

Validation of an ultrasonic device for routine use of the nitrogen washout technique

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INTRODUCTION

We have previously reported successful validation of an ultrasonic prototype device for assessing ventilation inhomogeneity and particularly the Lung Clearance Index (LCI) using Multiple Breath Washout with 4% Sulfurhexafluoride (MBW_{SF6}) including a multicenter feasibility study. However, routine use of MBW_{SF6} is limited because of the green house effect of SF₆, the extended test duration and because SF₆ is not licensed as medical gas in most countries. Nitrogen washout (MBW_{N2}) using 100% oxygen therefore is an attractive alternative. Consequently, the prototype equipment has been adapted for use with 100% oxygen and has recently been implemented into an existing lung function device (EasyOne Pro LAB™, ndd Switzerland), with the aim to facilitate application of MBW_{N2} for clinical routine.

AIM

The aim of the present validation study was

1. to compare MBW_{SF6} (prototype device) with MBW_{N2a} (prototype device) and
2. to compare MBW_{N2a} (prototype device) with MBW_{N2b} (EasyOne Pro LAB™).

METHOD

Subsequent MBW_{SF6}, MBW_{N2a} and MBW_{N2b} were performed in randomised order and during one test occasion in healthy volunteers. 2-3 single washouts were required for each of the three methods.

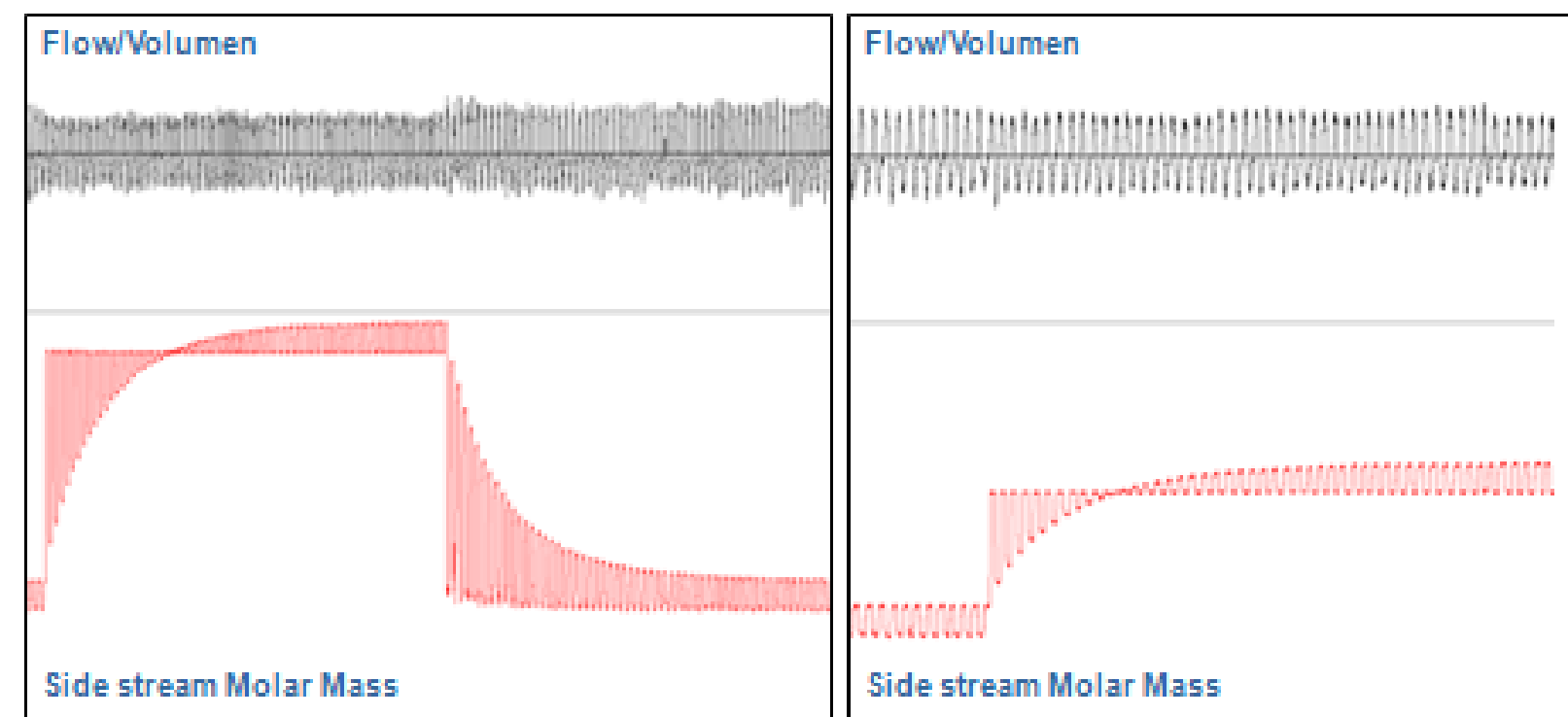
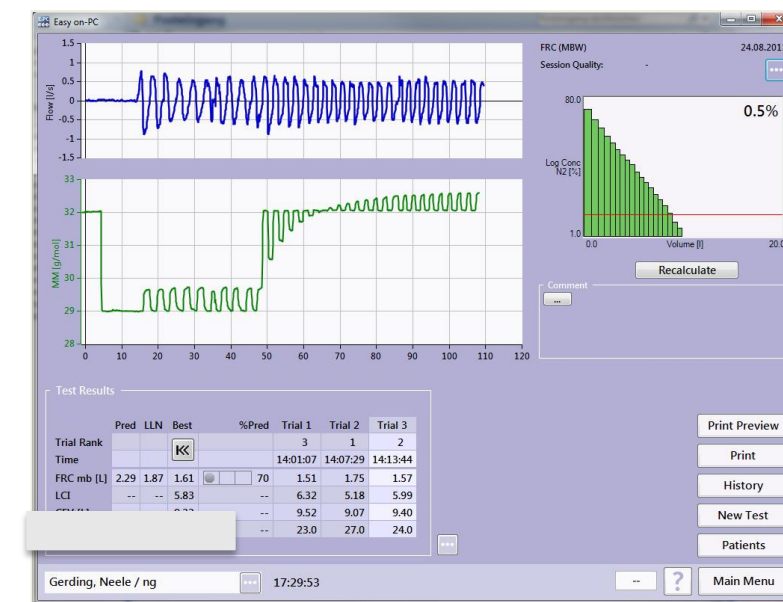


Figure 1: MBW_{SF6} MBW screenshot using the prototype device, requiring manual analysis and longer test duration due to use of SF₆ and multiple use accessories (disinfection between subsequent patients)

Figure 2: MBW_{N2a}



Figures 3 and 4: MBW_{N2b} with EasyOne Pro LAB™ and corresponding screenshot with real time traces of flow and molar mass and automated analysis

RESULTS

17 healthy volunteers (7-51years) were recruited for the study.

Mean LCI_{SF6} (SD) was 6.77 (0.53), mean LCI_{N2a} (SD) was 6.54(0.53) and mean LCI_{N2b} (SD) was 6.56 (0,76).

Mean difference (95% C.I., p-value) between LCI_{SF6} and LCI_{N2a} was 0.21 (-0.13;0.55, 0.210). Mean difference between LCI_{N2a} and LCI_{N2b} was 0.03 (-0.39;0.32, 0.839).

Within-test repeatability of the LCI ranged between 5-6% for each of the three methods.

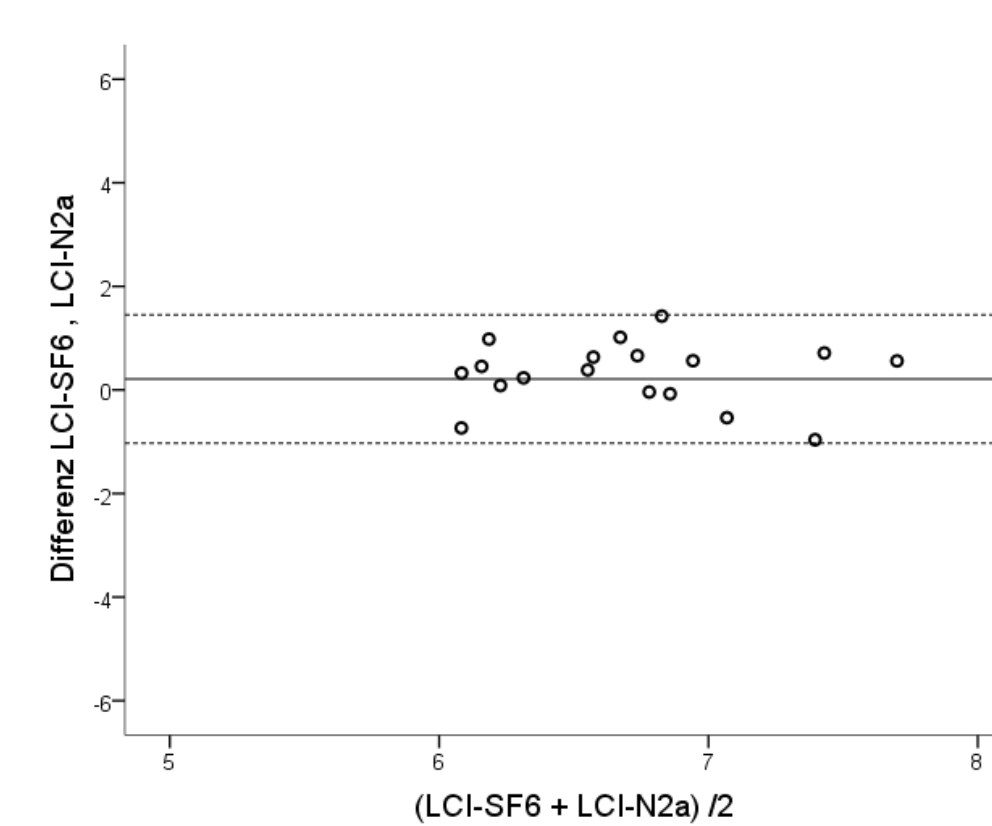


Figure 5: Agreement between individual LCI results for MBW_{SF6} and MBW_{N2a}

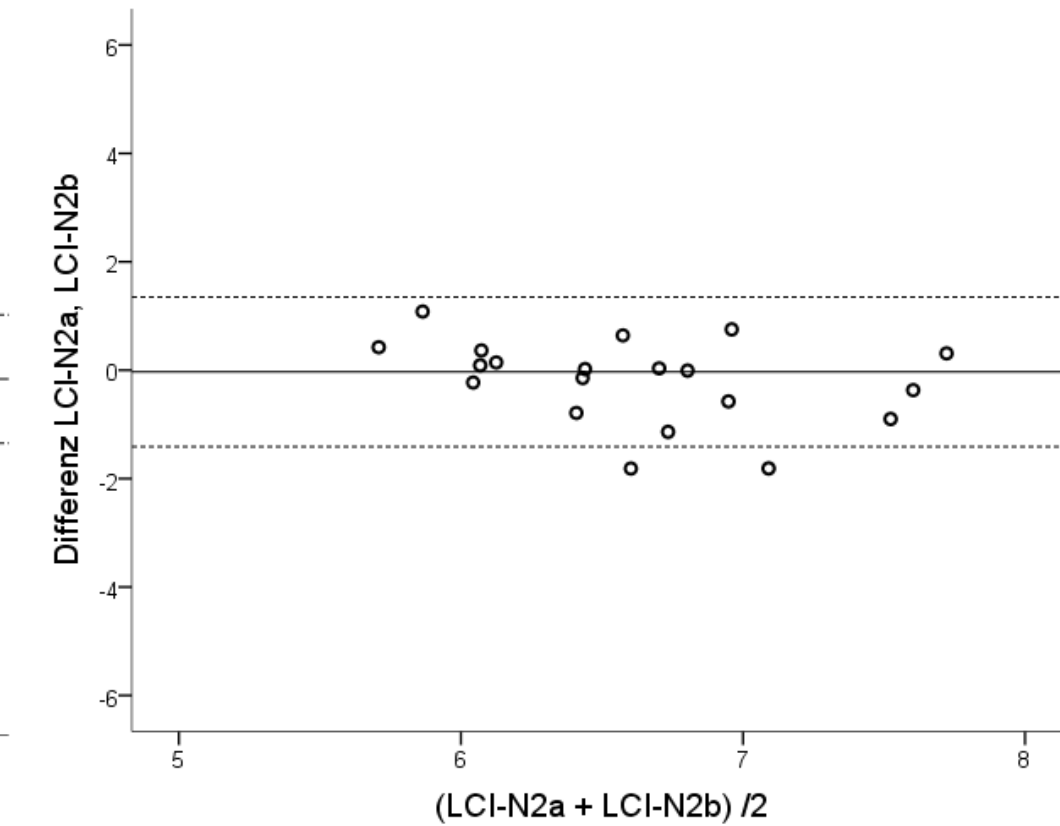


Figure 6: Agreement between individual LCI results for MBW_{N2a} and MBW_{N2b}

CONCLUSION

Nitrogen washout for assessing ventilation inhomogeneity and the LCI using commercially available equipment (EasyOne Pro LAB™) is feasible and yields results similar to those obtained with the preceding prototype device using either SF₆ or N₂. Handling the new device was very easy using 100% O₂ and single use accessories for hygienic safety. The EasyOne Pro LAB is suitable for measuring the LCI in clinical routine.