An Idealized Throat with Face for Facemask Testing

Travis MacLean, John Chen, Andrew R. Martin, Warren H. Finlay
Department of Mechanical Engineering, University of Alberta
Edmonton, AB, Canada

Introduction

The Alberta Idealized Throat (AIT) is a representative model that accurately mimics average extrathoracic deposition of orally-inhaled aerosols in adults (1-2). In the present work, we extend this model to testing of aerosol drug delivery through facemasks by adding an idealized facial geometry to the AIT. ERS Guidelines on the use of nebulizers (3) note that patients suffering acute shortness of breath are likely to mouth breathe when using a facemask; thus, a facial geometry model coupled with a mouth-throat is applicable. The utility of the AIT with face was demonstrated by assessing the fraction of salbutamol delivered to a filter downstream of the throat for three jet nebulizer-facemask combinations.
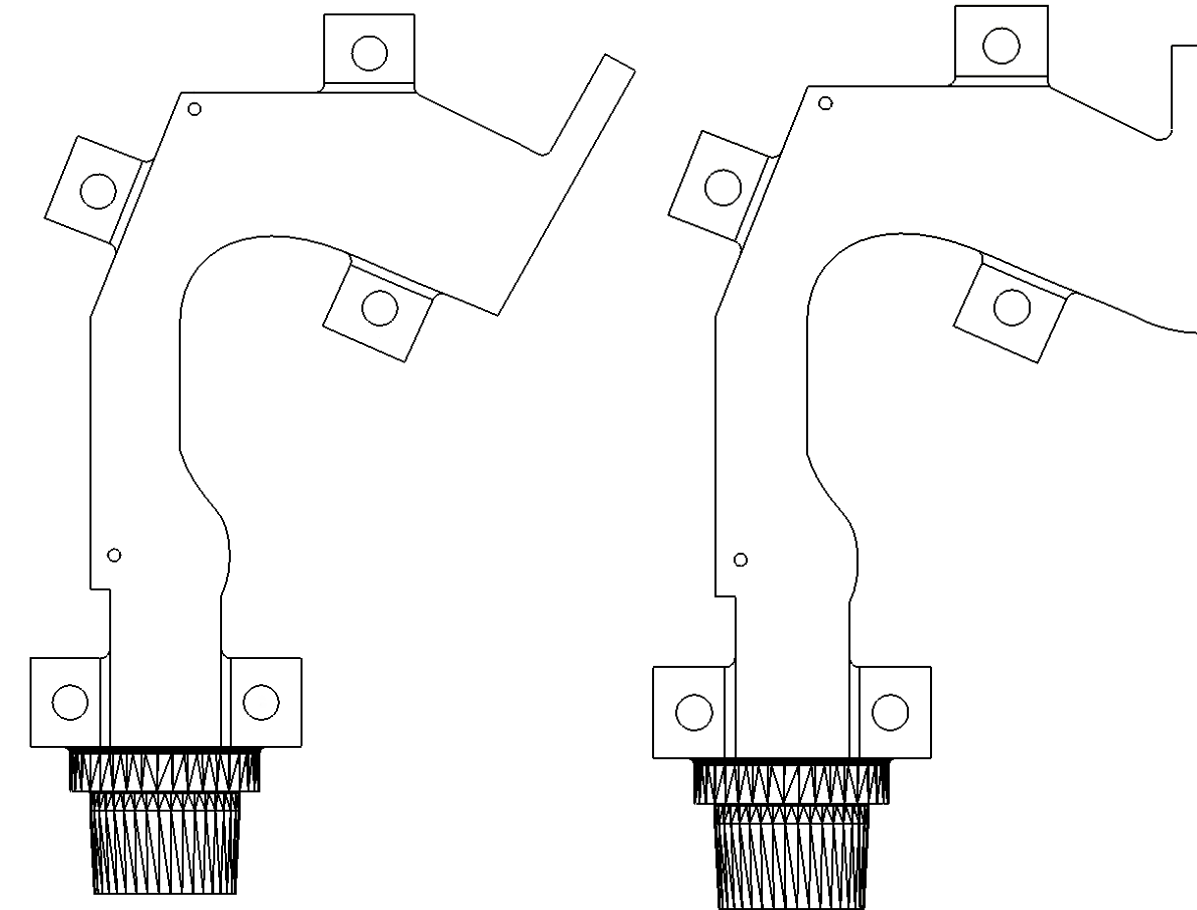
Materials & Methods

➤ An adult face model was created based on inspection of typical dimensions from 10 adult facial MRI scans. The face model was attached to two throat models: the original AIT and a modified AIT that allowed for smooth transition to the face model in a vertical orientation.

➤ Testing was performed using PARI LC Sprint (PARI, Munich, Germany) jet nebulizers (n=5) with a PARI Vios Compressor and a front-loaded facemask under both humidified (RH=78±4%) and dry conditions (RH=4±1%).

➤ Two additional nebulizer systems – Salter 8900 Series (n=5) (Salter Labs, Arvin, USA) and Westmed VixOne (n=5) (Westmed, Tucson, USA), each with bottom-loaded facemasks – were tested with 8 LPM nebulizer flow rates, supplied by a house source of compressed air, using the modified AIT and face under a humidified condition.

➤ All tests were done using 2.5 ml Salbutamol (1mg/ml) (Pharmascience, Inc., Montreal , Canada), 5 minute nebulization times and a breathing profile with TV=383ml, f=16.6 breaths/min and I/E=0.727 (4).

➤ Salbutamol deposited on each of the nebulizer, mask, face, throat and filter was separately extracted with water and assayed for salbutamol sulphate via UV absorbance.

➤ One-way, independent ANOVA with significance threshold $p=0.05$ was used to compare the recovered salbutamol between the three nebulizer-facemask combinations tested.

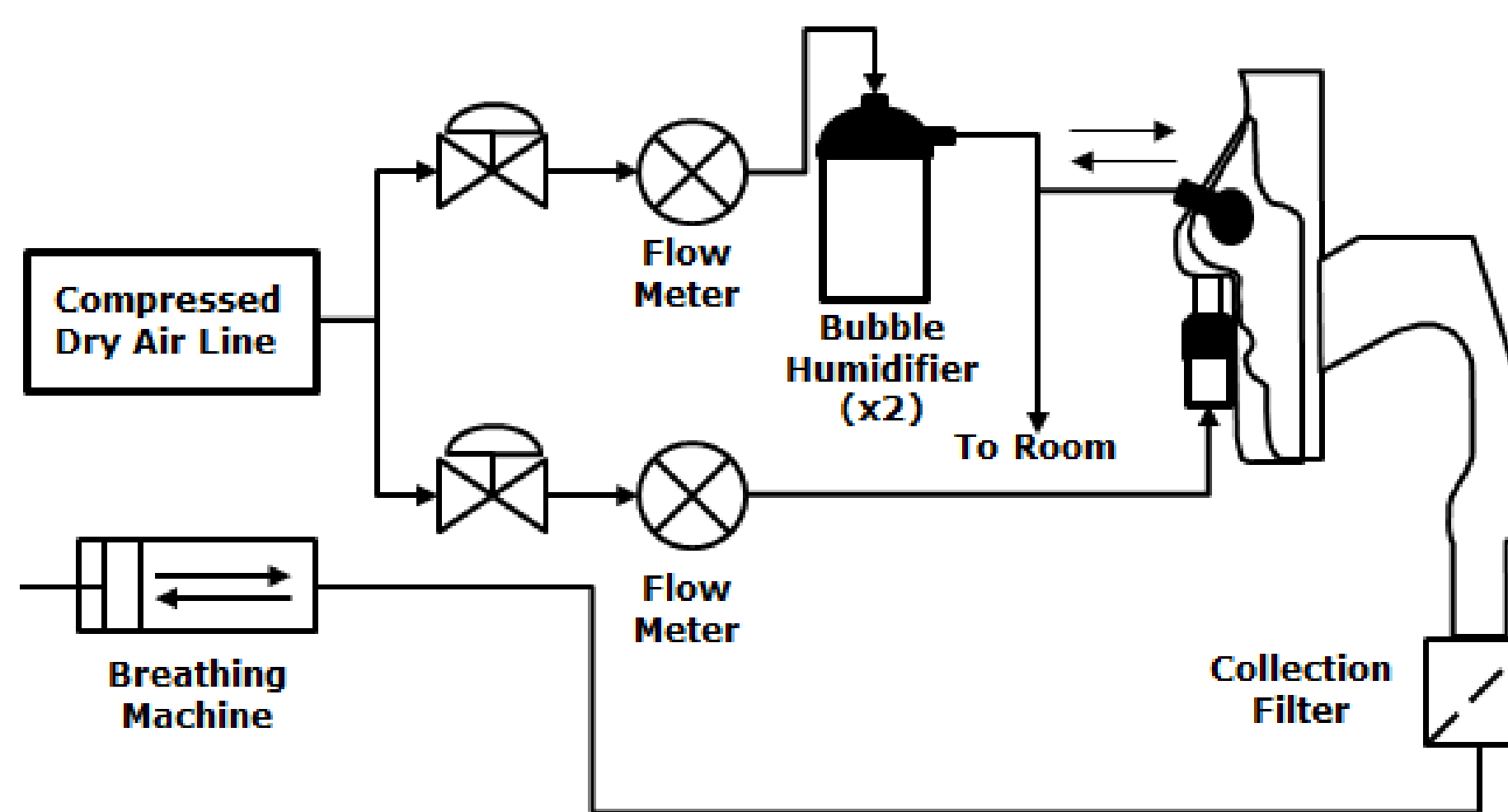**Figure 1. Original AIT (left) and modified AIT right).**

Figure 2. Experimental setup for testing of the three jet nebulizer-facemask combinations.

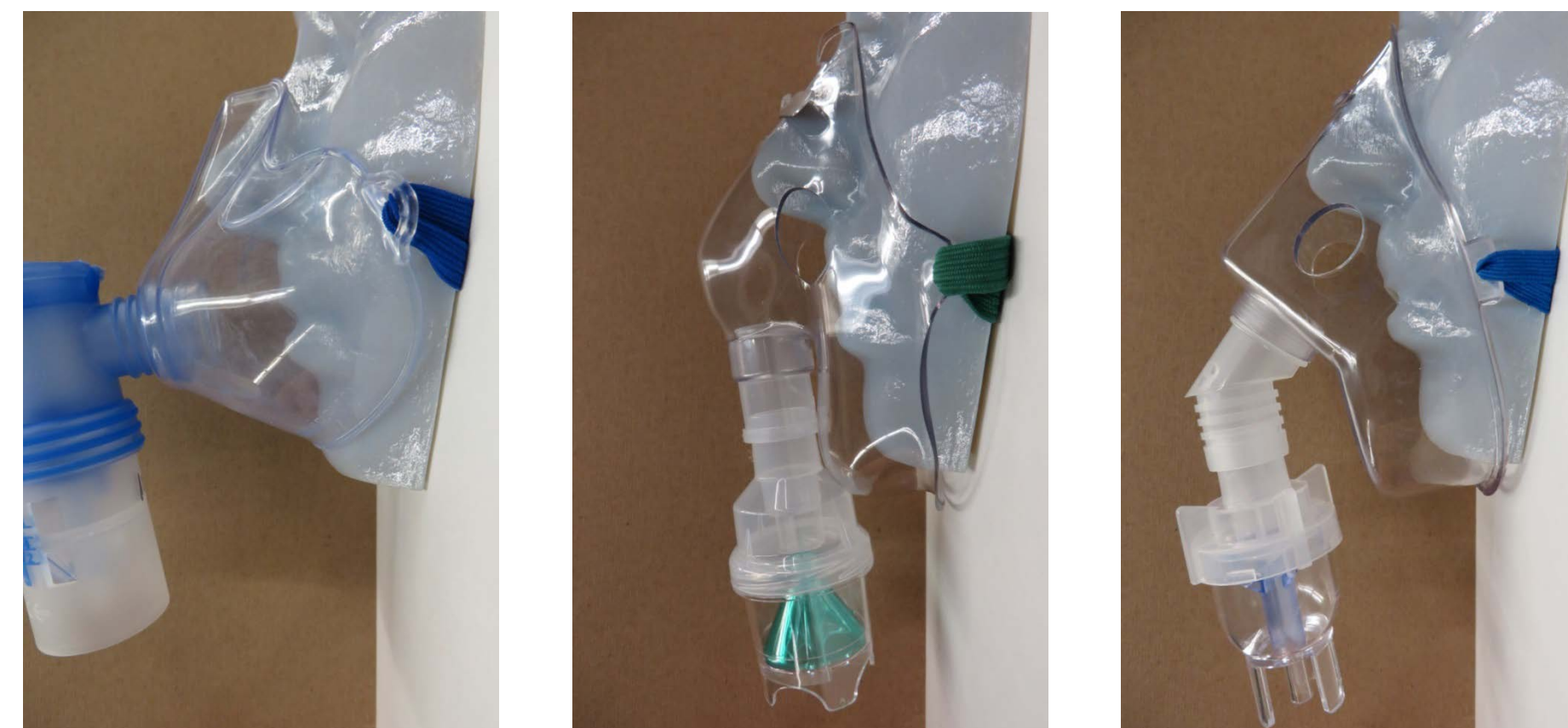Note: LC Sprint testing was done using a compressor for nebulization rather than wall air source.

Figure 3. Side profile of LC Sprint (left), Salter 8900 (middle) and VixOne (right) nebulizers with facemasks on idealized facial geometry.

Results

Table 1. Comparison of original and modified AIT under humidified and dry conditions.

Characteristic	LC Sprint: Original AIT Dry Conditions			LC Sprint: Original AIT Humid Conditions			LC Sprint: Modified AIT Dry Conditions			LC Sprint: Modified AIT Humid Conditions		
Deposition (µg)												
Filter	207	±	42	274	±	49	299	±	29	281	±	45
Nebulizer	1872	±	150	1746	±	147	1711	±	101	1742	±	138
Mask	10	±	8	11	±	7	6	±	4	8	±	4
Face	9	±	3	12	±	14	7	±	2	12	±	10
Throat	33	±	11	49	±	13	42	±	18	61	±	27
Total Recovered (µg)	2130	±	140	2092	±	121	2065	±	101	2104	±	89
% Recovered	85	±	5	83	±	4	82	±	4	83	±	3
Total Inhaled (µg)	240	±	51	323	±	61	341	±	45	342	±	64
% Inhaled (of Nom.)	10	±	2	13	±	3	14	±	2	14	±	3
% of Inhaled Total												
Throat	14	±	3	15	±	4	12	±	4	17	±	5
Filter	86	±	3	85	±	2	88	±	4	83	±	5
Neb. Output (mg/min)	166	±	15	182	±	16	192	±	22	183	±	12

➤ In initial testing with the LC Sprint, no significant difference in mask, face, throat or filter deposition was observed between the original or modified throat.

➤ Humidification did not significantly affect deposition in these initial tests.

Table 2. Comparison of LC Sprint, Salter 8900 and VixOne performance using modified AIT and humidified conditions.

Characteristic	LC Sprint: Modified AIT Humid Conditions			Salter 8900: Modified AIT Humid Conditions			VixOne: Modified AIT Humid Conditions		
Deposition (µg)									
Filter	281	±	45	182	±	23	258	±	57
Nebulizer	1742	±	138	1918	±	93	1604	±	182
Mask	8	±	4	48	±	15	117	±	32
Face	12	±	10	22	±	2	21	±	3
Throat	61	±	27	62	±	19	35	±	11
Total Recovered (µg)	2104	±	89	2233	±	67	2036	±	122
% Recovered	83	±	3	88	±	2	81	±	5
Total Inhaled (µg)	342	±	64	244	±	20	293	±	68
% Inhaled (of Nom.)	14	±	3	10	±	1	12	±	3
% of Inhaled Total									
Throat	17	±	5	25	±	7	12	±	1
Filter	83	±	5	75	±	7	88	±	1
Neb. Output (mg/min)	183	±	12	190	±	10	225	±	25

➤ No significant difference in total inhaled salbutamol was observed.

➤ The VixOne nebulizer had a significantly higher output rate than the other systems tested.

Conclusions

➤ Similar deposition in the throat models suggests that the modified AIT can be used in place of the original for testing oral inhalation from a facemask.

➤ Ambient humidity effects on throat deposition were found to be negligible with the high output nebulizers used.

➤ The present addition of the face model to the AIT may be useful in the development and testing of devices with facemasks for drug delivery to the lungs.

References

1. Zhang, Y., Gilbertson, K., Finlay, W.H., 2007. "*In Vivo-In Vitro* Comparison of Deposition in Three Mouth-Throat Models with Qvar and Turbuhaler Inhalers". *Journal of Aerosol Medicine* 20(3): 227-235.
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3. Boe, J., Dennis, J.H., O'Driscoll, B.R., Bauer, T.T., Carone, M., Dautzenberg, B., Diot, P., Heslop, K., Lannefors, L., 2001. "European Respiratory Society Guidelines on the use of nebulizers". *European Respiratory Journal* 18(1), 228-242.
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