracoscopy lung resection surgery. Anaesthesia 2014 Aug;69(8):891-8
- 33 Harbrect BG et al. Improved outcomes with routine respiratory therapist evaluation of non-intensive care unit surgery patients. Respir Care 2009;54(7):861-867

PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN CANADA AND OTHER COUNTRIES

Smiths Medical International Ltd. Hythe, Kent CT21 6JL, UK Phone: +44(0)1303 260551 www.smiths-medicaloem.com **Smiths Medical ASD, Inc.** 6000 Nathan Lane North Minneapolis, MN 55442, USA Tel: 1-614-210-7300 Toll-Free USA: 1-800-258-5361

Find your local contact information at: www.smiths-medical.com/customer-support

Smiths Medical is part of the global technology business Smiths Group plc. Please see the Instructions for Use/Operator's Manual for a complete listing of the indications, contraindications, warnings and precautions. acapella and Smiths Medical design marks are trademarks of Smiths Medical. The symbol () indicates it is registered in the U.S. Patent and Trademark Office and certain other countries. There is no connection between Smiths Medical and Intuitive Surgical. () 2016 Smiths Medical. All rights reserved. RE194321EN-092016

MHYTCA-1192

**(**€

smiths medical