Quantifying Facemask Sealing Efficiency when used on a Valved Holding Chamber During Simulated Breathing


Introduction
Valved holding chamber (VHC) facemasks are used by patients who are unable to effectively receive pressurized metered dose inhaler treatments using a VHC mouthpiece. A leak between a patient’s face and the facemask of a VHC can reduce the dose of medication delivered to the patient, which make the design of facemask a critical feature of a VHC. The relevance of in vitro facemask testing to real life situations has historically been hampered by the complexity of human facial anatomy. Previous attempts to model human faces for in vitro testing have comprised simple hard surface face replicas. The Soft Anatomical Model (SAM) face replica was created to address this issue (Figure 1). The SAM face is a soft cast of a 4 year old child (PA Consulting Group, Melbourne, UK) made from low durometer (10) silicone. The silicone simulates the soft, compliant fleshy areas of the human face, such as the surface of the face will deform slightly upon application of a facemask. This should allow more relevant tests to be performed that has been the case when using hard face replicas. The value of in vitro testing relies on the fact that tests can be conducted in a controlled manner using the same parameters for each test, changing only one variable at a time. Varying just one of a number of parameters, allows an assessment of the influence of that one parameter upon the overall outcome. A purpose built test fixture was designed to facilitate reproducible in vitro testing of VHC facemasks using directly relevant application forces (Figure 2). We used the test fixture with SAM face replica to test three VHC facemasks with different seal geometries.

Method
The test fixture and the SAM face replicas were utilized to test and compare three different facemasks for use with VHCs (Table 1). The size of each brand of facemask was selected using an assessment of seal efficiency to the SAM face replicas.

<table>
<thead>
<tr>
<th>Facemask name</th>
<th>Manufacturer</th>
<th>Seal geometry</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>PrestoLite facemask</td>
<td>Philips Respironics, Respiratory Drug Delivery, Parsippany, NJ</td>
<td>Three dimensional silicone cushion seal</td>
<td>Medium</td>
</tr>
<tr>
<td>Panda facemask</td>
<td>Gairns Healthcare Inc., Longmont, CO</td>
<td>Silicone flange</td>
<td>Medium</td>
</tr>
<tr>
<td>ComfortSeal facemask</td>
<td>Monaghan Medical Corp., Plainview, NY</td>
<td>Silicone cushion seal</td>
<td>Medium</td>
</tr>
</tbody>
</table>

The test fixture allows for simulated forces to be applied to each facemask to assess the force needed to obtain a seal. Forces of 0.45 kg (1 lb), 0.9 kg (2 lb) and 1.8 kg (4 lb) were applied to the facemask, while allowing airflow through the facemask and the SAM face replicas. Airflow through the SAM face replica was measured using a mass airflow meter (TSL Inc., Shoreview, MN). A Harvard respirator (Harvard Apparatus, Holliston, MA) was used to simulate a pediatric breathing pattern (Vt = 155 mL, bpm=25, 16=1.5).

Results
There was a wide variation in the leakage among the three facemask designs tested. The design of the facemask had a greater influence upon the percent leakage than the applied force. There was no leakage when testing the Prototype facemask at all amounts of applied force. Leakage from the other two facemasks was affected by the amount of applied force. Leakage from the Panda facemask was most affected by the applied force, whereas applied force had only a marginal effect upon leakage from the ComfortSeal facemask.

Discussion
The new purpose built test fixture offers the researcher the opportunity to conduct a wide variety of facemask testing under reproducible conditions and can be a valuable tool in the development of new more effective facemask designs. Leakage from the facemask to the face can significantly reduce the amount of drug that the patient receives. The results of these tests showed that there was a large variation in the effectiveness of seal facemask across different design, and that the effectiveness of increased application force was also facemask design dependent. It should, however, be noted that these in vitro tests were only performed on one pediatric face replica of a 4-year-old child, using one size of mask. Different face geometries from face replicas representing older and younger children should also be tested with appropriate mask sizes to give a more comprehensive assessment of the efficiency of various facemask designs across a representative age range.

Conclusions
- The results indicate that facemask design affects the leakage between face and facemask.
- The force required to minimize leakages varies depending on facemask design.
- The Prototype facemask did not leak at any of the applied forces.

References

Presented at the Association of Asthma Educators annual conference, 31st July – 2nd August, 2009, New Orleans, LA.