Valved holding chambers (VHCs) in conjunction with a facemask are often used by young children who are unable to use pressurized metered dose inhalers (pMDIs) effectively (1-2). Facemasks are often overlooked as a factor that can influence inhalation drug therapy because of the high cost, variable findings, and ethical quandaries regarding using young children as subjects in clinical studies. The lack of a standardized way to connect facemasks to conventional in vitro aerosol testing equipment is an additional complication (3). However, recent studies have demonstrated that facemasks play an important role in drug delivery from VHCs (4-5), and soft anatomical model (SAM) face replicas have been used to preserve clinical relevance during in vitro testing with facemasks (6). SAM-based in vitro test equipment has now evolved to simulate facemask height, applied force and application angle during evaluation of VHCs with facemasks under simulated breathing conditions (7). This paper builds on a previous study (7) to compare the percent facemask seal leakage and drug delivery efficiency from three VHC-facemask systems.

**METHODS**

SAM Face Replica Leakage Validation

Percentage leakages across the facemask was tested in as Figure 1, and defined as:

\[
\text{Percent leakage} = \left(\frac{Q_2 - Q_1}{Q_2}\right) \times 100
\]

Leakage across the facemask was determined to be 1.5% at a constant simulated inhaled airflow rate 30 L/min, which was judged to be satisfactory.

Facemask Leakage and Albuterol Delivery Efficiency Tests

All VHCs were of similar volume and dimensions, and claimed to exhibit anti-static properties. Each VHC was tested with its marketed facemask of the recommended size:

1. Pre-production OptiChamber Diamond VHCs with LiteTouch facemasks (Philips Respironics, Parsippany, NJ)
2. AeroChamber™ Plus 2 STAT™ VHCs with ComfortSeal™ facemasks (Monaghan, Plattsburg, NY)
3. Vortex® VHCs with Spinner® Duck facemasks (PARI, Midlothian, VA)

First, the optimal facemask position on the face for each VHC-facemask system was determined, as shown in Figure 2 (Actuator A). VHC-facemask systems and Actuator A were sealed to prevent leaks unrelated to facemask. A 1.9 kg applied force held the facemask to the face replica while constant flows of 15 and 30 L/min were applied. The height of the facemask relative to the facemask was adjusted until leakage was minimal for each VHC-facemask system.

**RESULTS AND DISCUSSION**

Albuterol delivery efficiency for each VHC-facemask system was determined, as shown in Figure 2 (Actuator B). The downstream side of the facemask was connected to a breathing simulator (ASL 5000, IngMar Medical, Pittsburgh, PA) and 50% tidal volume=155 ml, breathing rate=25 breath/min, inhalation to exhalation ratio=40:60. Each VHC-facemask system was tested with either 0.45 or 1.9 kg applied force under 0° face tilt for 1 simulated pediatric breath, as shown in Figure 3.

Five pMDI actuations were actuated into the VHC during each test to ensure a quantifiable amount of albuterol was collected on the filter. Albuterol sulfate recovered from the filter (Filter Dose) and VHC/facemask/actuator (Undelivered Dose) was quantified by HPLC and used to calculate:

\[
\text{Albuterol Delivery Efficiency} = \left(\frac{\text{Filter Dose}}{\text{Undelivered Dose}}\right) \times 100
\]

The delivery efficiency of the OptiChamber Diamond-LiteTouch system was significantly higher than both the AeroChamber 2 Stat-ComfortSeal and Vortex-Spinner Duck systems under the same applied force (p<0.05). This was attributed to the more efficient face seal in the LiteTouch, which allowed more airflow, and subsequently more complete drug entrainment and emptying from its OptiChamber Diamond VHC and onto the filter during each simulated inhalation.

**REFERENCES**


The LiteTouch facemask exhibited the lowest leakage (approximately 7 and 10% at 15 and 30 L/min, respectively), while the Spinner Duck facemask exhibited the highest leakage (approximately 94 and 91% at 15 and 30 L/min, respectively).