

Clinician's Data Analysis: Lung function improvement maintained over 16 to 24 months with use of AffloVest™ HFCWO vest by International Biophysics.

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Lung function improvement was observed in a previous evidence based study on 5 cystic fibrosis patients¹. Current data from the same five patients shows that their lung function scores improved and were maintained over a period of usage of 16 to 24 months.

In the previous paper¹ 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. All patient care was provided at a major U.S. hospital actively treating cystic fibrosis. The five patients involved in the study ranged in age at the time between 14 and 18 years of age. All patients 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. The data in this first analysis observed that the AffloVest improved breathing scores in the five patients over a 3 to 5 month period:

Average FVC: 0.308L, 09.5% Increase
Average FEV1: 0.312L, 11.5% Increase
Average FEF 25-75%: 0.744L, 21.3% Increase

The ongoing data collected for this clinician paper was collected from the same five patients after 16 to 24 months of treatment using the AffloVest. The data collected on the five AffloVest patients shows that lung improvement overall was maintained over that total time period.

Patient Data Summary Table (16 to 24 months)

	Initial Pre-AffloVest Use Value (Mean)	Final Value (Mean)	% Change Final vs. Initial
FVC (L)	3.23	3.77	+ 16.80%
FEV1 (L)	2.72	3.16	+ 16.02%
FEF 25% - 75% (L/sec)	3.49	4.02	+ 15.30%

For these 5 patients, the data observations have shown that patient lung function scores improved and are being maintained over time with use of the AffloVest.

Improvement in lung function scores along with AffloVest use had also previously been observed in a 25 patient clinician paper by Michelle W. Tackett, RRT and Vivian P. Henderson, RRT, Knoxville, Tennessee².

In this paper, a total of 25 patients were set up on the AffloVest. The data presented in this clinician paper was 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 and ACT therapy with the AffloVest.

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.

The 12 patients in the Tackett analysis 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. One patient 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.

These patient data analysis reviews are observing positive lung improvement scores that improve and that are maintained over time with patients that are adopting the AffloVest in their treatment plan.

In a study³ conducted at the UAB Gregory Fleming James Cystic Fibrosis Research Center no significant relationship was found between adherence to High Frequency Chest Wall Oscillation (HFCWO) Airway Clearance Therapy (ACT) and lung function. The HFCWO vests referred to in this study were all air bladder style vests.

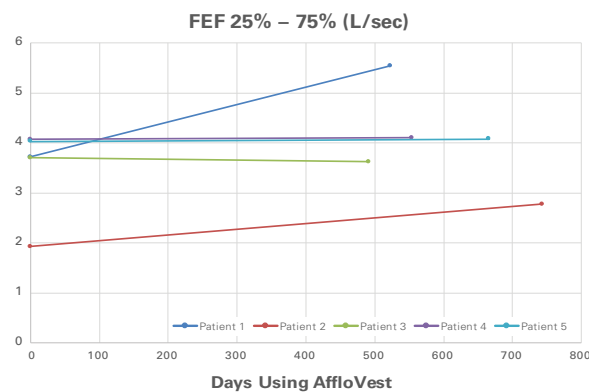
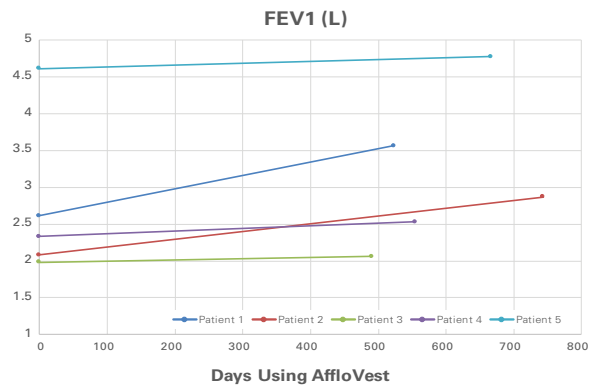
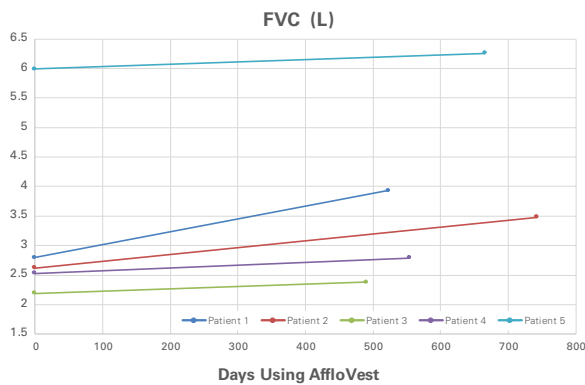
CONCLUSION

In conclusion, the data in this analysis observed improved breathing scores in the five patients using the AffloVest and that the improvement was maintained over 16 to 24 months.

Average FVC: + 16.80% Increase
 Average FEV1: + 16.02% Increase
 Average FEF 25-75%: + 15.30% Increase

The overall usage time between the first and last test was 16 months to 2 years. The clinician performing this study concluded that the AffloVest patients 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. Based on this data analysis, other CF programs may want to consider undertaking their own PFT data analysis with patients switching to or incorporating the AffloVest in their patient's therapy regimen.

AffloVest Patient Graphs



1. Cooper, Michael. An evidence-based study of adolescents with cystic fibrosis demonstrated that AffloVest® by International Biophysics contributed to improved lung function scores. Chicago, Illinois.
2. Tackett, Michelle, RRT, Henderson, Vivian, RRT. Lung function improvement with AffloVest HFCWO use: a clinician's perspective on PFT score data from 25 patients with cystic fibrosis. Knoxville, TN.
3. Oates et al. Adherence to Airway Clearance Therapy in Pediatric Cystic Fibrosis: Socioeconomic Factors and Respiratory Outcomes. Pediatric Pulmonology, 2015 Wiley Periodicals, Inc.

AffloVest Patient Data

Patient 1

Age: 15

Gender: Male

Days using AffloVest: 523

Parameter Measured	Predicted Value	Initial Pre-AffloVest Use Value	Final Value at 17 Months	%Change Final vs. Initial
FVC(L)	3.33	2.80	3.93	+ 40.36%
FEV1(L)	3.06	2.61	3.56	+ 36.40%
FEF 25%-75% (L/sec)	3.44	3.72	5.54	+ 48.92%

Patient 2

Age: 15

Gender: Male

Days using AffloVest: 743

Parameter Measured	Predicted Value	Initial Pre-AffloVest Use Value	Final Value at 24 Months	%Change Final vs. Initial
FVC(L)	3.33	2.62	3.48	+ 32.82%
FEV1(L)	3.06	2.08	2.87	+ 37.98%
FEF 25%-75% (L/sec)	3.44	1.93	2.78	+ 44.04%

Patient 3

Age: 16

Gender: Female

Days using AffloVest: 491

Parameter Measured	Predicted Value	Initial Pre-AffloVest Use Value	Final Value at 16 Months	%Change Final vs. Initial
FVC(L)	3.07	2.19	2.38	+ 8.68%
FEV1(L)	2.92	1.98	2.06	+ 4.04%
FEF 25%-75% (L/sec)	3.31	3.70	3.62	- 2.16%

Patient 4

Age: 19

Gender: Female

Days using AffloVest: 554

Parameter Measured	Predicted Value	Initial Pre-AffloVest Use Value	Final Value at 18 Months	%Change Final vs. Initial
FVC(L)	3.13	2.53	2.79	+ 10.28%
FEV1(L)	2.98	2.33	2.53	+ 8.58%
FEF 25%-75% (L/sec)	3.36	4.07	4.1	+ 0.74%

Patient 5

Age: 19

Gender: Male

Days using AffloVest: 667

Parameter Measured	Predicted Value	Initial Pre-AffloVest Use Value	Final Value at 22 Months	%Change Final vs. Initial
FVC(L)	4.08	5.99	6.26	+ 4.51%
FEV1(L)	3.76	4.61	4.77	+ 3.47%
FEF 25%-75% (L/sec)	4.14	4.03	4.08	+ 1.24%

