Effect of Simulated Facial Movement on the Seal Integrity of a Valved Holding Chamber Mask

D. von Hollen, J. Guzman, E. Lieberman, K. Nikander, Philips Respironics, Respiratory Drug Delivery, Parsippany, NJ, USA.

Introduction

Patients using a pressurized metered dose inhaler (pMDI) require good hand-breath coordination in order to effectively administer a dose of medication. A valved holding chamber (VHC) used with a pMDI can alleviate problems in drug administration for patients with a lack of hand-breath coordination. A facemask is used by patients who are unable to use a VHC with a mouthpiece alone effectively. An effective seal between the patient's face and the VHC facemask is essential for drug delivery performance as a leak can reduce the dose delivered. 1, 2 Therefore, a conforming, leak-preventing design is critical. The range of facial geometries and ages of users of a VHC facemask as well as variation in application during clinical use pose a significant challenge in terms of both facemask design and in vitro testing. In vitro testing can mimic clinical use in such a way to allow scientifically valid investigations to be performed on operational parameters of device performance and is an important part of the device development process. Test standards have been developed for the testing of pMDIs with VHCs, but there is no equivalent standardization for VHC facemask testing.

In vitro testing of facemasks can be performed using a Soft Anatomical Model (SAM), a soft cast face replica of a 4 year old child (PA Consulting Group, Melbourne, UK) that is formed from an underlying rigid structure overlaid with flexible 10 durometer silicone, to mimic the compliance of fleshy areas of the face. 3 The SAM face replica can be fitted to a custom test rig designed to mimic multiple aspects of patient use/misuse (including applied force and angle of application) for in vitro testing of the sealing efficiency of VHC facemasks. The facemask under test is attached to the test rig via custom adapters. These are designed to mimic the original VHC-facemask connection for each facemask. The adapter is attached to a sliding shuttle that allows reproducible application of the facemask to the SAM face replica, which is mounted on the test rig so as to allow for forward/backward movement to ensure accuracy positioning under the facemask. At the top of the sliding shuttle, a restraining rod can be loaded with weights to mimic relevant applications of force. 4 The SAM face replica can also be tilted to mimic the range of angles of application that occur during clinical use. Two in-line flow meters positioned on either side of the facemask connection determine the peak airflow through the test rig.

Method

Table 1: Photographs of facemasks applied to SAM face at various angles of tilt and 0.45 kg applied force. The SAM face is positioned such that the chin is to the left of the picture, and the top of the head is to the right.

<table>
<thead>
<tr>
<th>Angle of tilt</th>
<th>0 degrees</th>
<th>10 degrees</th>
<th>-10 degrees</th>
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<tbody>
<tr>
<td>Pediatric face mask</td>
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<tr>
<td>LiteTouch face mask</td>
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<td>ComfortSeal face mask (AeroChamber Max)</td>
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Five facemasks were selected for testing according to the manufacturers’ sizing charts. The 5 facemasks were the Pediatric facemask (OptiChamber Advantage, Philips Respironics), prototype LiteTouch facemask (Philips Respironics), ComfortSeal facemask (AeroChamber Max, Monaghan Medical), ComfortSeal facemask (AeroChamber Max, Monaghan Medical), and a Panda facemask (PocketChamber, iSpire Health, Inc.).

Each mask was attached to the custom test rig using a custom adapter and lowered onto the SAM face replica. The facemasks were tested using a pediatric breathing pattern (Vt=155mL, bpm=22, EE=1:1.5). Mass airflow meters (TSI Inc., Shoreview, MN) were used to measure the peak airflow through the test rig at the input of the facemask and the output of the facemask (which represented the flow through the VHC) over approximately 10 cycles of breathing. The variables tested were the weights of 0.45kg, 0.9kg and 1.8kg and face tilt angles of 0°, ± 5° and ± 10°. The restraining rod at the top of the shuttle was loaded with weights of 0.45kg, 0.9kg or 1.8kg to mimic relevant applications of force. The SAM face replica was tilted to -10°, -5°, 0°, +5° or +10° to mimic different angles of application. The test was repeated for each weight, angle and facemask combination in triplicate and the percentage leakage for each facemask was calculated using ((Peak input flow- Peak output flow)/Peak input flow) x 100.

Results

The percentage leakage recorded in the tests ranged between 2.2% and 97.2% and varied according to the brand of facemask, applied force and angle of application. The prototype LiteTouch facemask produced the least amount of leakage in 14 of the 15 test conditions.

Conclusions

• The prototype LiteTouch facemask had the most efficient seal with the least amount of leakage under all but one of the applied force and application angle test conditions.

Discussion

The results show that the seal efficiency of the facemasks tested depended upon the brand of facemask tested and the angle of application. There was also variation according to the force applied, high levels of applied force resulted in lower leakage for most of the facemasks. However, application angle had the greatest effect upon leakage, particularly at a tilt of ±10°. The LiteTouch facemask had the least amount of leakage under all of the applied force and application angle test conditions, apart from at ±10° with the smallest applied force tested, 0.45kg. The construction of the custom test rig allowed researchers to conduct an in vitro, reproducible study into various aspects of the VHC facemask which could contribute positively to the design development process.

References


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