In vitro characterization of adding a partition separating mouth from nose in a pediatric facemask

K4-120

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Introduction

Comparison of the *in vitro* properties of two pediatric masks for valved holding chambers of identical shape with one comprising a septum blocking nasal inhalation.
A newly designed mask with septum[1] (MS, Or'hal®, Laboratoire Protec'Som) was compared *in vitro* to a similar mask but without septum (MP, Protec'Som). Essential characteristics of child facemasks were measured in vitro: flexibility, volume and seal to the face, and their relationship to in vitro drug deposition[2].

Material and methods

Both masks were used with the same valved-holding chamber (VHC, Tips-haler®, Laboratoire Protec'Som). Flexibility, volume and seal of the masks were measured against 5 forces (0; 0.5; 1; 1.5; 2kg). Flexibility was estimated as a force-dependent length reduction of the masks onto a hard and flat surface; and expressed as the slope of length versus force regression line (figure 1A). Masks volumes were determined by the water displacement method[3] (figure 2A). Seal was evaluated by applying mask-VHC to a realistic 3D supple face model (Copley Scientific) and delivering constant airflow (figure 3A). Integrity of the seal was expressed as the ratio of airflow before and after the mask-VHC-face system. Aerosol delivery (figure 4A) was assessed using an *in vitro* mouth inhalation model (Copley Scientific) at two clinically relevant application forces (0.5 and 1kg) and a breathing simulator (Copley Scientific). Aerosol (Fluticasone propionate, Flixotide®, GlaxoSmithKline) was captured on a filter (Copley Scientific) and drug concentration was assayed by spectrophotometry at 236nm.

References

1. Ditcham, W. *et al.* Lung deposition of 99mTc-radiolabeled albuterol delivered through a pressurized metered dose inhaler and spacer with facemask or mouthpiece in children with asthma. *J Aerosol Med Pulm Drug Deliv* 27 Suppl 1, S63-75 (2014).
2. Amirav, I. & Newhouse, M. T. Review of optimal characteristics of face-masks for valved-holding chambers (VHCs). *Pediatr. Pulmonol.* 43, 268–274 (2008).
3. Shah, S. A., Berlinski, A. B. & Rubin, B. K. Force-Dependent Static Dead Space of Face Masks Used With Holding Chambers. *Respir Care* 51, 140–144 (2006).

Conclusion

The results show that within the scope of our *in vitro* model, changes in volume and seal did not affect drug deposition.
The use of facemasks adds complexity to the design and assessment of VHCs. Despite 80% of VHCs (in France, in 2015) selling with pediatrics masks, research is still scarce. The primary function of this mask with septum is to block nasal breathing, oral inhalation being favored for lung treatment, and recommended by guidelines[1].
However, mask design should not otherwise compromise drug delivery. Mask-to-face seal and dead space volume can affect medication delivery, especially for children with low tidal volume. It is therefore essential to develop robust *in vitro* models to test those parameters when designing new masks.

Results

Masks characteristics

Flexibility

Logically, the addition of a septum inside the mask decreased masks' capacity for deformation (MP: -0.80, r^2=9894; MS: -0.57, r^2=0.9758). The effect on masks length show at forces beyond 1 kg (figure 1B).

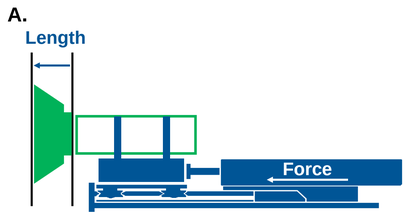
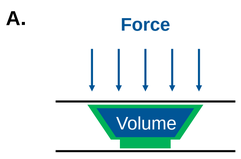


Figure 1 : Masks flexibility.
A. Flexibility testing apparatus assembly.
B. Masks length as a function of applied force.

Volume



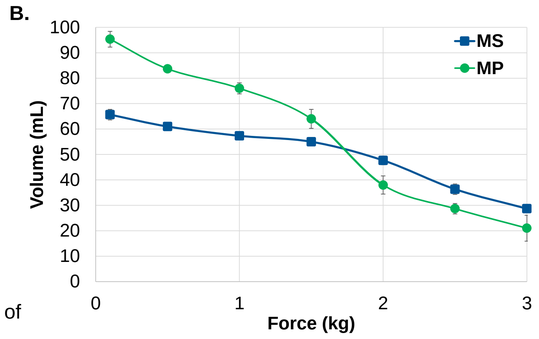
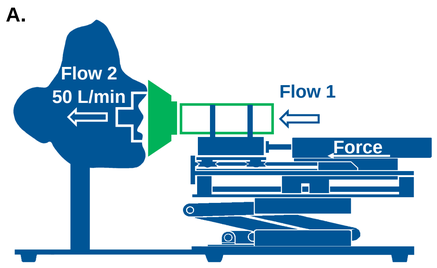


Figure 2 : Masks volume.
A. Volume testing apparatus assembly.
B. Masks volume as a function of applied force.

Despite initial volume reduction (27% at 0.5kg) due to the partition, MP and MS volume were equivalent at higher application forces (above 1.5 kg) due to reduced flexibility (figure 2B).
Out of 10 masks for VHCs currently on the market in France (data not shown), the lowest volume at rest was 60 mL and the largest volume at rest was 120 mL (only 4 masks had a volume below 70 mL).

Seal

The septum also increased seal efficiency to the face model by 15% at 0.5kg and 29% at 2kg (figure 3B).



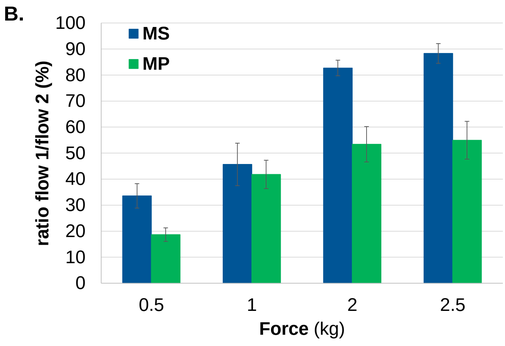
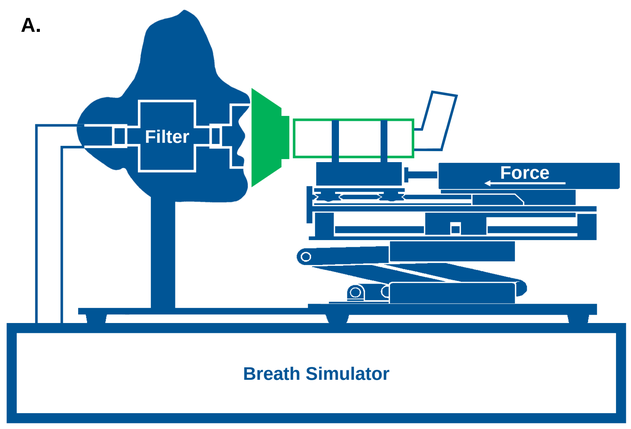


Figure 3 : Mask-to-face seal.
A. Seal testing apparatus assembly. **B.** Flow ratio as a function of applied force.

Aerosol delivery



Despite changes in seal, for aerosol deposition, at the 2 application forces tested (0.5 and 1kg), there was no statistically significant differences between the 2 masks. Increased application force increased the filter dose (MS: +7.2%; MP: +8.7%) and decreased drug deposited onto the mask (MS: -5%; MP: -4.6%)

Figure 4 : *In vitro* aerosol delivery
A. Testing apparatus assembly.
B. 0.5kg of applied force.
C. 1kg of applied force.