An evidence-based study of adolescents with cystic fibrosis demonstrated that AffloVest® by International Biophysics contributed to improved lung function scores

Michael Cooper, RT, Chicago, Illinois

Cystic fibrosis (CF) is a life-threatening genetic disease that primarily affects the lungs and digestive system. An estimated 30,000 children and adults in the United States (70,000 worldwide) have CF. Approximately 1,000 new cases are being diagnosed each year.[1] Individuals with CF have difficulty clearing pathogens from the lung and experience chronic pulmonary infections and inflammation. Death is usually a result of respiratory failure. The median expected survival age has reached 36 years.[2]

For patients with cystic fibrosis, maintaining proper airway function is essential, especially for children and young adults. The primary treatment that has been widely used is Chest Physical Therapy (CPT). CPT includes Postural Drainage and Percussion (PD & P), a way to help people with cystic fibrosis (CF) breathe with less difficulty and stay healthy. PD & P uses gravity and percussion to loosen the thick, sticky mucus in the lungs so it can be removed by coughing. Unclogging the airways is key to keeping lungs healthy by helping to reduce the severity of lung infections and improve overall lung function. In children and young adults with CF, CPT can be done by physical therapists (PT), respiratory therapists (RT), nurses, and even parents[3]. The Cystic Fibrosis Foundation recommends CPT and PD & P to target different portions of the lungs, as prescribed by a physician. Although effective, parental involvement in CPT becomes more difficult as the child grows and becomes more independent.

To help streamline this process, another treatment option was introduced to the CF community in the 1980s. The high frequency chest wall oscillation device (HFCWO) provided an alternative and effective treatment for patient's to use at home. The device is an air-bladder vest that is connected to hoses and an electrical air generator, thus eliminating the need for a PT, RT, nurse or parent to administer. Additional advantages included semi-portability, freedom to comply with treatment frequency in the privacy of the home and access to necessary treatment on a patients' schedule. From a technical perspective, a one-year multi-chart retrospective study conducted by Jan Tecklin, et. al., concluded that Brasefield chest x-ray scores were statistically significantly better with HFCWO than CPTX.[4] The technology typically relies on air to create a single waveform through an air bladder that delivers air in large volumes, at high amplitude to rapidly inflate and deflate the bladder. To do so, the device must tightly squeeze the patient's torso with rapid, repeated compression, at times causing discomfort for patient users. The air-bladder type device is loud during operation, both for patients and family members, and must remain plugged into the wall for the duration of treatment, limiting patients' mobility. This technology was originally developed and introduced in the 1980's, and these air-bladder type vests have provided great benefits to thousands of patients over the years.

A new type of HFCWO vest technology is now available that offers several advantages over air-bladder type vests. The AffloVest® is a portable HFCWO device that is battery operated, thus eliminating the need to be connected to an electrical outlet during use. The AffloVest technology is self-contained. It mechanically generates waveforms from 8 individual oscillating motors sewn into the vest, thus eliminating the need for an air-bladder, hoses and

This clinical case study was not commissioned by Afflovest® or its parent company International Biophysics Corporation. The clinician involved developed this study and collected the clinical information on his own. All patients independently obtained an AffloVest by prescription from their physicians via their own insurance or private pay for their own personal use. Results were documented during routine clinical visits.

air generator. These 8 oscillating motors create 8 individual percussive waveforms, effectively creating disruption and mobilizing secretions in the lungs without squeezing the patient's chest. These individual motors target different areas of the lungs that can be missed by certain types of air bladder HFCWO's. The AffloVest technology does not require squeezing the patient's chest and is customizable to individual patient needs offering 3 oscillation programs (percussion, vibration and drainage) as well as 3 treatment levels (soft/5Hz, medium/13Hz and intense/20Hz). Prescribing physicians can customize treatment plans for individual patient needs. The AffloVest is very quiet and can be used while walking or during other patient activities. These advantages offer freedom to comply with treatment whenever and wherever it is convenient for the patient. This may lead to increased compliance as reported by the patients in this study.

In a study conducted by Oermann et. al., published in Pediatric Pulmonology, a randomized, multicenter crossover pilot study evaluated the efficacy and patient satisfaction with high frequency chest wall oscillation (HFCWO) and oscillating positive expiratory pressure (OPEP) compared to percussion and postural drainage (PD & P) in the home use setting. The study concluded that, given a choice of therapy, 50% of subjects chose HFCWO, 37% OPEP, and 13% PD & P.[5]

In the following case study, five adolescent patients used the AffloVest® by International Biophysics for 3–5 months each and saw increased Pulmonary Function Test (PFT) scores. The PFT routinely measures airflow, lung volumes, gas exchange, response to bronchodilators, and respiratory muscle function. This study was performed at a major U.S. hospital actively treating cystic fibrosis patients. The five patients involved in the study ranged in age between 14 and 18 years of age. All were using an air bladder HFCWO vest for their prescribed treatment plan, before switching to the AffloVest. The objective of the study was to measure lung function scores before and after use to determine efficacy. These data show FVC, FEV1, and FEF scores before and after using AffloVest.

Patient 1
Age: 14 years
Sex: male

	FVC (L)	FEV1 (L)	FEF 25–75% (L/sec)
Predicted Value	3.33	3.06	3.44
Air Bladder Vest	2.80	2.61	3.72
Afflovest	3.15	3.10	6.09

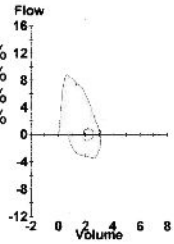
Improvements with the AffloVest were noted over current treatment as follows: FVC increased 12.5%, FEV1 increased 18.8%, and FEF increased 63.7%. The patient's mother states that her son is much more motivated to use his vest due to ease of use and freedom of movement during treatment.

Trend Report

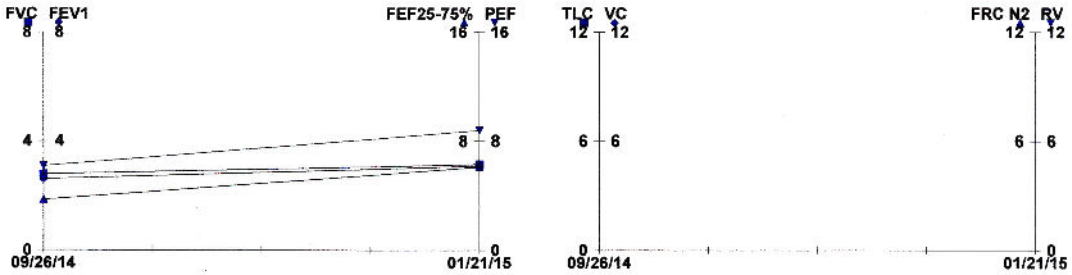
Gender: Male Age: 14
Height(in): 63 161(cm)
Weight(lb): 108 49.1 (kg)

Diagnosis: Cystic Fibrosis
Date: 01/21/15
Medication Set 1:

Previous Study: 09/26/14		**Current Study:** 01/21/15			
FVC	2.80 Liters	FVC	3.15 Liters	(91) %	improved by 13%
FEV1	2.61 Liters	FEV1	3.10 Liters	(97) %	improved by 18%
FEF25-75%	3.72 L/sec	FEF25-75%	6.09 L/sec	(170) %	improved by 64%
PEF	6.19 L/sec	PEF	8.79 L/sec	(129) %	improved by 42%
TLC	Liters	TLC	Liters	() %	improved by
RV	Liters	RV	Liters	() %	improved by
DLCO	mL/mmHg/min	DLCO	mL/mmHg/min	() %	improved by



Date	FVC	FEV1	FEF25-75%	PEF	TLC	RV	DLCO
01/21/15	3.15 Liters	3.10 Liters	6.09 L/sec	8.79 L/sec	Liters	Liters	mL/mmHg/min
09/26/14	2.80	.2.61	3.72	6.19			



Comments:
Spirometry data is Acceptable and Repeatable. Good patient effort.

Interpretation:

Patient 2
Age: 14 years
Sex: male

	FVC (L)	FEV1 (L)	FEF 25–75% (L/sec)
Predicted Value	3.33	3.06	3.44
Air Bladder Vest	2.62	2.08	1.93
Afflovest	3.01	2.44	2.39

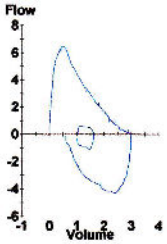
Improvements with the AffloVest were noted over current treatment as follows: FVC increased 14.9%, FEV1 increased 17.3%, and FEF increased 23.8%. In addition, his mother states that her son enjoys wearing the AffloVest and it has helped him increase his basketball performance.

Trend Report

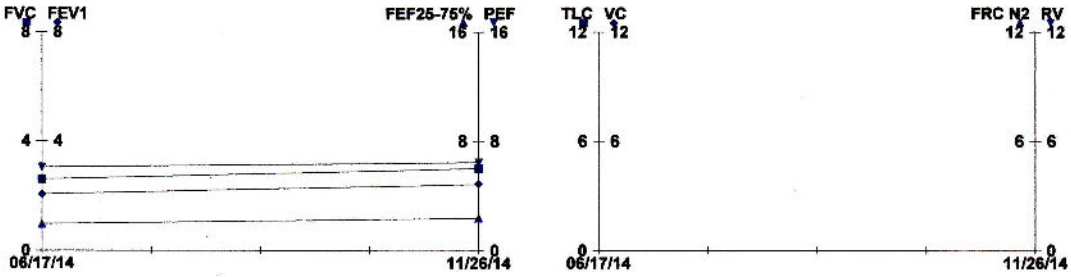
Gender: Male Age: 14
Height(in): 62 158(cm)
Weight(lb): 107 48.8 (kg)

Diagnosis: Cystic Fibrosis
Date: 11/26/14
Medication Set 1:

Previous Study: 06/17/14		Current Study: 11/26/14			
FVC	2.62 Liters	FVC	3.01 Liters	(90) %	improved by 15%
FEV1	2.08 Liters	FEV1	2.44 Liters	(80) %	improved by 17%
FEF25-75%	1.93 L/sec	FEF25-75%	2.39 L/sec	(70) %	improved by 24%
PEF	6.11 L/sec	PEF	6.46 L/sec	(98) %	improved by 6%
TLC	Liters	TLC	Liters	() %	improved by
RV	Liters	RV	Liters	() %	improved by
DLCO	mL/mmHg/min	DLCO	mL/mmHg/min	() %	improved by



Date	FVC	FEV1	FEF25-75%	PEF	TLC	RV	DLCO
11/26/14	3.01 Liters	2.44 Liters	2.39 L/sec	6.46 L/sec	Liters	Liters	mL/mmHg/min
06/17/14	2.62	2.08	1.93	6.11			



Comments:
Spirometry data is Acceptable and Repeatable. Good patient effort.

Patient 3
Age: 15 years
Sex: female

	FVC (L)	FEV1 (L)	FEF 25–75% (L/sec)
Predicted Value	3.07	2.92	3.31
Air Bladder Vest	2.19	1.98	3.70
Afflovest	2.31	2.04	3.83

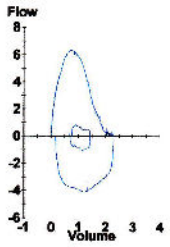
Improvements with the AffloVest were noted over current treatment as follows: FVC increased 5.5%, FEV1 increased 3.0% and FEF increased 3.5%. Her mother states that the vest has helped her complete her dance exercises.

Trend Report

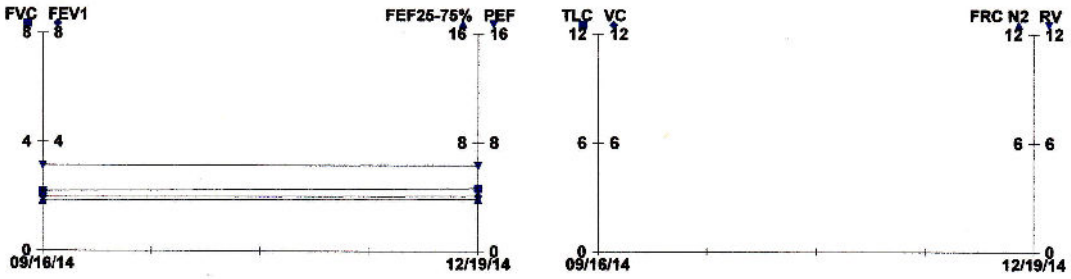
Gender: Female Age: 15
Height(in): 61 155(cm)
Weight(lb): 101 45.9 (kg)

Diagnosis: Cystic Fibrosis
Date: 12/19/14
Medication Set 1:

Previous Study: 09/16/14		**Current Study:** 12/19/14		
FVC	2.19 Liters	FVC 2.31 Liters	(75) %	improved by 6%
FEV1	1.98 Liters	FEV1 2.04 Liters	(70) %	improved by 3%
FEF25-75%	3.70 L/sec	FEF25-75% 3.83 L/sec	(116) %	improved by 3%
PEF	6.27 L/sec	PEF 6.31 L/sec	(105) %	improved by 1%
TLC	Liters	TLC Liters	() %	improved by
RV	Liters	RV Liters	() %	improved by
DLCO	mL/mmHg/min	DLCO mL/mmHg/min	() %	improved by



Date	FVC	FEV1	FEF25-75%	PEF	TLC	RV	DLCO
12/19/14	2.31 Liters	2.04 Liters	3.83 L/sec	6.31 L/sec	Liters	Liters	mL/mmHg/min
09/16/14	2.19	1.98	3.70	6.27			



Comments:
Spirometry data is Acceptable and Repeatable. Good patient effort.

Patient 4
Age: 18 years
Sex: female

	FVC (L)	FEV1 (L)	FEF 25–75% (L/sec)
Predicted Value	3.13	2.98	3.36
Air Bladder Vest	2.53	2.33	4.07
Afflovest	2.77	2.51	4.16

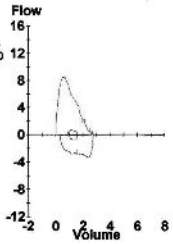
Improvements with the AffloVest were noted over current treatment as follows: FVC increased 9.5%, FEV1 increased 7.7% and FEF increased 2.2%. Patient indicates that she is taking the AffloVest with her to college and she has been using it more frequently to comply with treatment plan.

Trend Report

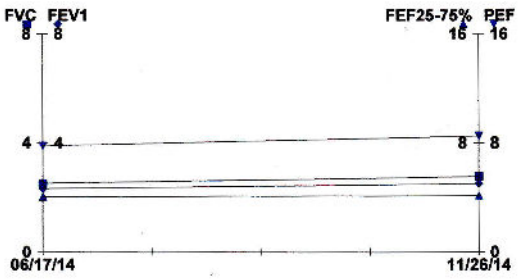
Gender: Female Age: 18
Height(in): 62 156(cm)
Weight(lb): 104 47.3 (kg)

Diagnosis: Cystic Fibrosis
Date: 11/26/14
Medication Set 1:

Previous Study: 06/17/14		**Current Study: 11/26/14**		
FVC	2.53 Liters	FVC 2.77 Liters	(89) %	improved by 10%
FEV1	2.33 Liters	FEV1 2.51 Liters	(84) %	improved by 8%
FEF25-75%	4.07 L/sec	FEF25-75% 4.16 L/sec	(124) %	improved by 2%
PEF	7.79 L/sec	PEF 8.49 L/sec	(129) %	improved by 9%
TLC	Liters	TLC Liters	() %	improved by
RV	Liters	RV Liters	() %	improved by
DLCO	mL/mmHg/min	DLCO mL/mmHg/min	() %	improved by



Date	FVC	FEV1	FEF25-75%	PEF	TLC	RV	DLCO
11/26/14	2.77 Liters	2.51 Liters	4.16 L/sec	8.49 L/sec	Liters	Liters	mL/mmHg/min
06/17/14	2.53	2.33	4.07	7.79			



Comments:
Spirometry data is Acceptable and Repeatable. Good patient effort.

Interpretation:

Patient 5
Age: 18 years
Sex: male

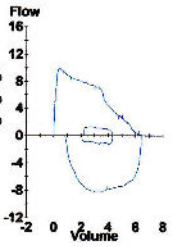
	FVC (L)	FEV1 (L)	FEF 25–75% (L/sec)
Predicted Value	4.08	3.76	4.14
Air Bladder Vest	5.99	4.61	4.03
Afflovest	6.43	5.08	4.70

Improvements with the AffloVest were noted over current treatment as follows: FVC increased 7.3%, FEV1 increased 10.2% and FEF increased 16.6%. Patient indicates that he has used it more frequently and it has helped him with his sports.

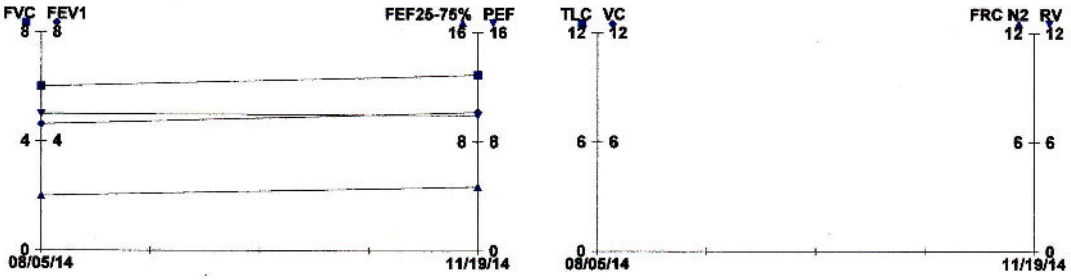
Trend Report

Gender: Male Age: 18 Diagnosis:
Height(in): 68 173(cm) Date: 11/19/14
Weight(lb): 182 82.7 (kg) Medication Set 1:

Previous Study: 08/05/14		Current Study: 11/19/14			
FVC	5.99 Liters	FVC	6.43 Liters	(159) %	improved by 7%
FEV1	4.61 Liters	FEV1	5.08 Liters	(137) %	improved by 10%
FEF25-75%	4.03 L/sec	FEF25-75%	4.70 L/sec	(115) %	improved by 16%
PEF	10.00 L/sec	PEF	9.91 L/sec	(118) %	decreased by 1%
TLC	Liters	TLC	Liters	() %	improved by
RV	Liters	RV	Liters	() %	improved by
DLCO	mL/mmHg/min	DLCO	mL/mmHg/min	() %	improved by



Date	FVC	FEV1	FEF25-75%	PEF	TLC	RV	DLCO
11/19/14	6.43 Liters	5.08 Liters	4.70 L/sec	9.91 L/sec	Liters	Liters	mL/mmHg/min
08/05/14	5.99	4.61	4.03	10.00			



Comments:
Spirometry data is Acceptable and Repeatable. Good patient effort.

Summary

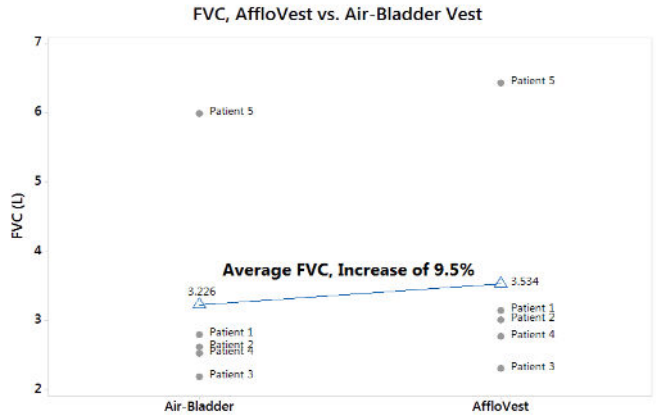
In conclusion, the data demonstrates the AffloVest improved breathing scores in the five patients followed in this study as compared to using an air bladder vest previously.

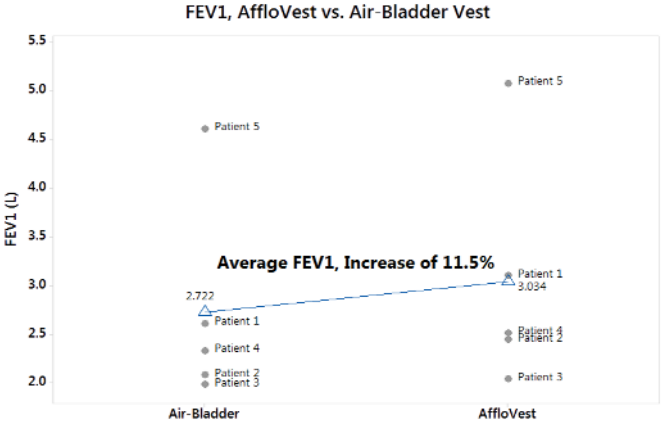
Average FVC: 0.308L, 09.5% Increase
Average Fev1: 0.312L, 11.5% Increase
Average FEF 25-75%: 0.744L, 21.3% Increase

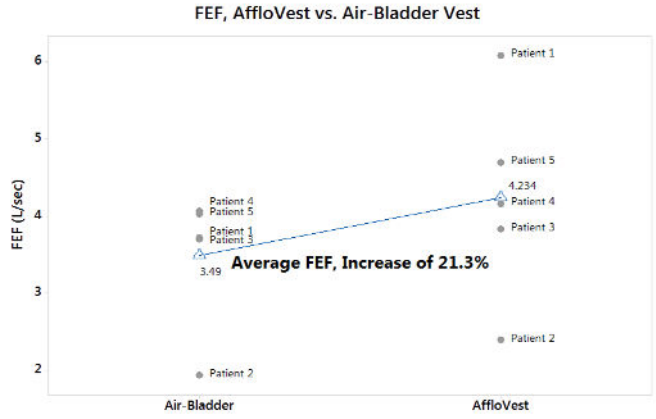
The overall usage between tests was 3–5 months. The clinician performing this study concluded that the AffloVest showed improvement in each patient's condition. The average patient used the AffloVest 2-3 times a day, and the average settings were 8 minutes at medium (13Hz) and 16 minutes at intense (20Hz) for total treatment time of 24 minutes.

In addition to lung function improvements, patients stated that they enjoyed wearing the AffloVest and used it more often as compared to their air-bladder vest, thus increasing treatment compliance. While many variables can contribute to improved lung function, all five patients participating in this small study demonstrated improved lung function after using the AffloVest.

For more information visit www.afflovest.com or call 888.711.1145.







References:

1. www.cff.org
2. Flume, O'Sullivan, Robinson, et al. Cystic Fibrosis Pulmonary Guidelines. *American Journal of Respiratory and Critical Care Medicine* 2007; 176:957-969.
3. Cystic Fibrosis Foundation Fact Sheet, 2012
4. Tecklin, Clayton, and Scanlin. High frequency chest wall oscillation vs. traditional chest physical therapy in CF-a large, one-year, controlled study. *Pediatr Pulmonol* 2000; (suppl 20):459.
5. Oermann, Retsch-Bogart, Quittner, et al. An 18-month study of the safety and efficacy of repeated courses of inhaled aztreonam lysine in cystic fibrosis. *Pediatr Pulmonol* 2010; 45:1121-1134.