GOLDILOCKS AND THE THREE LUNG VOLUME MEASUREMENTS

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- HARD (Gas Dilution)
- HARDER (Plethysmography)
- EASIEST (MiniBox+)
Disclosure

- NONE
- ON SAB OF PULM-ONE
- NO PAYMENT, NO EQUITY
Helium Gas Dilution
HELIUM DILUTION

\[(V_{\text{gas}})(C_1) = (V_{\text{gas}} + V_L)(C_2)\]

\[V_L = \frac{(V_{\text{gas}})(C_1 - C_2)}{C_2}\]

Where \( C_1 \) = helium concentration at the start of the experiment
\( C_2 \) = helium concentration when gas mixing is complete
HELUM DILUTION METHOD

- KNOWN [He] EQUILIBRATED WITH LUNG VOLUME
- ACCOUNT FOR CO₂ PRODUCTION / O₂ CONSUMPTION
- BTPS CORRECTION
- ASSUME NO LEAK
  NO HELIUM SWALLOWED
  TURN IN AT FRC
  He NOT ABSORBED
  COMPLETE EQUILIBRATION
  NITROGEN NOT EXCRETED
Paths of Helium Loss

- Solution in H2O (negligible)
- Equipment leaks (equilibration fails)
- Leaks around nose clip, mouthpiece
- Ruptured tympanic membrane
- Swallowing
- Absorption into fluids, tissues
COMPLETE EQUILIBRATION
HELium Analyzer

- Range 0-10%
- Resolution: 0.01%
- 95% response time of < 15 sec to 2% step change in HE concentration
- < 0.02% drift for 10 minutes
End of Test Criteria

- $\Delta [\text{He}] < 0.02\%$ in 30 secs (3x, z 15 seconds)

Based on:

- Limits of resolution of He meter
- Estimate of $\Delta [\text{He}]$ of $< 0.01\%$ per minute due to He absorption and N2 excretion
Body Plethysmography
PLETHYSMOGRAPHY

\[ P_1V_1 = (P_1 + \Delta P)(V_1 + \Delta V) \]

\[ V_{tg} = -\frac{\Delta V}{\Delta P} \cdot (P_{ALV} - 47) \]
PLETHYSMOGRAPHY ASSUMPTIONS

- Isothermal gas compression in lung
- Proper calibration for polytropic conditions in plethysmograph
- Uniform pressure changes throughout lung
- Only thoracic gas is compressed
- No gas flow
Helium vs Plethysmograph

- **NORMAL**: results very similar
- **RESTRICTION**: results very similar
- **OBSTRUCTION**: Pleth > helium but...... CONTROVERSIAL
Helium vs Plethysmograph controversy

REFERENCE:

MiniBox+
MINIBOX+

LUNG VOLUME MEASUREMENT WITHOUT BODY
PLETHYSMOGRAPHY OR GAS DILUTION
MiniBox+

- **Measurements**
  - Spirometry
    - FEV1
    - FEV6
    - FEF25-75%
  - Lung Volume Measurement
    - TLC and subdivisions
  - Diffusion
    - CO Diffusion capacity
    - Real-time analysis/rapid gas analyzer
MiniBox+

Key Features

- Easy to learn, easy to use touch screen tablet
- Small footprint
- Low maintenance
- Low cost per test
Spirometry

- Meets ATS/ERS standards
  - Heated pressure differential pneumotach
  - End of test criteria *Progress Wheel*
    - At least 6 seconds and <25 ml volume change for 1-second
Diffusion

- Meets ATS/ERS standards
  - Multi-gas analyzer for CO, CH₄
  - Single gas tank
    - 0.300% CO, 0.300% CH₄, 21% O₂, Balance N₂
Lung Diffusion Capacity Measurement

Test completed successfully

Press Save to see results
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pred.</th>
<th>Best</th>
<th>% Predicted</th>
<th>#1</th>
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</thead>
<tbody>
<tr>
<td>DLCO</td>
<td>24.17</td>
<td>22.08</td>
<td>91%</td>
<td>22.08</td>
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<tr>
<td>VA</td>
<td></td>
<td>6.16</td>
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<td>6.16</td>
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<td>KCO</td>
<td>4.92</td>
<td>3.58</td>
<td>77%</td>
<td>3.58</td>
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<tr>
<td>VI</td>
<td></td>
<td>3.52</td>
<td></td>
<td>3.52</td>
</tr>
</tbody>
</table>

Graphs showing changes in volume and gas over time.
Lung Volume Measurement

- Traditional
  - Gas dilution
    - Long duration (4-7 minutes)
    - Wait time for repeatability
  - Body Plethysmography
    - Specific panting maneuver
    - No airflow for 4-7 seconds
    - Respiratory maneuver complex
    - Technologist influence
Lung Volume Measurement

- **MiniBox+**
  - Innovative solution
  - Tidal breathing and slow vital capacity
  - ~90 seconds to complete
  - Respiratory maneuver not complex
Lung Volume Measurement

- **How it works**
  - 6 interruptions during tidal breathing
    - Rapid 100 msec shutter close and open (mouth pressure)
  - Effect of interruptions on internal box
    - Pressure and flow
  - Data Model
    - Proprietary Model and Algorithm
  - Thoracic Gas Volume (TGV) is determined from which FRC is measured spirometrically as the difference between TGV and end-expiratory lung volume
Lung Volume Measurement

- Interruption is during inspiration (~1/3 of normal tidal)
- Interruption counter provides feedback on when interruption segment is complete
- Slow vital capacity can be performed either IC, VC or ERV, VC method
Lung Volume Measurement

- No wait time requirement between efforts
- No body cabin
- No complex panting maneuver against an occluded airway
Lung Volume Measurement

- Comparison – CT scan vs. plethysmography

Lung Volume Measurement

- **Comparison – He dil. vs. plethysmography**

MiniBox+ Lung Volume Measurement

Initial Model Development

All

Healthy

Obstructed

Restricted

N = 300 subjects
adj $R^2 = 0.82$

N = 150 subjects
adj $R^2 = 0.85$

N = 113 subjects
adj $R^2 = 0.74$

N = 37 subjects
adj $R^2 = 0.66$

$TLC_{RELH} = 1.02 \times TLC_{MB} + 0.10$

$TLC_{RELH} = 0.99 \times TLC_{MB} + 0.06$

$TLC_{RELH} = 1.03 \times TLC_{MB} + 0.07$

$TLC_{RELH} = 0.84 \times TLC_{MB} + 0.51$

CV = 9.9%

CV = 8.0%

CV = 11.2%

CV = 13.7%
MiniBox+ Lung Volume Measurement

- Comparison – MiniBox+ vs. Plethysmography
MiniBox+ Lung Volume Measurement

**STUDY DATA**

**Body Box device - Morgan Scientific Inc.**

<table>
<thead>
<tr>
<th>No. subjects</th>
<th>27</th>
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<tbody>
<tr>
<td>Male / Female</td>
<td>14 / 13</td>
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<tr>
<td>Age (years)*</td>
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<tr>
<td>Height (cm)*</td>
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<tr>
<td>Weight (kg)*</td>
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<td>No, Healthy</td>
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<tr>
<td>No, Unhealthy</td>
<td>15</td>
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</tbody>
</table>

* Mean

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**STUDY DATA**

**Body Box device - MGC Diagnostics.**

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
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<tr>
<td>Age (years)*</td>
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<tr>
<td>Height (cm)*</td>
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<tr>
<td>Weight (kg)*</td>
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<tr>
<td>No, Healthy</td>
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</tr>
<tr>
<td>No, Unhealthy</td>
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</table>

* Mean

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Boston Study

Cincinnati Study
## MiniBox+ Lung Volume Measurement

<table>
<thead>
<tr>
<th>Study Type</th>
<th>MiniBox multi-center study, in Israel</th>
<th>MiniBox Boston study</th>
<th>MiniBox Cincinnati study</th>
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</thead>
<tbody>
<tr>
<td>No. subjects</td>
<td>134</td>
<td>27</td>
<td>50</td>
</tr>
<tr>
<td>CV [%]</td>
<td>12.1%</td>
<td>10.9%</td>
<td>9.1%</td>
</tr>
</tbody>
</table>

**Comparative Studies Results Versus Body Plethysmography**

<table>
<thead>
<tr>
<th>Study Description</th>
<th>MiniBox + Lung Volume Measurement</th>
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<tbody>
<tr>
<td>O'Donnel et al. (CHEST, 2010) – Helium Gas Dilution</td>
<td>O'Donnel et al. (CHEST, 2010) – CT (Computerized Tomography)</td>
</tr>
<tr>
<td>No. subjects</td>
<td>149</td>
</tr>
<tr>
<td>CV [%]</td>
<td>18.9%</td>
</tr>
</tbody>
</table>
MiniBox+ Lung Volume Measurement

- Review
  - Unique and innovative technique
  - Compares well to Body Plethysmography
  - Simple respiratory maneuvers that are easy for the patient to perform
  - Very user friendly for technicians and patients
MiniBox+ Lung Volume Measurement

- Review (cont.)
  - Short test time (~90 seconds)
  - Multiple efforts without wait period
  - Small footprint
  - Notably less expensive than body plethysmography