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

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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 makes the design of facemask a critical feature of a VHC. [1,2] 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). [3]

The SAM face is a soft cast of a 4 year old child (PA Consulting Group, Melbourne, UK) [4-7] made from low durometer (10) silicone. The silicone simulates the soft, compliant fleshy areas of the human face, such that the surface of the face will deform slightly upon application of a facemask. This should allow more relevant tests to be performed than has been the case when using hard face replicas.

The value of *in vitro* testing relies on the fact that tests that 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 clinically relevant application forces (Figure 2). [8]

We used the test fixture with SAM face replica to test three VHC facemasks with different seal geometries. [9-10]

Figure 1. Front and side aspect views of the SAM face replica.

Method

The test fixture and the SAM face replica 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 replica.

Table 1. Details of facemasks tested.

Facemask name	Manufacturer	Seal geometry	Size
Prototype facemask	Philips Respironics, Respiratory Drug Delivery, Parsippany, NJ	Three dimensional silicone cushion seal	Medium
Panda facemask	nSpire Health, Inc. Longmont, CO	Silicone flange	Medium
ComfortSeal facemask	Monaghan Medical Corp., Plattsburgh, NY	Silicone cushion seal	Medium

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 replica. Airflow through the SAM face replica was measured using a mass airflow meter (TSI Inc., Shoreview, MN). A Harvard respirator (Harvard Appartus, Holliston, MA) was used to simulate a pediatric breathing pattern (Vt = 155 mL, bpm=25, I:E=1:1.5).

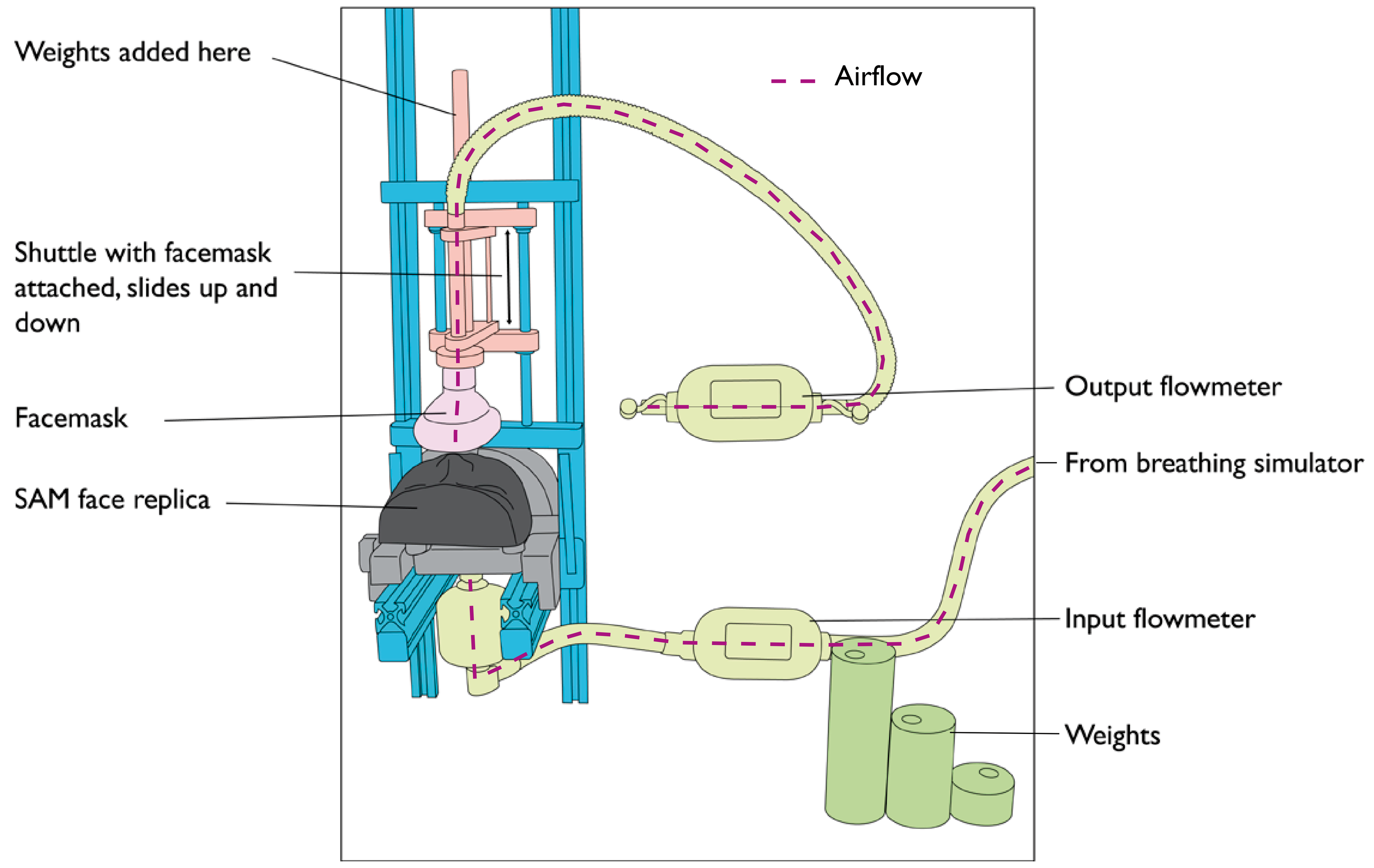

Figure 2. Test fixture and connections to flow meters.

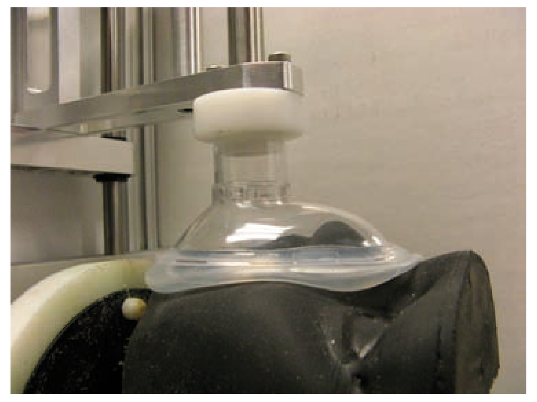

Figure 3. Example of Prototype facemask fitted to the test fixture.

Figure 4. Example of Panda facemask fitted to the test fixture.

Figure 5. Example of ComfortSeal facemask fitted to the test fixture.

The input flow meter was placed after the Harvard respirator and before the SAM replica in order to establish a baseline (no leakage) maximum available peak inhalation flow. In order to perform the leakage test, each facemask was positioned to obtain the best possible seal (Figures 3-5). The output flow meter was connected to the VHC side of the facemask via a custom adapter representing the VHC fitting. The flow at this fitting represented the flow through the VHC. The facemask was lowered onto the SAM face replica and individual weights were applied to the test rig to simulate a clinical application of a constant force. The Harvard respirator was activated for 10 cycles and the peak inhalation flow through the mass flow meter over the 10 cycles was recorded. This process was repeated in triplicate for each facemask. During each test condition the percentage of leakage for each facemask was calculated using [1 - (mean peak inhalation flow/baseline peak inhalation flow)] x 100.

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.

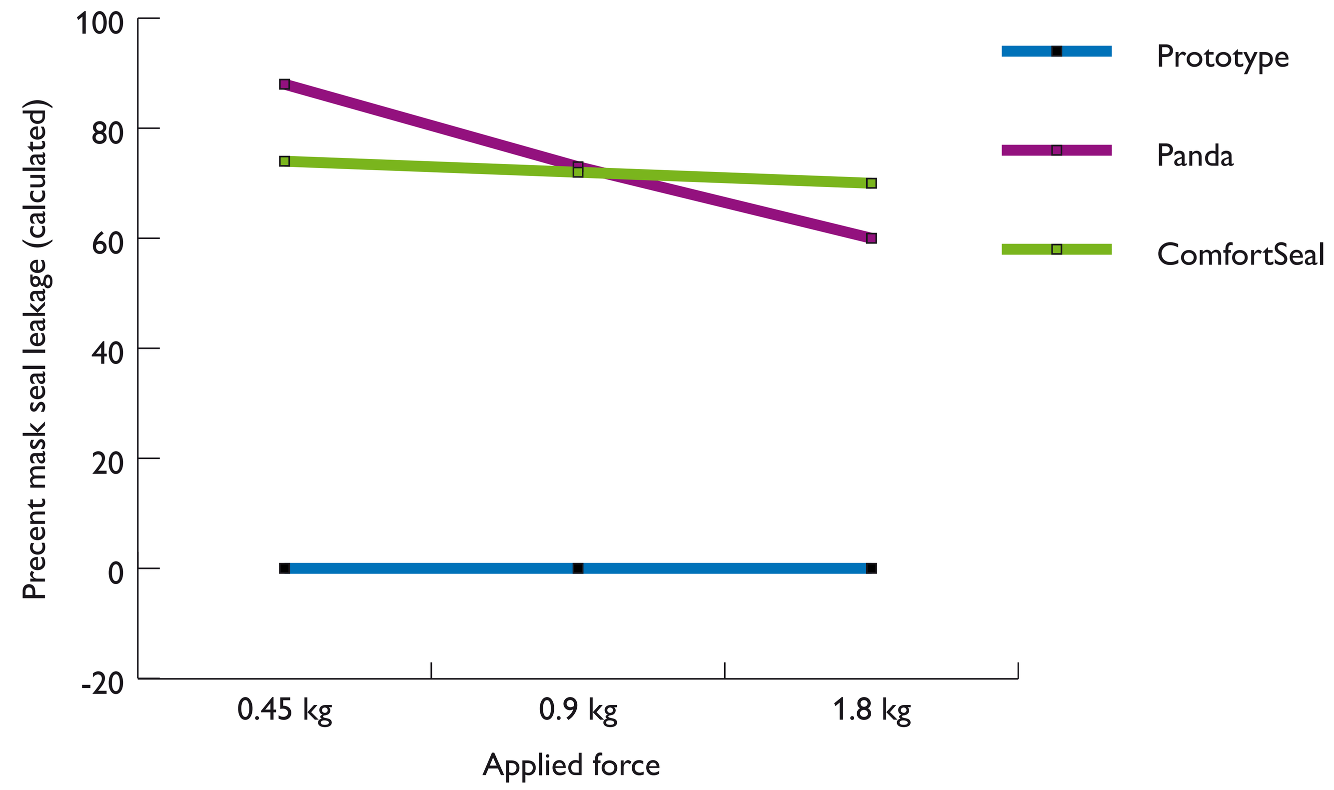

Figure 6. Leak from each of the facemasks.

Discussion

The new purpose built test fixture offers researchers the opportunity to conduct a wide variety of facemask tests 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. [1,2,5,11] The results of these tests showed that there was a large variation in the effectiveness of facemask seal across different facemask designs, and that the effectiveness of increased application force was also facemask design dependant. 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

1)Esposito-Festen, J.E., Ates B., Van Vliet F.J.M., Verbraak A.F.M., De Jongste J.C., Tiddens H.A.W.M. Effect of a facemask leak on aerosol delivery from a pMDI-spacer system. J. Aerosol. Med. 2004;17:1-6.
2)Amirav I., Newhouse M.T., Aerosol therapy with valved holding chambers in young children: Importance of facemask seal. Pediatrics. 2001;108:389-394.
3) Lieberman E.A., Sousa N.M., von Hollen D. In vitro techniques for evaluating eye deposition of aerosolized drug associated with nebulizer facemasks. In: Proceedings of Respiratory Drug Delivery 2008. May 11-15; Scottsdale: Virginia Commonwealth University, 2008.
4) Nikander K., Berg E., Smaldone G.C. Jet nebulizers versus pressurized metered dose inhalers with valved holding chambers: effects of the face mask on aerosol delivery. J Aerosol Med. 2007;20(Suppl 1):s46-s55
5) Smaldone G.C., Berg E,. Nikander K. Variation in pediatric aerosol delivery: Importance of face mask. J Aerosol Medicine. 2005;18(3):354-363.
6) Smaldone G.C., Sangwan S., Shah A. Face mask design, facial deposition, and delivered dose of nebulized aerosols. J Aerosol Med. 2007;20(Suppl 1):s66-s77
7) Sangwan S., Gurses B.K., Smaldone G.C. Face masks and facial deposition of aerosols. Pediatr Pulmonol. 2004;37:447-452
8) Shah S.A., Berlinski A.B., Rubin B.K. Force-dependant static dead space of face masks used with holding chambers. Resp Care. 2006;51(2):140-144.
9) von Hollen D., Lieberman E., Nikander K., Sousa K. A novel method to assess the seal efficiency of valved holding chamber facemasks. Respir Care. 2008;53(11)
10) von Hollen D., Lieberman E., Nikander K. Comparison of the sealing efficiency of valved holding chamber masks during simulated breathing. J Allergy Clin Immunol. 2009;123(2):S66.
11) Erzinger S., Schueep K.G., Brooks-Wildhaber J., Devadason S.G., Wildhaber J.H. Facemasks and aerosol delivery. J Aerosol Med. 2007:20 (Suppl 1):S78-S84.

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