S2 File: Supplementary results for participant data

Contents

1 Stratified by order of testing .................................................................2
  1.1 copd-6 before MicroDL.................................................................2
  1.2 MicroDL before copd-6.................................................................3

2 Stratified by devices used .................................................................4
  1.3 Excluded combinations of copd-6 and MicroDL devices .................4
  1.4 Combination of copd-6 device number 2 and MicroDL device number 2 4
  1.5 Combination of copd-6 device number 2 and MicroDL device number 3 5

3 Analysis based on FEV₆ instead of FEV₁ .........................................6

4 Analysis based on FEV₁/FEV₆ ............................................................7

5 Analysis restricted to first three blows with the MicroDL device ........8
  1.6 Overall results ..............................................................................8
  1.7 Stratified by order of testing: copd-6 before MicroDL ...................9
  1.8 Stratified by order of testing: MicroDL before copd-6 .................10

6 Analysis with stricter repeatability criteria ......................................11
1 Stratified by order of testing

1.1 copd-6 before MicroDL

<table>
<thead>
<tr>
<th>FEV\textsubscript{1,copd6} - FEV\textsubscript{1,MicroDL}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of observations: 84</td>
</tr>
<tr>
<td>Median: 0.08</td>
</tr>
<tr>
<td>Interquartile range: [0.01 ; 0.12]</td>
</tr>
<tr>
<td>[2.5 percentile ; 97.5 percentile]: [-0.39 ; 0.33]</td>
</tr>
<tr>
<td>Range: [-0.66 ; 0.34]</td>
</tr>
<tr>
<td>Mean: 0.05</td>
</tr>
<tr>
<td>95% confidence interval for mean: [0.02 ; 0.09]</td>
</tr>
</tbody>
</table>
1.2 MicroDL before copd-6

\[ \text{FEV}_{1,\text{copd}6} - \text{FEV}_{1,\text{MicroDL}} \]

- Number of observations: 87
- Median: 0.05
- Interquartile range: [-0.03; 0.11]
- Range: [-0.39; 0.38]
- Mean: 0.03
- 95% confidence interval for mean: [0.00; 0.06]
2 Stratified by devices used

1.3 Excluded combinations of copd-6 and MicroDL devices

Eight individuals were excluded from these stratified analyses, because fewer than 15 persons had been tested with the same combination of devices and fulfilled quality criteria. This amount of data was deemed insufficient for statistical analysis, as pre-specified in the analysis protocol.

1.4 Combination of copd-6 device number 2 and MicroDL device number 2

![Plot](image)

\[
\text{FEV}_{1,\text{copd6}} - \text{FEV}_{1,\text{MicroDL}}
\]

Number of observations 60
Median 0.06
Interquartile range \([-0.03 ; 0.12]\]
[2.5 percentile ; 97.5 percentile] \([-0.39 ; 0.33]\]
Range \([-0.40 ; 0.34]\]
Mean 0.04
95% confidence interval for mean \([0.00 ; 0.08]\)
1.5 Combination of copd-6 device number 2 and MicroDL device number 3

FEV\textsubscript{1,copd6} - FEV\textsubscript{1,MicroDL}

Number of observations 103
Median 0.06
Interquartile range [-0.03 ; 0.12]  
[2.5 percentile ; 97.5 percentile] [-0.20 ; 0.33]  
Range [-0.39 ; 0.38]  
Mean 0.05  
95% confidence interval for mean [0.03 ; 0.08]
3 Analysis based on FEV$_6$ instead of FEV$_1$

The results below are based on data from 21 individuals who performed acceptable spirometry with both the copd-6 and the MicroDL devices, and whose best FVC with the MicroDL was from a blow that reached a plateau and stopped within 6 seconds of the start of the blow. In these cases, FEV$_6$ = FVC, meaning we can directly compare FEV$_6$ from the copd-6 with FVC from the MicroDL. Due to the low number of data points, no trend line has been plotted.

\[
\begin{array}{c}
\text{FEV}_{6,\text{copd6}} - \text{FEV}_{6,\text{MicroDL}} \\
\text{Number of observations} & 21 \\
\text{Median} & 0.05 \\
\text{Interquartile range} & [-0.01 ; 0.16] \\
\text{95% prediction interval} & [-0.08 ; 0.30] \\
\text{Range} & [-0.08 ; 0.30] \\
\text{Mean} & 0.08 \\
\text{95% confidence interval for mean} & [0.02 ; 0.13]
\end{array}
\]
4 Analysis based on FEV₁/FEV₆

The results below are based on the 21 individuals as the preceding analysis. I.e., subjects who performed acceptable spirometry with both the MicroDL and copd-6 devices, and whose spiromgrams showed that they had FEV₆ = FVC. Due to the low number of points, no trend line has been fitted.

\[
\frac{\text{FEV}_1}{\text{FEV}_6}^{\text{copd}6} - \frac{\text{FEV}_1}{\text{FEV}_6}^{\text{MicroDL}}
\]

Number of observations  21
Median          -0.02
Interquartile range  [-0.03 ; 0.01]
95% prediction interval [-0.10 ; 0.06]
Range          [-0.10 ; 0.06]
Mean           -0.01
95% confidence interval for mean [-0.03 ; 0.00]
5 Analysis restricted to first three blows with the MicroDL device
To rule out that any differences between the MicroDL and copd-6 devices were due to the number of blows performed with each device (5-9 with the MicroDL, always 3 with the copd-6), analyses were repeated based on the first three blows only for the MicroDL. Otherwise, the same quality criteria were applied as in the main analysis (at least 2 acceptable blows with the MicroDL, difference in best and second-best FEV₁ and FVC both < 0.25 liter).

1.6 Overall results

<table>
<thead>
<tr>
<th>FEV₁,copd6 - FEV₁,MicroDL</th>
<th>Number of observations</th>
<th>Median</th>
<th>Interquartile range</th>
<th>[2.5 percentile ; 97.5 percentile]</th>
<th>Range</th>
<th>Mean</th>
<th>95% confidence interval for mean</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>[0.01 ; 0.14]</td>
<td>[-0.22 ; 0.36]</td>
<td>[-0.39 ; 0.79]</td>
<td>0.07</td>
<td>[0.05 ; 0.10]</td>
</tr>
</tbody>
</table>
1.7 Stratified by order of testing: copd-6 before MicroDL

\[
\text{FEV}_{1,\text{copd}6} - \text{FEV}_{1,\text{MicroDL}}
\]

- Number of observations: 74
- Median: 0.08
- Interquartile range: [0.03; 0.15]
- [2.5 percentile; 97.5 percentile]: [-0.31; 0.36]
- Range: [-0.36; 0.79]
- Mean: 0.08
- 95% confidence interval for mean: [0.05; 0.12]
1.8 Stratified by order of testing: MicroDL before copd-6

**FEV\textsubscript{1,copd6} - FEV\textsubscript{1,MicroDL}**

Number of observations 76
Median 0.07
Interquartile range [-0.02 ; 0.13]
[2.5 percentile ; 97.5 percentile] [-0.22 ; 0.42]
Range [-0.39 ; 0.43]
Mean 0.06
95% confidence interval for mean [0.03 ; 0.10]
6 Analysis with stricter repeatability criteria

For this sensitivity analysis, we used stricter repeatability criteria: For the copd-6, the difference between the best and second-best values of FEV\textsubscript{1} and FEV\textsubscript{6} had to be < 0.15 liters (< 0.10 liters if the best FEV\textsubscript{6} was < 1.00 liters). For the MicroDL, we used the same cut-offs, but for FVC instead of FEV\textsubscript{6}.

<table>
<thead>
<tr>
<th>FEV\textsubscript{1,copd6} - FEV\textsubscript{1, MicroDL}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of observations</td>
</tr>
<tr>
<td>Median</td>
</tr>
<tr>
<td>Interquartile range</td>
</tr>
<tr>
<td>[2.5 percentile ; 97.5 percentile]</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td>Mean</td>
</tr>
<tr>
<td>95% confidence interval for mean</td>
</tr>
</tbody>
</table>