Lung function improvement with AffloVest® HFCWO use: a clinician's perspective on PFT score data from 25 patients with cystic fibrosis.

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Chronic pulmonary, respiratory, and neurological diseases and disorders such as cystic fibrosis, bronchiectasis, MD, ALS and others are often complex, life-long conditions that affect the pulmonary, digestive, and other body systems. Patients can have difficulty clearing mucus and pathogens from the lungs which can lead to chronic infections and inflammation. Maintaining airway clearance is critical. Traditionally, treatment has been by Chest Physical Therapy, comprised of postural drainage and/or percussion and/or High Frequency Chest Wall Oscillation (HFCWO) vests utilizing air bladder style technology.

Previous studies, Tecklin, Jan et al.[2] and Oermann et al.[3] demonstrated improvement, efficacy and patient satisfaction with HFCWO treatment in general. In a previous 5 patient study in 2015 conducted by Michael Cooper, RT, Chicago, Illinois[1] treatment with the AffloVest contributed to improved lung function scores compared to previous scores. Average FVC, FEV1, and FEF 25-75% increased 9.5%, 11.5%, and 21.3% respectively with the AffloVest.

The AffloVest technology, which does not utilize an air bladder, is a battery operated, portable HFCWO device providing patient mobility during treatment. Eight (8) oscillating motors sewn into the vest generate 8 individual oscillation waveforms helping to mobilize secretions in the patient's lungs. These oscillation motors target the different areas of the lungs (upper and lower lobes, front and back). The digital, programmable controller offers 3 oscillation treatments (percussion, vibration, and drainage) and 3 treatment levels (soft/5Hz, medium/13Hz and intense/20Hz). Prescribing clinicians can program customized treatment plans for their patients. The fact that the AffloVest is quiet and truly portable allows the patient to perform normal daily activities during treatment. This may lead to increased patient use of the device as stated by the clinicians and patients in this article.

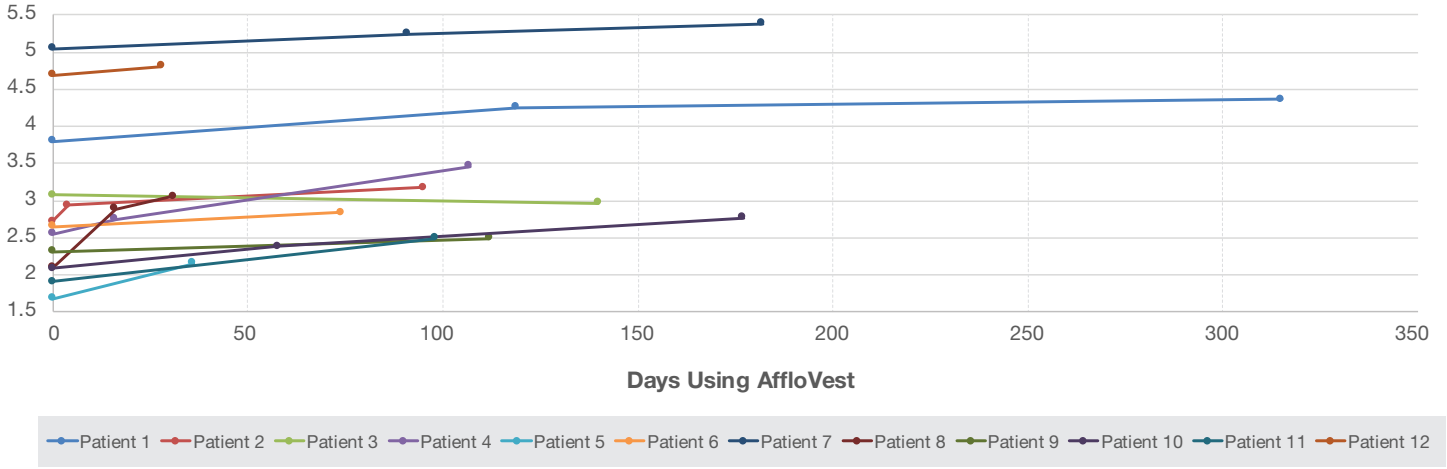
A total of 25 patients were set up on the Afflovest. The data presented in this clincian paper is from twelve patients (48%) who experienced increases in their lung function scores after adopting AffloVest technology into their Airway Clearance Treatment (ACT) regimen. The remaining 13 patients (52%) saw no significant increase, and no decrease, in their lung function. All patients had the benefit of increased mobility, convenience, ACT therapy and comfort of the Afflovest. The 12 patients ranged in age from 11 to 18 years old and they all used the AffloVest for periods ranging from less than a month to almost a full year. Eleven (11) of the 12 had been using air bladder style vests previously. Patient 6 had previously used no ACT until adopting the AffloVest. The lung function scores collected were FVC, FEV1, and FEF 25-75. Average FVC, FEV1, and FEF 25-75% increased 15.22%, 17.41%, and 11.21% respectively with the AffloVest.

Mean PFT scores and percent increase

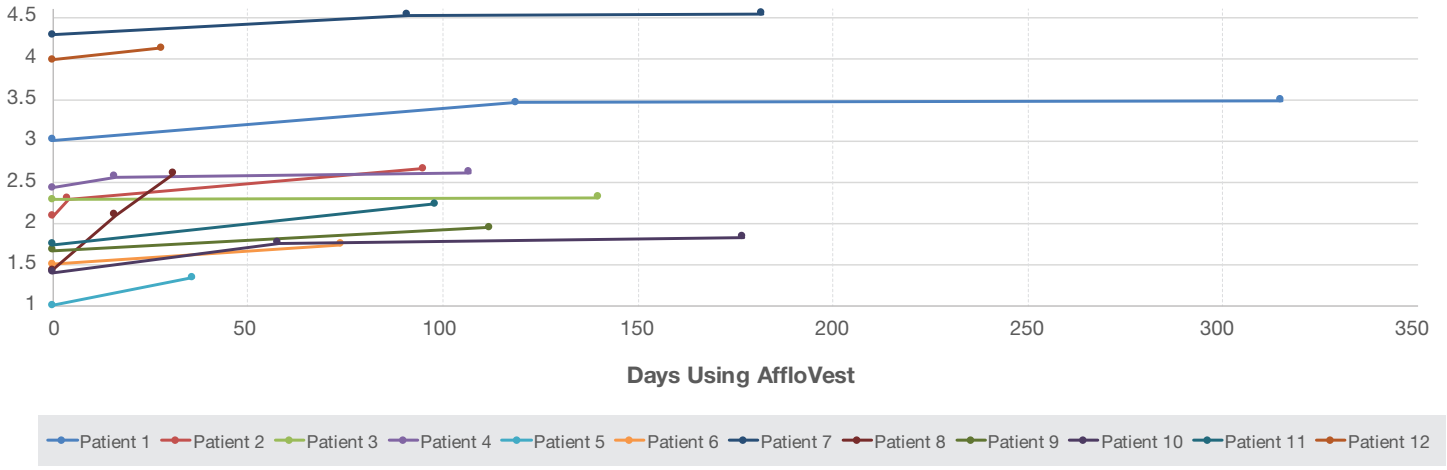
	Initial Pre-AffloVest Use Value (Mean)	Final Value (Mean)	% Change Final vs. Initial
FVC (L)	2.89	3.33	+15.22%
FEV1 (L)	2.24	2.63	+17.41%
FEF 25% - 75% (L/sec)	2.23	2.48	+11.21%

The data described in this paper were collected independently by the clinician author and not at the direction of International Biophysics Corporation (IBC). 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. At the conclusion of data collection and collation, the author contacted IBC and shared the findings. Following review of the findings, IBC provided modest financial and editorial support to the author in connection with the preparation of this clinician paper.

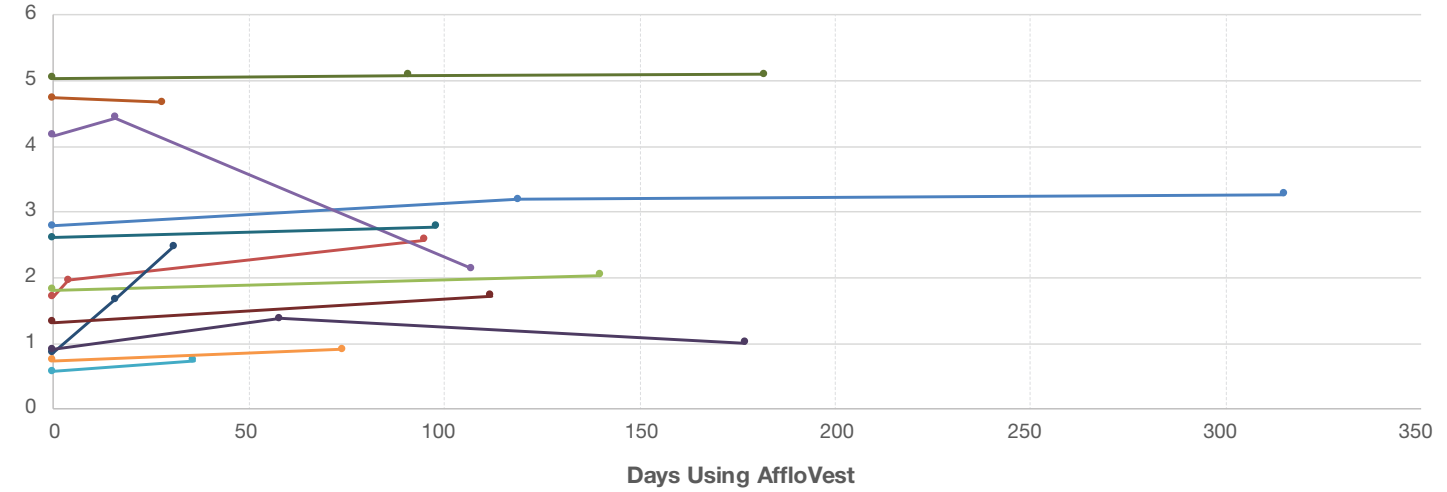
FVC (L)



FEV1 (L)



FEF 25% - 75% (L/sec)



*** Both patients 4 and 8 had invalid test results due to erroneous spirometry output data. The erroneous data were not included in scoring calculations.*

Patient 1

Age: 14 Gender: Male Days using AffloVest: 315

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 119	Final Value Day 315	%Change Final vs. Initial
FVC	4.14	3.80	4.25	4.36	+ 14.74%
FEV1	3.52	3.02	3.47	3.50	+ 15.89%
FEF 25-75%	4.10	2.79	3.2	3.27	+ 17.20%

Patient 2

Age: 12 Gender: Female Days using AffloVest: 95

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 4	Final Value Day 95	%Change Final vs. Initial
FVC	3.09	2.72	2.94	3.18	+ 16.91%
FEV1	2.58	2.09	2.3	2.67	+ 27.75%
FEF 25-75%	2.69	1.72	1.96	2.58	+ 50.00%

Patient 3

Age: 17 Gender: Female Days using AffloVest: 140

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 140	%Change Final vs. Initial
FVC	3.46	3.08	NA	2.97	- 3.57%
FEV1	3.06	2.29	NA	2.32	+ 1.31%
FEF 25-75%	3.75	1.82	NA	2.04	+ 12.09%

Patient 4

Age: 12 Gender: Female Days using AffloVest: 107

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 16	Final Value Day 107	%Change Final vs. Initial
FVC	2.90	2.55	2.75	3.46	+ 35.69%
FEV1	2.44	2.44	2.57	2.62	+ 7.38%
FEF 25-75%	2.59	4.17	4.44	*2.14	

*Patient 4 test reading suggests an erroneous test result based on spirometry profile. This data point is omitted from all calculations.

Patient 5

Age: 13 Gender: Male Days using AffloVest: 36

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 36	%Change Final vs. Initial
FVC	3.32	1.68	NA	2.16	+ 28.57%
FEV1	2.97	1.01	NA	1.35	+ 33.66%
FEF 25-75%	3.37	0.58	NA	0.74	+ 27.59%

Patient 6

Age: 17 Gender: Male Days using AffloVest: 74

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 74	%Change Final vs. Initial
FVC	3.8	2.65	NA	2.84	+ 7.17%
FEV1	3.34	1.51	NA	1.75	+ 15.89%
FEF 25-75%	3.93	0.74	NA	0.91	+ 22.97%

Patient 7

Age: 17 Gender: Male Days using AffloVest: 182

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 91	Final Value Day 182	%Change Final vs. Initial
FVC	5.20	5.05	5.24	5.38	+ 6.53%
FEV1	4.53	4.29	4.53	4.55	+ 6.06%
FEF 25-75%	4.96	5.04	5.09	5.1	+ 1.19%

Patient 8

Age: 13 Gender: Female Days using AffloVest: 31

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 16	Final Value Day 31	%Change Final vs. Initial
FVC	2.94	2.1	2.89	3.06	+ 45.71%
FEV1	2.77	1.44	2.11	2.61	+ 81.25%
FEF 25-75%	3.43	* 0.87	1.67	2.48	

*Patient 8 test reading suggests an erroneous test result based on spirometry profile. This data point is omitted from all calculations.

Patient 9

Age: 11 Gender: Male Days using AffloVest: 112

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 112	%Change Final vs. Initial
FVC	2.06	2.31	NA	2.49	+ 7.79%
FEV1	1.88	1.68	NA	1.96	+ 16.67%
FEF 25-75%	2.28	1.33	NA	1.73	+ 30.08%

Patient 10

Age: 15 Gender: Female Days using AffloVest: 177

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value Day 58	Final Value Day 177	%Change Final vs. Initial
FVC	3.09	2.09	2.38	2.77	+ 32.54%
FEV1	2.79	1.41	1.77	1.84	+ 30.50%
FEF 25-75%	3.46	0.91	1.38	1.01	+ 10.99%

Patient 11

Age: 12 Gender: Female Days using AffloVest: 98

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 98	%Change Final vs. Initial
FVC	2.82	1.91	NA	2.49	+ 30.37%
FEV1	2.60	1.75	NA	2.24	+ 28.00%
FEF 25-75%	3.24	2.61	NA	2.78	+ 6.51%

Patient 12

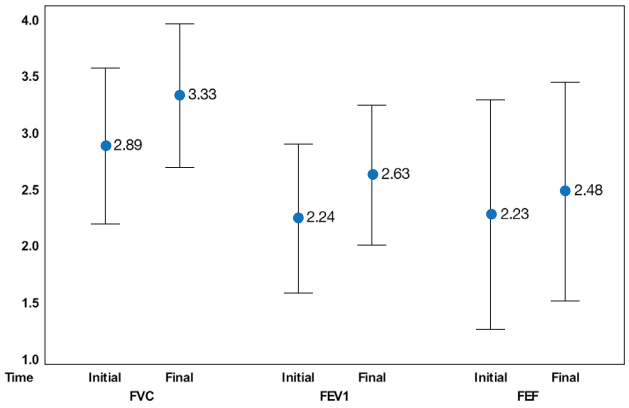
Age: 18 Gender: Male Days using AffloVest: 28

Parameter measured	Predicted Value	Initial Pre-AffloVest Use Value	Interim Value	Final Value Day 28	%Change Final vs. Initial
FVC	5.19	4.69	NA	4.81	+ 2.56%
FEV1	4.46	3.99	NA	4.13	+ 3.51%
FEF 25-75%	4.92	4.74	NA	4.67	- 1.48%

Summary

The data collected from these patients show that PFT scores improved in the 12 patients after adopting the AffloVest into their Airway Clearance Treatment (ACT) regimen.

Average FVC increase: 0.45L, +15.22% increase
Average FEV1 increase: 0.39L, +17.41% increase
Average FEF 25-75% increase: 0.26L, +11.21% increase



PFT score means - Final vs. Initial

The usage between tests averaged 78 days, and the duration of use ranged from 28 days to 315 days. The AffloVest was prescribed to these patients hoping to increase frequency of use and pulmonary function test scores. Patients with the most FEV1 score improvements appear to be those who reported little or no compliance before initiating the use of AffloVest; for these patients, AffloVest's technology and portability coupled with ease of use helped increase the frequency of patient use. The majority of the patients who demonstrated pulmonary function test improvements after adopting the AffloVest into their ACT regimen remained improved over time and continued to improve over time.

In addition to the improvement in lung function scores, patients elaborated on their experience with the AffloVest:

- Patients liked having the ability to read, write, watch TV, play games and work on their computer during treatment.
- Parents said their children were more likely to use the AffloVest because of its mobility/portability and were able to carry on with normal activities.
- The AffloVest is easier to carry and travel.

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

References:

1. Cooper, Michael. An evidence-based study of adolescents with cystic fibrosis demonstrated that AffloVest® by International Biophysics contributed to improved lung function scores.
2. 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.
3. 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.