



## Original Article

## Comparison of facemask and mouthpiece interfaces for multiple breath washout measurements

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### Abstract

**Background:** Different interfaces (mouthpiece/nose clip vs. facemask) are used during multiple breath washout (MBW) tests in young children.

**Methods:** We investigated the effect of interface choice and breathing modalities on MBW outcomes in healthy adults and preschool children.

**Results:** In adults (n = 26) facemask breathing significantly increased LCI, compared to mouthpiece use (mean difference (95% CI) 0.4 (0.2; 0.6)), with results generalizable across sites and different equipment. Exclusively nasal breathing within the facemask increased LCI, as compared to oral breathing. In preschoolers (2–6 years, n = 46), no significant inter-test difference was observed across interfaces for LCI or FRC. Feasibility and breathing stability were significantly greater with facemask (incorporating dead space volume minimization), vs. mouthpiece. This was more pronounced in subjects <4 years of age.

**Conclusion:** Both nasal vs. oral breathing and mouthpiece vs. facemask affect LCI measurements in adults. This effect was minimal in preschool children, where switching between interfaces is most likely to occur.

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**Keywords:** Facemask; Lung clearance index; Functional residual capacity; Cystic fibrosis; Preschool

### 1. Introduction

There is great interest in multiple breath washout (MBW) within the CF community, for both researchers and clinicians. The Lung Clearance Index (LCI) is a sensitive tool for detection of early lung disease, which may not be detected by conventional spirometry outcomes [1]. The LCI can detect response to clinical interventions, despite small study subject numbers [2–6]. In

addition, feasibility to perform the measurement in preschool children (age 2–6 years) is high (typically >80%), making the test desirable to use in young children with CF [7–9]. Feasibility in preschool children has improved with modifications to the test procedure, which include the use of a facemask sealed with therapeutic putty as an alternative to the standard mouthpiece and nose clip assembly (termed mouthpiece in the remainder of the manuscript) [4, 10], yet the full impact of interface choice remains unclear. This is the focus of the current manuscript.

Whilst a facemask is commonly used in preschool children, it also presents challenges. The facemask provides an alternate pathway for ventilation (through nasal breathing), affects airway

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resistance, and adds equipment-related dead space volume ( $V_D$ ), which has been shown to affect LCI results [11]. When assessed at multiple time points through life, children eventually have to switch to a mouthpiece, thus potentially complicating interpretation of longitudinal data. However, the impact of interface change on initial MBW results has not been investigated.

We sought to investigate the effect of using a facemask compared with a mouthpiece in a series of three studies performed in adults, where directed breathing is feasible, and the specific group of interest, preschool children, where this is not. Our aims were (i) to investigate the magnitude of the effect of interface choice on MBW outcomes in adult subjects, (ii) to explore the underlying mechanism for any difference observed by partitioning the  $V_D$  and nasal breathing components and (iii) to directly compare the feasibility and MBW results obtained with the two interface choices in preschool subjects.

## 2. Methods

The three studies, described sequentially below, were performed across three sites: Sick Kids Hospital, Toronto; University College London Great Ormond Street Institute of Child Health (ICH), London and The Children's Hospital at Westmead (CHW), Sydney. Ethics approval was obtained for the specific studies at each site (REB #1000019945, 04/Q0508/42 and QIE-2017-02-03). The two adult studies were performed at Sick Kids and ICH, where healthy adult subjects were recruited from local staff members and friends/relatives of staff. The preschool study was performed at CHW, with preschool aged subjects (defined as 2–6 years) recruited from those performing clinical MBW tests.

### 2.1. Study one

This adult study was performed at ICH using Sulfur hexafluoride ( $SF_6$ ) based custom built inert gas washout equipment, described in detail previously [4]. Subjects were randomly allocated to perform triplicate blocks of MBW trials through either a facemask or mouthpiece interface, followed by a final triplicate with a mouthpiece interface to define inter-test repeatability for mouthpiece results (the conventional interface used in this age group).

### 2.2. Study two

The second adult study was performed at Sick Kids using validated commercial Nitrogen ( $N_2$ ) based MBW equipment (ExhalyzerD  $N_2$ , Eco Medics AG, Duernten, Switzerland), described in detail previously [11]. Adults performed triplicate MBW measurements with 1) a mouthpiece, 2) a facemask (with no specific breathing instructions given), 3) a facemask with exclusively nasal breathing and 4) a facemask with exclusively oral breathing. Therapeutic putty was used in the facemask to minimize  $V_D$  as much as possible without obstructing airflow. The order of interface during triplicate trials was randomly assigned.

### 2.3. Study three

In the preschool study, subjects performed MBW with both a mouthpiece and facemask interface, with order alternated between subjects to ensure that loss of concentration during a prolonged testing session did not negatively affect the results obtained with one particular interface. An initial practice period with each interface occurred prior to testing on the day of visit (up to 15 minute duration). A defined weight of therapeutic putty (50 g) was used with facemasks to ensure an adequate seal and to minimize any additional  $V_D$ . Facemask size was selected based on the best fit for the individual child (Rendell Baker silicone anaesthetic masks, size 2 or 3). Tests utilising both interfaces were performed using the same commercial Nitrogen ( $N_2$ ) based MBW equipment described earlier. Testing was performed in an age appropriate room with the parent present, with the subject seated upright either alone in a chair or on the parent's lap. Video distraction with an age appropriate movie was used during testing. One operator focused on the child and maintaining adequate distraction and interface seal integrity whilst another operator operated the MBW software. Total test duration was up to 60 min, with each interface used for up to 30 min.

In all three studies, MBW testing was performed and results calculated using device specific software [12]. Functional residual capacity ( $FRC_{mbw}$ ) was reported as FRC at the mouth (i.e. measured FRC minus pre-gas sampling point  $V_D$ ). LCI was calculated by dividing the cumulative expired volume (CEV) by FRC measured at the same point (i.e. at the gas sampling point – i.e.  $FRC_{gsp}$ ). CEV was corrected for equipment  $V_D$  but not the additional facemask  $V_D$ , as this component of  $V_D$  is difficult to accurately define. Fowler  $V_D$  was reported as measured within the respective software, based on the  $CO_2$  expirogram and originally described method [13]. Mean expired tidal volume ( $V_T$ ) and  $V_T/FRC$  were calculated for each trial. Results were reported as the mean result across technically acceptable MBW runs. Feasibility of LCI and FRC was assessed in preschool subjects, using a definition of two and three technically acceptable trials. Technical acceptability was based on previously published acceptability criteria, developed from recommendations contained within the consensus guideline [14]. An additional index of breathing pattern stability was calculated as the coefficient of variation for  $V_T$  ( $CV\% V_T$ ) [15]. Paired *t*-tests and Bland Altman plots were used to compare differences within the same subject. The relationship between the observed within-subject differences and explanatory variables was explored using multi-variable linear regression. A *t*-test was used to compare whether the observed differences was statistically different from zero. Statistical analysis was performed using R [16]. Statistical significance was defined as  $p < .05$ .

## 3. Results

### 3.1. Adult data

In study one, 17 adult subjects were recruited: 40% male, mean (SD, range) age 36 (10: 22–56) years. Data quality from

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