

Effect of High Frequency Chest Wall Oscillation Vests on Spirometry Measurements: An IRB Published Clinical Study

Despite the widespread clinical use of the High Frequency Chest Wall Oscillation (HFCWO) devices, little has been published regarding the vests' effects while in use on standard spirometry measurements - TV, PEF, FVC, FEV1 and FEF25-75%.

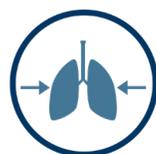
In this study, the data show for the first time that compressor-based HFCWO vests significantly decreased FVC, FEV1 and FEF25-75% from baseline during use. Although both groups showed a decline in FEF25-75%, the compressor style group decrease in FEF25-75% was 3 times that of the AffloVest®. There was no effect on TV or PEF measurements.

This study has been published in Respiratory Therapy. An abstract of the study will be published in Pediatric Pulmonology.



No Evidence of Increased Cephalad Airflow Bias in the Lungs During Use

The mechanism of increased cephalad airflow bias in the lungs does not appear to be supported by the standard clinical lung function spirometry parameters measured during use. None of the vest groups showed statistically significant increased airflow in the lungs. This does not support increased cephalad airflow bias in the lungs as a mode of action for HFCWO during use.



Reduced FVC/FEV1 Shown in Compressor Style Vest Group

A statistically significant decline of FVC and FEV1 from baseline during use was experienced with compressor style vests, while AffloVest did not.



Reduced FEF25-75%

Compressor style vests showed a decline of 14% during use, 3X more than the AffloVest's decline in FEF25-75% during use.

Study Results

| Parameter | Baseline Mean [range] | AffloVest Mean [range] | p-Value | Compressor Mean [range] | p-Value | p-value AffloVest vs. Compressor |
|---------------|-----------------------|------------------------|---------|-------------------------|---------|----------------------------------|
| *TV(L) | 0.93 [0.30-2.32] | 1.00 | n.s. | 1.07 [0.24-2.69] | n.s. | n.s. |
| *PEF(L/s) | 8.19 [3.96-11.82] | 8.28 [3.50-12.00] | n.s. | 8.13 [4.23-12.89] | n.s. | n.s. |
| *FVC(L) | 4.29 [2.48-6.57] | 4.25 [2.50-7.42] | n.s. | 4.12 [2.29-6.73] | 0.019 | n.s. |
| *FEV1(L) | 3.51 [2.05-5.54] | 3.46 [2.00-6.19] | n.s. | 3.30 [1.92-5.83] | < 0.005 | < 0.005 |
| *FEF25-75%(L) | 3.71 [1.77-6.43] | 3.54 [1.63-6.37] | 0.031 | 3.19 [1.19-6.22] | < 0.005 | < 0.005 |

*American Thoracic Society (ATS) guidelines for lung function parameters.