

Comparison of Portable Spirometers (COPS) Study

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Background

As a result of the COVID-19 pandemic, the global spirometry market is expected to reach \$441.6 million by 2028, as companies try to increase their market share with new spirometers for home use. This investigation aimed to compare the performance of two portable spirometers, marketed for home use, with a hospital-based pulmonary function testing unit.

Methods

- Two home spirometers were tested (Aluna & SmartOne) to assess any differences in the FEV1 measurements against a hospital-based unit (Medgraphics).
- 72 separate trial days, with the same study subject, under identical environmental conditions.
- 10-minute rest periods between spirometers.
- Trails 1-26: The control spirometer was tested first followed by the Aluna and then the SmartOne spirometers.
- Trials 27-52: The control spirometer was tested first, and then the order of the home spirometers was reversed.
- Trials 52-72: The control spirometer was tested last with the test units being tested prior, in alternating 10 trial sequences.
- Up to 6 attempts per spirometer was selected as the limit to obtain 3 acceptable spiograms.
- Descriptive statistics were performed to assess the quality of each spirometer FEV1 measurement.
- Bland-Altman analysis was used to measure the agreement in FEV1 measurements between the test spirometers and the control.
- Pearson's coefficient (r) was calculated to assess the agreement between the FEV1 measurements of both test spirometers against the control.
- One-way ANOVA (comparison of means) was conducted to assess the variation between the FEV1 measurements.
- Tukey-Kramer comparison of means was carried out to ascertain if the differences between the spirometers measurements was valid.

Results

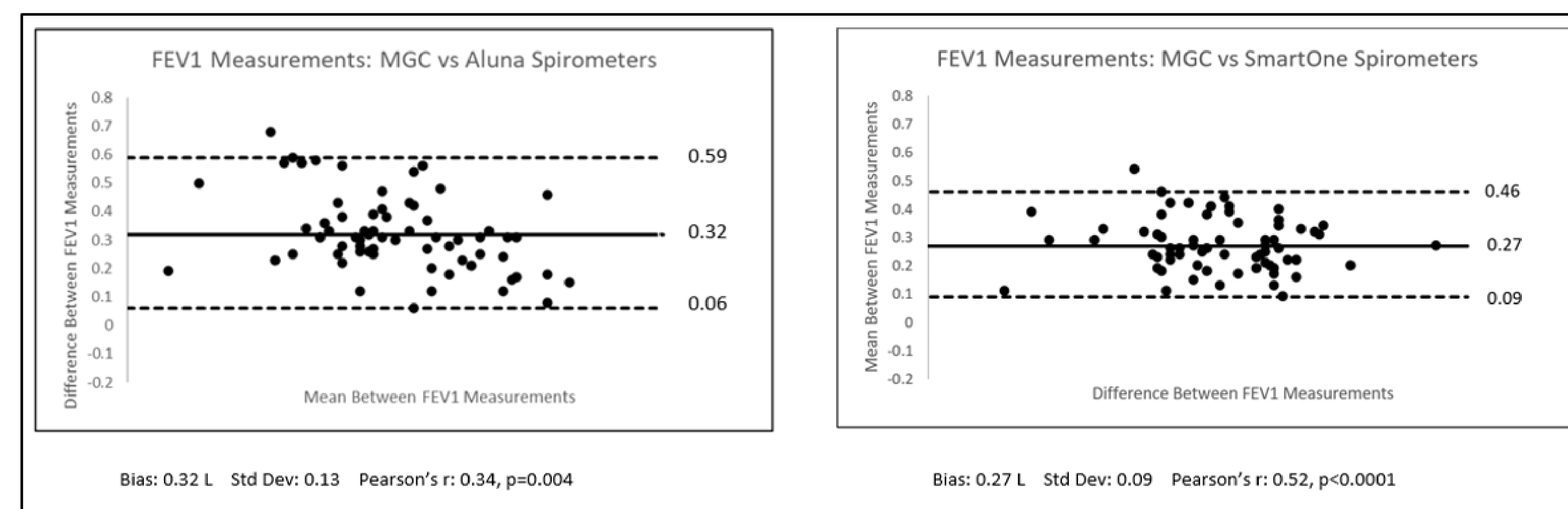
Of all 72 trials; four had to be removed from consideration because the Aluna failed to provide any reportable data, while it produced less than 3 acceptable attempts for an additional 14 trials. No such problems were seen with the SmartOne or MGC control.

Table 1: FEV1 Descriptive Statistics Between the Control and Test Spirometers

| Spirometer | FEV1 mean (SD) | Covariance | Min | Max | < 3 Acceptable Trials |
|------------|----------------|------------|--------|--------|-----------------------|
| MGC | 3.07 (0.09) L | 2.9% | 2.74 L | 3.30 L | 0 |
| Aluna | 2.74 (0.14) L | 4.9% | 2.42 L | 3.03 L | 18 |
| SmartOne | 2.79 (0.10) L | 3.6% | 2.52 L | 2.52 L | 0 |

Bland-Altman plots demonstrated overall agreement in the FEV1 measurements, although the SmartOne spirometer had measurements that were clustered closer to the mean. Pearson's (r) demonstrated a moderately significant association with the measurements made by the control, with the SmartOne outperforming the Aluna unit (0.53 vs 0.34, $P < .001$).

Figure 1: Bland Altman Levels of Agreement Between the Test Spirometers and the Control with Pearson's Correlation (r).



ANOVA analysis revealed the FEV1 measurements were significantly different ($P < .001$) from each unit, while Tukey-Kramer analysis ruled out the null hypothesis between the spirometers.

Conclusion

Despite the moderate correlation, both test units consistently reported lower FEV1 data than the control.

Of the test spirometers, the SmartOne had a stronger correlation with the Control unit, than the Aluna.

Test Spirometers

Aluna Spirometer

- Knox Medical Diagnostics Inc (San Francisco, CA.)
- Stainless Steel Mesh Resistive Elements
- Measures the pressure differential as air passes through the stainless-steel mesh
- Transducer converts the differential into flow (L/sec)

SmartOne Spirometer.

- Medical International Research New Berlin, WI.
- Bidirectional Turbine with Infrared Disrupter
- The velocity of the exhaled air is measured by counting the rotations of the turbine via a digital infrared interruption sensor
- The algorithm in the firmware converts rotations into flow (L/sec)

Disclosures

- The authors of this study report no conflicts of interest.
- IRB Approval #22-36971