

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

Study conducted at the VA Medical Center, Cincinnati, OH

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 the VA Medical Center in Cincinnati, and included 50 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 MGC Diagnostics.

DISCUSSION

Our results show that TLC_MiniBox is remarkably accurate compared to TLC_Pleth across the entire population studied. Among our prospective cohort of 50 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 9.1%, 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	
No. subjects	50
Male / Female	28 / 22
Age (years)*	71.1
Height (cm)*	166.9
Weight (Kg)*	75.4
No. Healthy	18
No. Unhealthy	32

* Mean

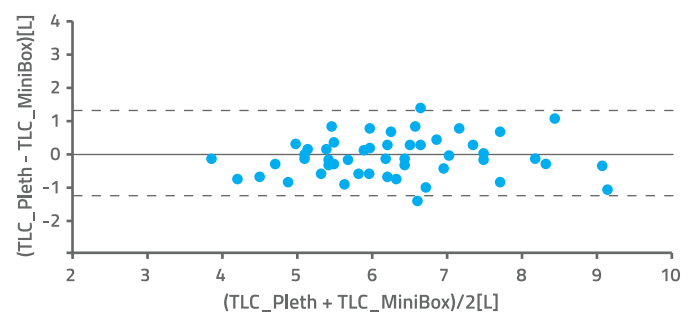


Figure 1: Associated Bland-Altman plots comparing MiniBoxTM TLC (TLC_MiniBox) to Plethysmographic TLC (TLC_Pleth) for all subjects. The solid lines represent the mean bias while the dashed lines represent the upper and lower limits ($\pm 1.96 \times SD$). The mean coefficient of variation (CV) is displayed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

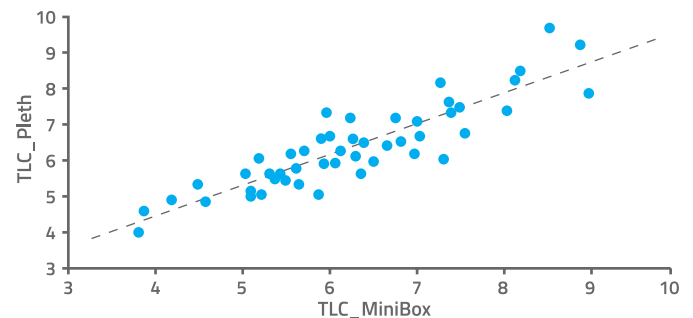


Figure 2: Scatter plots of plethysmographic TLC (TLC_Pleth) vs. MiniBoxTM TLC (TLC_MiniBox) for all subjects. For subjects that were measured more than once on the device, the TLC is presented as the average value of all measurements. The dashed lines represent the unity line and the dotted lines represent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

Comparative study results over time: MiniBox vs. Body Plethysmography

	MiniBox multi-center study, Israel, 2014	MiniBox Boston study, USA, 2017	MiniBox Cincinnati study, USA, 2017	MiniBox Verona study, Italy, 2019	MiniBox Enschede study, Netherlands, 2019
No. subjects	134	27	50	134	30
CV [%]	12.1%	10.9%	9.1%	7.9%	7.8%

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

Study conducted by Dr. David J. Kanarek, Pulmonologist, Massachusetts General Hospital, Boston, MA

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

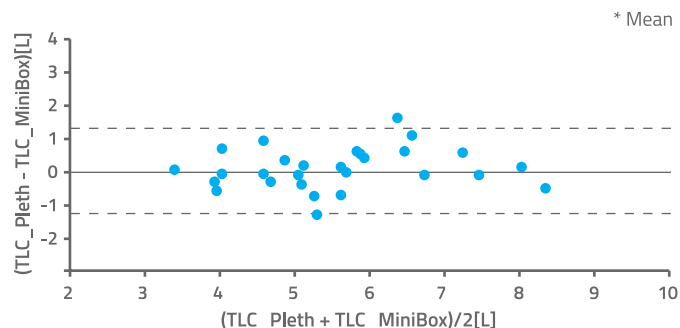


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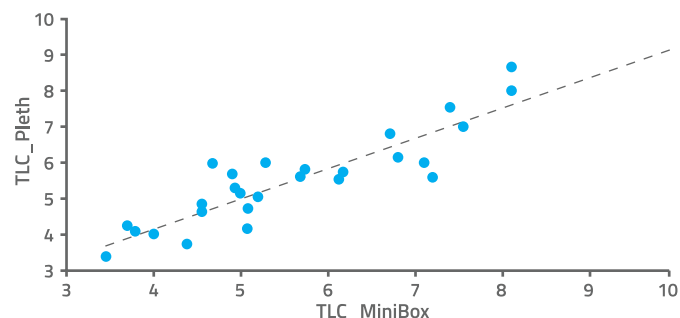


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COMPARATIVE STUDIES RESULTS VERSUS BODY PLETHYSMOGRAPHY

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