

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

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Introduction

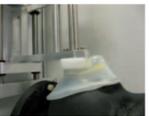
Patients using a pressurized metered dose inhaler (pMDI) require good hand-breath coordination in order to effectively administer a dose of medication. A valved holding chamber (VHC) used with a pMDI can alleviate problems in drug administration for patients with a lack of hand-breath coordination. A 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 poses a significant challenge in terms of both facemask design and *in vitro* testing. *In vitro* testing can mimic clinical use in such a way as to allow scientifically valid investigations to be performed on operational parameters of device performance and this 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.³⁻⁶ 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 accurate positioning under the facemask. At the top of the sliding shuttle, a retaining rod can be loaded with weights to mimic relevant applications of force.⁷ 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 face-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 0.9 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.

Angle of tilt	0 degrees	10 degrees	-10 degrees
Pediatric facemask			
LiteTouch facemask			
ComfortSeal facemask (AeroChamber Plus)			
ComfortSeal facemask (AeroChamber Max)			
Panda facemask			

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 Plus, Monaghan Medical), ComfortSeal facemask (AeroChamber Max, Monaghan Medical), and a Panda facemask (PocketChamber, nSpire 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 ($V_t=155\text{mL}$, $\text{bpm}=25$, $I:E=1:1.5$). Mass airflow meters (TSI Inc., Shoreview, MN) were used to measure the peak airflow through the test rig at the input of the face replica 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° , $\pm 5^\circ$ and $\pm 10^\circ$. The retaining 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° , $+5^\circ$ or $+10^\circ$ 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 $((\text{Peak input flow} - \text{Peak output flow}) / \text{Peak input flow}) \times 100$.

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.

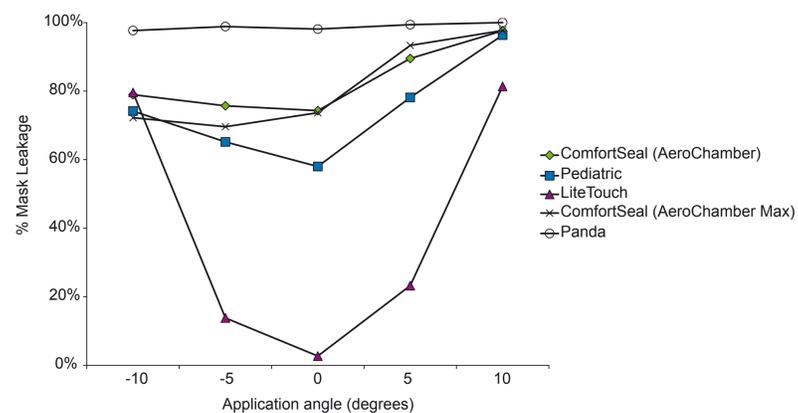


Figure 2. Effect of application angle on leak between face and facemask with 0.45 kg applied force.

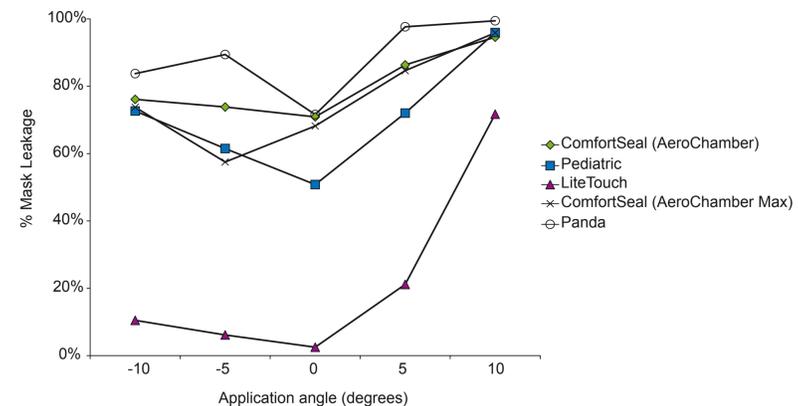


Figure 3. Effect of application angle on leak between face and facemask with 0.9 kg applied force.

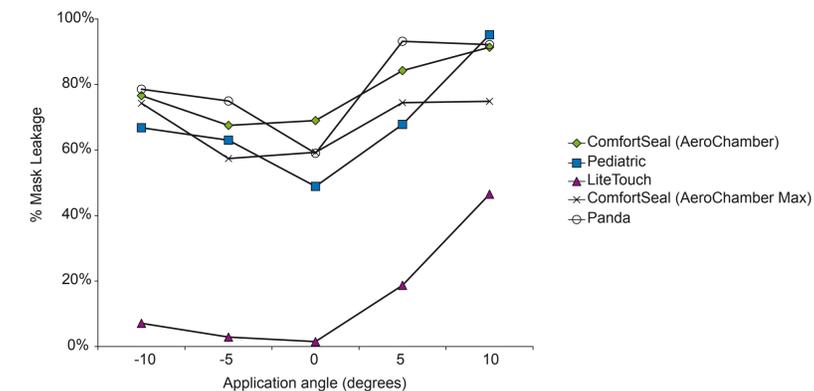


Figure 4. Effect of application angle on leak between face and facemask with 1.8 kg applied force.

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 $+10^\circ$. 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.

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.
- Application angle had the greatest impact upon leakage between the VHC facemask and the SAM replica; the change in angle of application from 0° to $\pm 5^\circ$ and $\pm 10^\circ$ increased the leakage in the majority of test conditions.
- Clinical factors such as positioning and the force of application can be assessed *in vitro* and in combination to challenge the effectiveness of facemask designs. This could be used to assist the design process.

References

- Esposito-Festen JE, Ates B, van Vliet FJM, Verbraak AFM, de Jongste JC, Tiddens HAWM. Effect of a facemask leak on aerosol delivery from a pMDI-spacer system. *J Aerosol Med*. 2004;17:1-6.
- Amirav I, Newhouse MT. Aerosol therapy with valved holding chambers in young children: Importance of facemask seal. *Pediatrics*. 2001;108:389-394.
- Nikander K, Berg E, Smaldone GC. Jet nebulizers versus pressurized metered dose inhalers with valved holding chambers: effects of the facemask on aerosol delivery. *J Aerosol Med*. 2007;20(Suppl 1):s46-s55.
- Smaldone GC, Berg E, Nikander K. Variation in pediatric aerosol delivery: Importance of face mask. *J Aerosol Med*. 2005;18(3):354-363.
- Smaldone GC, Sangwan S, Shah A. Face mask design, facial deposition, and delivered dose of nebulized aerosols. *J Aerosol Med*. 2007;20(Suppl 1):s66-s77.
- Sangwan S, Gurses BK, Smaldone GC. Facemasks and facial deposition of aerosols. *Pediatr Pulmonol*. 2004;37:447-452.
- Shah SA, Berlinski AB, Rubin BK. Force-dependant static deadspace of facemasks used with holding chambers. *Resp Care*. 2006;51(2):140-144.
- Erzinger S, Schueep K, Brooks-Wildhaber J, Devadason SG, Wildhaber JH. Facemasks and aerosol delivery. *J Aerosol Med*. 2007;20(Suppl 1):S78-S84.

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