Total Lung Capacity (TLC) MiniBox™ vs. Body Plethysmography

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INTRODUCTION

The MiniBox system is based on a novel technique for the measurement of lung volumes. The system is designed to measure lung volumes without the utilization of gases or a Plethysmographic cabin. The system sits on a desk and allows a rapid and user-friendly measurement.

The MiniBox technique has been validated in a prospective multi-center study on over 134 subjects, in Israel.

The purpose of this study, as well as others to come, is to test the accuracy of the measurement on different populations, in different geographies, against several Body Plethysmography devices.

METHOD

This study was held at a private practice in Boston, and included 27 subjects. Each of the patients enrolled was measured at the same day in random order on the MiniBox and the reference Body Plethysmography device, manufactured by Morgan Scientific, Inc.

DISCUSSION

Our results show that TLC_MiniBox is remarkably accurate compared to TLC_Pleth across the entire population studied. Among our prospective cohort of 27 subjects, who were healthy or had varying severities of obstructive and restrictive diseases, TLC_MiniBox correlated well with TLC_Pleth (adjusted r2 = 0.85).

Furthermore, the study showed a CV (Coefficient of Variation) of 10.9%, lower than the CV shown in our multi-center study (134 subjects) of 12.1%, or the CV shown by O'Donnell et al (CHEST, 2010) between Helium Gas Dilution and Computerized Tomography (CT) versus Body Plethysmography of 18.9% and 15.6%, respectively.

STUDY DATA

Body Box device-Morgan Scientific Inc.

Male / Female 14 / 13 Age (years)* 67.6 Height (cm)* 167.5 Weight (Kg)* 78.5 No. Healthy 12 No. Unhealthy 15	No. subjects	27
Height (cm)* 167.5 Weight (Kg)* 78.5 No. Healthy 12	Male / Female	14 / 13
Weight (Kg)* 78.5 No. Healthy 12	Age (years)*	67.6
No. Healthy 12	Height (cm)*	167.5
,	Weight (Kg)*	78.5
No. Unhealthy 15	No. Healthy	12
	No. Unhealthy	15

* Mean

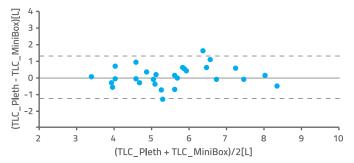


Figure 1: Associated Bland-Altman plots comparing MiniBoxTM TLC (TLC_MiniBox) to Plethysmographic TLC (TLC_Pleth) for all subjects. The solid lines represent the mean bias while the dashed lines represent the upper and lower limits (±1.96*SD). The mean coefficient of variation (CV) is displayed within each graph.

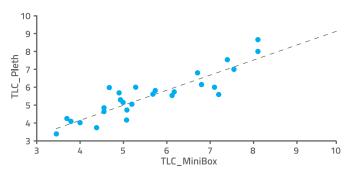


Figure 2: Scatter plots of plethysmographic TLC (TLC_Pleth) vs. MiniBoxTM TLC (TLC_MiniBox) for all subjects. For subjects that were measured more than once on the device, the TLC is presented as the average value of all measurements. The dashed lines represent the unity line and the dotted lines represent the confidence intervals. The linear regression equation and the adjusted R2 are displayed within each graph.

COMPARATIVE STUDIES RESULTS VERSUS BODY PLETHYSMOGRAPHY MiniBox O'Donnel et al. (CHEST, 2010) -O'Donnel et al. (CHEST, 2010) -MiniBox multi-center MiniBox study, in Israel Boston study Cincinnati study Helium Gas Dilution CT (Computerized Tomography) No. subjects 134 27 50 149 149 CV [%] 12.1% 10.9% 9.1% 18.9% 15.6%

