Rush University, College of Health Sciences

An Evaluation of the Prototype OxyMulti Mask Prototype Compared to the Oxymask™ Aerosol, OxyMulti Mask™ and Airlife™ Aerosol Mask for Aerosol Delivery in Adults

Respiratory Care Program, Aerosol Lab

Prepared by : Meagan N. Dubosky MS, RRT-ACCS, NPS, AE-C
2/7/2014

Objectives

To compare the amount of drug delivered to an in-vitro, spontaneously breathing, adult lung model using four different aerosol masks; Prototype OxyMulti Mask, Oxymask™ Aerosol, OxyMulti Mask™ and Airlife™ Aerosol mask.

To evaluate the effect these four masks (Prototype OxyMulti Mask, Oxymask™ Aerosol, OxyMulti Mask™ and Airlife™ aerosol mask) have on particle size using common delivery devices.

Introduction

A large number of patient interfaces are available to deliver inhaled aerosol medications to spontaneously breathing patients. Aerosol masks and mouthpieces are commonly used in the acute care setting. The mouthpiece is the preferred method of delivery due to the physiologic filtering by the nose compared to breathing through the mouth[1]. The mouthpiece does require the patient to participate in the treatment and people in hospitals are often tired and ill. Aerosol masks are ideal interfaces with these patients because they require minimal patient coordination and allow the patient to rest while receiving their aerosol treatment.

There are also varying types of devices used in hospitals for oxygen administration. A benefit of the new hybrid delivery interfaces, such as the current OxyMulti Mask™ and the Prototype OxyMulti Mask, is the ability of the mask to be used for aerosol therapy and oxygen therapy providing a wide range of FiO_2 (24% to 80%).[2] The Prototype OxyMulti Mask may create an advantage to the patient and clinician by enabling delivery of different levels of FiO_2 and aerosol with one device. This product may provide a cost savings when compared to using multiple other devices.

The Prototype OxyMulti Mask has a diffuser that creates a vortex directing flow toward the patient's mouth.[2] Figure 1 illustrates the cross section of the diffuser. It is comprised of a cup and pin design directing oxygen towards the nose and mouth. Aerosol diffuses out from the inlet and pin in the shape of a mushroom. During inspiration, the diffuser causes a vortex to form a flame like plume towards the face, forcing the delivery of oxygen and/or aerosol towards the mouth.[2] Oxygen and aerosol not directed towards the mouth may result in the loss of aerosol and lower oxygen concentrations in other adult aerosol masks.

Several factors affect aerosol delivery to the lungs including particle size, patient cooperation, mask seal, and spontaneous breathing patterns. There are no reports at this time regarding the effect of the diffuser on particle size or aerosol delivery with the Prototype OxyMulti Mask. The purpose of this study is to quantify the characteristics and quantity of aerosol delivered to the distal regions of a spontaneously breathing lung model using both jet and vibrating mesh nebulizers with the Prototype OxyMulti Mask, Oxymask™ Aerosol (Figure 2), OxyMulti Mask™ (Figure 3) and an adult aerosol mask (Figure 4). The methodology used is based on a published model.[3]

Figure 1. Cross- sectional drawing of the Prototype OxyMulti Mask.

Courtesy of Southmedic Inc

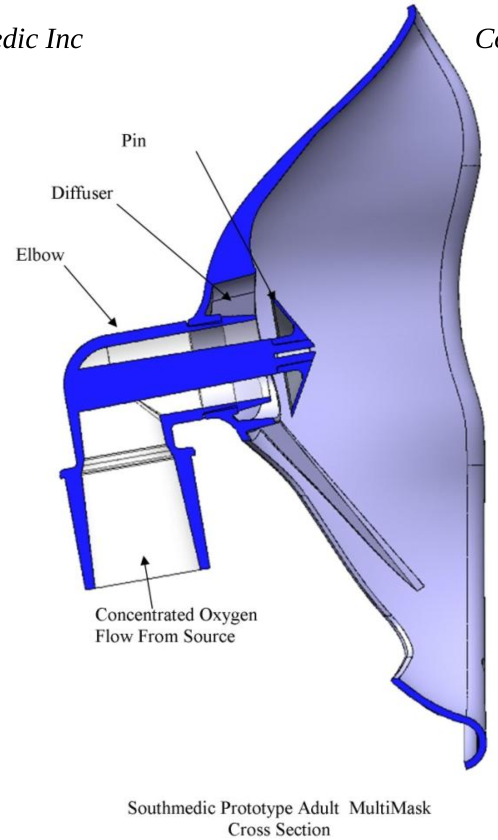


Figure 2. Cross- sectional drawing of the Oxymask™ Aerosol.

Courtesy of Southmedic Inc

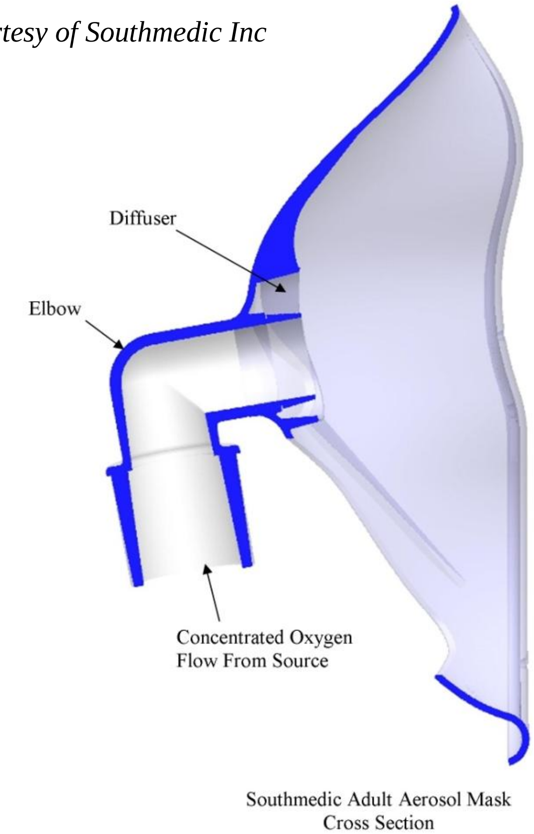


Figure 3. Cross- sectional drawing of the Adult OxyMulti Mask™.

Courtesy of Southmedic Inc

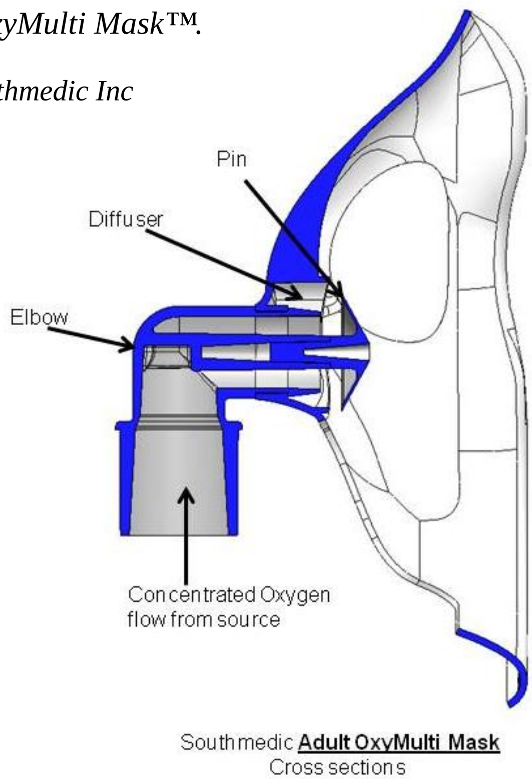


Figure 4. Photo of Airlife™ Aerosol Mask.

Carefusion

Methods

Experimental Setup and Research Design- Dose Deposition

An adult upper airway manikin (Laerdal, Stavenger, Norway) elevated at 30 degrees was attached to a training test lung (TTL) (Michigan Instruments, Grand Rapids, Michigan) with both bronchi attached to a collecting filter (Carefusion, San Diego, California) using a Y adapter. A conventional mechanical ventilator, PB7200 (Puritan Bennett™, Covidien Inc., Mansfield, Massachusetts), was attached to the TTL and programmed to simulate an adult asthmatic breathing pattern (peak inspiratory flowrate 60 L/min, tidal volume 500 mL, respiratory rate 25 breath/min, inspiratory-expiratory ratio 1:3, sinusoidal waveform). Tidal volume and flow rate was monitored with a respiratory profile monitor (Novametrix CosmoPlus, Wallingford, Connecticut) to ensure accuracy of breath delivery.

All experiments were conducted using two jet nebulizers, Uni-Heart® (Westmed, Tucson, Arizona) operated at 2 and 4 L/min and the Misty Max 10™ (Carefusion, San Diego, California) operated at 8 and 10 L/min., as well as a vibrating mesh nebulizer (Aeroneb Solo, Aerogen, Galway, Ireland) with flows of 0, 2, 4, 8 and 10 L/min through it to deliver albuterol sulfate (2.5mg/ 3mL) from the aerosol generator to the manikin via 4 mask interfaces, Prototype OxyMulti Mask, Oxymask™ Aerosol, OxyMulti Mask™ (Southmedic, Barrie, Ontario, Canada) and Airlife™ aerosol mask (Carefusion, San Diego, California).

Each treatment was run until sputter or 10 minutes, whichever occurred first, with each mask (n=3). Appendix A presents the scheme of this study design. Following each nebulizer treatment, deposited drug was eluted from the filter using 10 milliliters of 0.01% NaOH and analyzed by spectrophotometry (276mm) to quantify mass of drug. Equipment utilized in dose deposition analysis detailed in Appendix B.

Experimental Setup and Research Design- Particle Size

Particle size for each nebulizer was measured as mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD), using the Anderson 8-stage cascade impactor (ACI) operating at a flow of 28.3 L/min, verified with a flow calibrator. The ACI classifies aerosol particle sizes from 0.4 µm to 9 µm aerodynamic diameter by collecting particles on plates within the device. The ACI was operated at ambient temperatures and each nebulizer and mask pairing ran for 60 seconds. Appendix A represents the scheme of the study design of this research. Following each nebulizer treatment, drug deposited on ACI plates and throat was eluted using 5 milliliters (plates) and 10 milliliters (throat) of 0.01% NaOH and analyzed by spectrophotometry (276mm).

All experiments were conducted using two jet nebulizers, Uni-Heart® (Westmed, Tucson, Arizona) operated at 2 and 4 L/min and the Misty Max 10™ (Carefusion, San Diego, California) operated at 8 and 10 L/min., as well as a vibrating mesh nebulizer (Aeroneb Solo, Aerogen, Galway, Ireland) with flows of 0, 2, 4, 8 and 10 L/min through it to deliver albuterol sulfate (2.5mg/ 3mL) from the aerosol generator to the ACI via 4 mask interfaces, Prototype OxyMulti Mask, Oxymask™ Aerosol, OxyMulti Mask™ (Southmedic, Barrie, Ontario, Canada) and Airlife™ aerosol mask (Carefusion, San Diego, California). Equipment utilized in particle size determination detailed in Appendix C.

Data were analyzed using statistics software (SPSS 21.0, SPSS, Chicago, Illinois) with mean and standard deviation reported for all measurements. Significance was set at $p < 0.05$. Dose deposition, MMAD, and GSD data were evaluated using one way analysis of variance, with a Bonferroni adjustment for multiple comparisons, with the mean difference significant at the .05 level.

Report Summary

Dose Deposition

When comparing the amount of drug delivered to an in-vitro, spontaneously breathing, adult lung model using four different aerosol masks, the mean amount of drug delivered was greatest in the OxyMask™ Aerosol (329 ± 126 µg) followed by the OxyMulti Mask™ (269 ± 86 µg), Prototype OxyMulti Mask (241 ± 105 µg) and Airlife™ aerosol mask (210 ± 102 µg) (Table 1).

A one-way analysis of variance was conducted to explore the effect of four different masks (Prototype OxyMulti Mask, n=27; OxyMulti Mask™, n=27; OxyMask™ Aerosol, n=27; and Airlife™ aerosol mask, n=27) on mean drug delivery. There was a statistically significant difference in mean amount of drug delivered between the four masks: $F=_{3,104}$ 6.21, p=0.001 (Table 2). Post-hoc comparisons using the Bonferroni test indicated that the mean difference in drug delivered for the OxyMask™ Aerosol (329 ±126 µg) was significantly different from the Airlife™ aerosol mask (210 ± 102) and the Prototype OxyMulti Mask (240 ± 105 µg) (Table 3). The OxyMulti Mask™ did not differ significantly from either of the masks.

Data on each of the four masks was split by flow and a one-way analysis of variance was conducted (Table 4). Flow rates of 0, 2, 4, 8, and 10 L/min were used with each nebulizer and mask combination and statistical significance between the masks was found at flows of 0, 8 and 10 L/min (Table 5). We must use caution when interpreting this sub-analysis data since the group size decreased to 6 per group. These findings may change if the sample size is increased. When flow was 0 L/min, the OxyMask™ Aerosol (410 ± 28 µg) had greater drug deposition than all three other mask; Prototype OxyMulti Mask (317 ± 20 µg), OxyMulti Mask™ (351± 15 µg), Airlife™ aerosol mask (208 ± 15 µg). Both the OxyMulti Mask™ and Prototype OxyMulti Mask had a statistically significant greater amount of drug deposition without flow when compared to the Airlife™ aerosol mask. When flow was 8 L/min the OxyMask™ Aerosol (379 ± 27 µg) had significantly greater drug deposition than all other masks; Prototype OxyMulti Mask (281 ± 28 µg), OxyMulti Mask™ (273 ± 26 µg), Airlife™ aerosol mask (241 ± 24 µg). When flow was 10 L/min the OxyMask™ Aerosol (386 ± 9 µg) had significantly greater drug deposition than the three other masks: Prototype OxyMulti Mask (237 ± 14 µg), OxyMulti Mask™ (268 ± 19 µg) and Airlife™ aerosol mask (233 ± 29 µg). At 10 L/min flow, the OxyMulti Mask™ had significantly greater drug deposition than the Airlife™ aerosol mask (Table 6). Graph 1 represents the mean drug deposition of each aerosol mask at each flow rate (L/min) tested.

Particle Size

The mean MMAD/GSD of the OxyMulti Mask™ (2.54 ± 0.25/2.02 ± 0.10 µm), OxyMask™ Aerosol (2.74 ± 0.34/2.04 ± 0.07 µm), Prototype OxyMulti Mask (2.79 ± 0.28/2.07 ± 0.10 µm) and Airlife™ aerosol mask (2.87 ± 0.19/2.11 ± 0.08 µm) were found to be similar (Table 7).

A one-way analysis of variance was conducted to explore the effect of the four different masks (OxyMulti Mask™, n=27; Prototype OxyMulti Mask, n=27; Oxymask™ Aerosol, n=27; and Airlife™ aerosol mask, n=27) on particle size, defined as mean MMAD and GSD. Statistical significance did exist when comparing the mean MMAD between the four masks: $F=_{3,104}$ 7.18, p = <0.001. There were statistically significant differences in mean GSD between the three masks: $F=_{3,104}$ 4.36, p = 0.006 (Table 8). Although the OxyMulti Mask™ showed a statistically significant difference in MMAD compared to the other masks, these differences are not clinically significant. The particle size means are between 2.5 and 2.9 µm which would most likely result in the same depth of deposition. The statistically significant difference is a result of the lack of variability in the data. Post-hoc comparisons using the Bonferroni test for MMAD is included (Table 9), however, with a small sample size we cannot be assured that these results would remain if the n was increased. We were unable to produce reliable GSD post-hoc data due to the small sample size. Flow rates of 0, 2, 4, 8, and 10 L/min were used with each mask and nebulizer combination with MMAD and GSD found to be similar (Table 10). Graphs 2 and 3 below illustrate the small variability in MMAD and GSD between these masks.

Table 1. Overall mean drug deposition for each aerosol mask

Mask (n)	**Drug in µg Mean (SD)**
OxyMask™ Aerosol (27)	329.14 (125.72)
MultiMask (27)	268.95 (85.80)
Prototype OxyMulti Mask (27)	240.79 (105.09)
Airlife™ aerosol mask (27)	210.08 (102.15)
Total Runs	**108**

Table 2. ANOVA Results. Deposition difference between masks. (drug in µg)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	207934.659	3	69311.553	6.210	.001[a]
Within Groups	1160847.585	104	11161.996		
Total	136782.244	107			

* The mean difference is significant at the 0.05 level.
a. Significant difference in mean amt of drug delivered between 4 mask groups.

Table 3. Post-hoc Bonferroni test comparing masks (drug in µg)

(I) Mask	(J) Mask	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
MultiMask	Aerosol Mask	58.87148	28.75438	.259	-18.4680	136.2110
	Prototype	28.16519	28.75438	1.000	-49.1743	105.5047
	Oxymask Aerosol	-60.18630	28.75438	.233	-137.5258	17.1532
Aerosol Mask	MultiMask	-58.87148	28.75438	.259	-136.2110	18.4680
	Prototype	-30.70630	28.75438	1.000	-108.0458	46.6332
	Oxymask Aerosol	-119.05778*	28.75438	.000[a]	-196.3973	-41.7183
Prototype	MultiMask	-28.16519	28.75438	1.000	-105.5047	49.1743
	Aerosol Mask	30.70630	28.75438	1.000	-46.6332	108.0458
	Oxymask Aerosol	-88.35148*	28.75438	.016[a]	-165.6910	-11.0120
Oxymask Aerosol	MultiMask	60.18630	28.75438	.233	-17.1532	137.5258
	Aerosol Mask	119.05778*	28.75438	.000[a]	41.7183	196.3973
	Prototype	88.35148*	28.75438	.016[a]	11.0120	165.6910

* The mean difference is significant at the 0.05 level.
a.OxyMask™ Aerosol deposition greater than Airlife™ Aerosol Mask and Prototype OxyMulti Mask
Aerosol Mask = Airlife™ aerosol mask
Prototype = Prototype OxyMulti Mask

Table 4. ANOVA Results. Deposition difference between masks stratified by flow. (drug in µg)

Flow		Sum of Squares	df	Mean Square	F	Sig.
0	Between Groups	64567.449	3	21522.483	52.799	.000
	Within Groups	3261.020	8	407.628		
	Total	67828.469	11			
2	Between Groups	9565.944	3	3188.648	.121	.947
	Within Groups	526859.200	20	26342.960		
	Total	536425.144	23			
4	Between Groups	42899.482	3	14299.827	.736	.543
	Within Groups	388381.693	20	19419.085		
	Total	431281.175	23			
8	Between Groups	64548.903	3	21516.301	30.689	.000
	Within Groups	14021.985	20	701.099		
	Total	78570.889	23			
10	Between Groups	92550.069	3	30850.023	80.560	.000
	Within Groups	7658.905	20	382.945		
	Total	100208.974	23			

Table 5. Post-hoc Bonferroni comparing drug deposition for each aerosol mask at flows where significance found. (drug in µg)

Flow	(I) Mask	(J) Mask	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
0	MultiMask	Aerosol Mask	142.73333*	16.48489	.000[a]	85.3844	200.0823
		Prototype	34.16667	16.48489	.432	-23.1823	91.5156
		Oxymask Aerosol	-58.86667*	16.48489	.044[b]	-116.2156	-1.5177
	Aerosol Mask	MultiMask	-142.73333*	16.48489	.000[a]	-200.0823	-85.3844
		Prototype	-108.56667*	16.48489	.001[c]	-165.9156	-51.2177
		Oxymask Aerosol	-201.60000*	16.48489	.000[d]	-258.9489	-144.2511
	Prototype	MultiMask	-34.16667	16.48489	.432	-91.5156	23.1823
		Aerosol Mask	108.56667*	16.48489	.001[c]	51.2177	165.9156
		Oxymask Aerosol	-93.03333*	16.48489	.003[e]	-150.3823	-35.6844
	Oxymask Aerosol	MultiMask	58.86667*	16.48489	.044[b]	1.5177	116.2156
		Aerosol Mask	201.60000*	16.48489	.000[d]	144.2511	258.9489
		Prototype	93.03333*	16.48489	.003[e]	35.6844	150.3823
8	MultiMask	Aerosol Mask	32.44167	15.28724	.279	-12.3059	77.1892
		Prototype	-7.81667	15.28724	1.000	-52.5642	36.9309
		Oxymask Aerosol	-106.37333*	15.28724	.000[f]	-151.1209	-61.6258
	Aerosol Mask	MultiMask	-32.44167	15.28724	.279	-77.1892	12.3059
		Prototype	-40.25833	15.28724	.096	-85.0059	4.4892
		Oxymask Aerosol	-138.81500*	15.28724	.000[g]	-183.5626	-94.0674
	Prototype	MultiMask	7.81667	15.28724	1.000	-36.9309	52.5642
		Aerosol Mask	40.25833	15.28724	.096	-4.4892	85.0059
		Oxymask Aerosol	-98.55667*	15.28724	.000[h]	-143.3042	-53.8091
	Oxymask Aerosol	MultiMask	106.37333*	15.28724	.000[f]	61.6258	151.1209
		Aerosol Mask	138.81500*	15.28724	.000[g]	94.0674	183.5626
		Prototype	98.55667*	15.28724	.000[h]	53.8091	143.3042

10	MultiMask	Aerosol Mask	34.58333*	11.29816	.037[i]	1.5123	67.6544
		Prototype	30.71500	11.29816	.079	-2.3561	63.7861
		Oxymask Aerosol	-118.26667*	11.29816	.000[j]	-151.3377	-85.1956
	Aerosol Mask	MultiMask	-34.58333*	11.29816	.037[i]	-67.6544	-1.5123
		Prototype	-3.86833	11.29816	1.000	-36.9394	29.2027
		Oxymask Aerosol	-152.85000*	11.29816	.000[k]	-185.9211	-119.7789
	Prototype	MultiMask	-30.71500	11.29816	.079	-63.7861	2.3561
		Aerosol Mask	3.86833	11.29816	1.000	-29.2027	36.9394
		Oxymask Aerosol	-148.98167*	11.29816	.000[l]	-182.0527	-115.9106
	Oxymask Aerosol	MultiMask	118.26667*	11.29816	.000[j]	85.1956	151.3377
		Aerosol Mask	152.85000*	11.29816	.000[k]	119.7789	185.9211
		Prototype	148.98167*	11.29816	.000[l]	115.9106	182.0527

* The mean difference is significant at the 0.05 level.
a. Flow = 0, MultiMask drug deposition greater than Airlife™aerosol mask.
b. Flow = 0, Oxymask™ Aerosol drug deposition greater than MultiMask.
c. Flow = 0, Prototype OxyMulti Mask drug deposition greater than Airlife™aerosol mask.
d. Flow = 0, Oxymask™ Aerosol drug deposition greater than Airlife™aerosol mask.
e. Flow = 0, Oxymask™ Aerosol drug deposition greater than Prototype OxyMulti Mask.
f. Flow = 8, Oxymask™ Aerosol drug deposition greater than MultiMask.
g. Flow = 8, Oxymask™ Aerosol drug deposition greater than Airlife™ aerosol mask.
h. Flow = 8, Oxymask™ Aerosol drug deposition greater than Prototype OxyMulti Mask.
i. Flow = 10, MultiMask drug deposition greater than Airlife™ aerosol mask.
j. Flow = 10, Oxymask™ Aerosol drug deposition greater than MultiMask.
k. Flow = 10, Oxymask™ Aerosol drug deposition greater than Airlife™ aerosol mask.
l. Flow = 10, Oxymask™ Aerosol drug deposition greater than Prototype OxyMulti Mask.
Aerosol Mask = Airlife™ aerosol mask
Oxymask = Oxymask™ Aerosol
Prototype = Prototype OxyMulti Mask

Table 6. Mean drug deposition for each aerosol mask at each flow tested (drug in µg)

Flow		N	Mean	Std. Deviation	Std. Error	Minimum	Maximum
0	MultiMask	3	351.0000	15.43988	8.91422	333.30	361.70
	Aerosol Mask	3	208.2667	14.93229	8.62116	191.40	219.80
	Prototype	3	316.8333	19.76318	11.41028	297.50	337.00
	Oxymask Aerosol	3	409.8667	27.90275	16.10966	379.00	433.30
	Total	12	321.4917	78.52531	22.66830	191.40	433.30
2	MultiMask	6	231.4833	154.33722	63.00791	84.00	392.60
	Aerosol Mask	6	206.1400	168.57326	68.81975	50.00	371.32
	Prototype	6	219.7183	159.24214	65.01033	71.40	383.54
	Oxymask Aerosol	6	260.3067	166.66391	68.04026	90.53	450.26
	Total	24	229.4121	152.71815	31.17346	50.00	450.26
4	MultiMask	6	261.9333	86.52571	35.32397	169.10	351.90
	Aerosol Mask	6	160.7467	139.83310	57.08663	30.00	331.84
	Prototype	6	186.9367	146.40740	59.77057	47.11	351.01
	Oxymask Aerosol	6	249.8750	170.88364	69.76295	89.21	434.47
	Total	24	214.8729	136.93559	27.95186	30.00	434.47
8	MultiMask	6	273.4500	26.46195	10.80305	239.50	321.00
	Aerosol Mask	6	241.0083	24.33017	9.93275	210.79	268.16
	Prototype	6	281.2667	28.44977	11.61457	258.41	333.95
	Oxymask Aerosol	6	379.8233	26.51067	10.82294	327.37	402.89
	Total	24	293.8871	58.44763	11.93057	210.79	402.89
10	MultiMask	6	267.9167	19.23886	7.85423	242.00	291.40
	Aerosol Mask	6	233.3333	29.49421	12.04096	183.95	260.79
	Prototype	6	237.2017	14.33667	5.85292	212.89	253.41
	Oxymask Aerosol	6	386.1833	9.28433	3.79031	376.05	398.42
	Total	24	281.1588	66.00691	13.47360	183.95	398.42

Aerosol Mask = Airlife™ aerosol mask
Prototype = Prototype OxyMulti Mask

Graph 1. Mean Drug Deposition

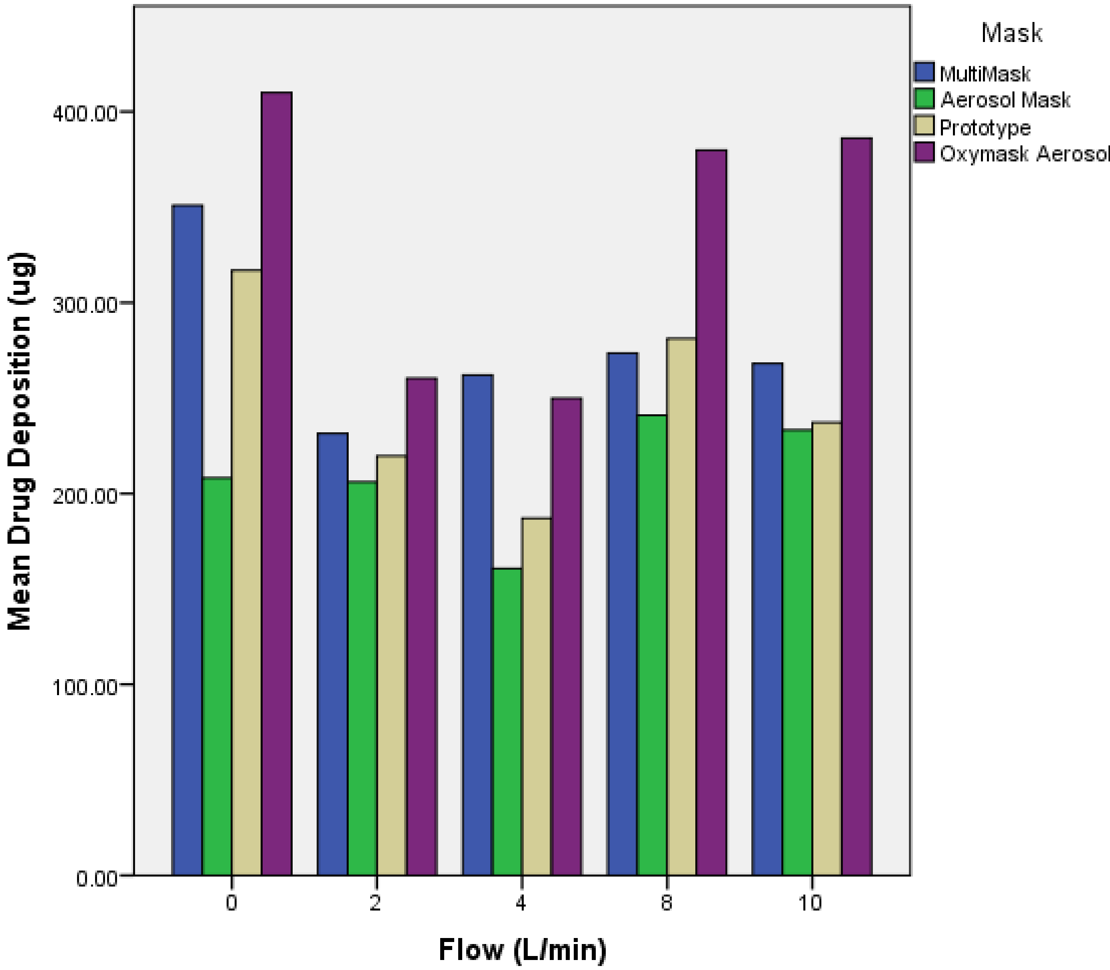


***Table 7. Overall particle size for each aerosol mask (*µm)

Mask (n)	**MMAD Mean (SD)**	**GSD Mean (SD)**
MultiMask (27)	2.54 (0.25)	2.02(0.10)
Oxymask™ Aerosol (27)	2.74 (0.34)	2.04 (0.07)
Prototype OxyMulti Mask (27)	2.79 (0.28)	2.07 (0.10)
Airlife™ Aerosol Mask (27)	2.87 (0.19)	2.11 (0.08)
	Total Runs	**108**

Table 8. ANOVA Results MMAD and GSD

		Sum of Squares	df	Mean Square	F	Sig.
MMAD	Between Groups	1.545	3	.515	7.178	.000[a]
	Within Groups	7.464	104	.072		
	Total	9.009	107			
GSD	Between Groups	.107	3	.036	4.363	.006[b]
	Within Groups	.853	104	.008		
	Total	.961	107			

* The mean difference is significant at the 0.05 level.
a. Significant difference in mean MMAD between 4 masks. ($p < 0.05$)
b. Significant difference in mean GSD between 4 masks. ($p<0.05$)

Table 9. Post-hoc Bonferroni test comparing MMAD and GSD for each mask(μm)

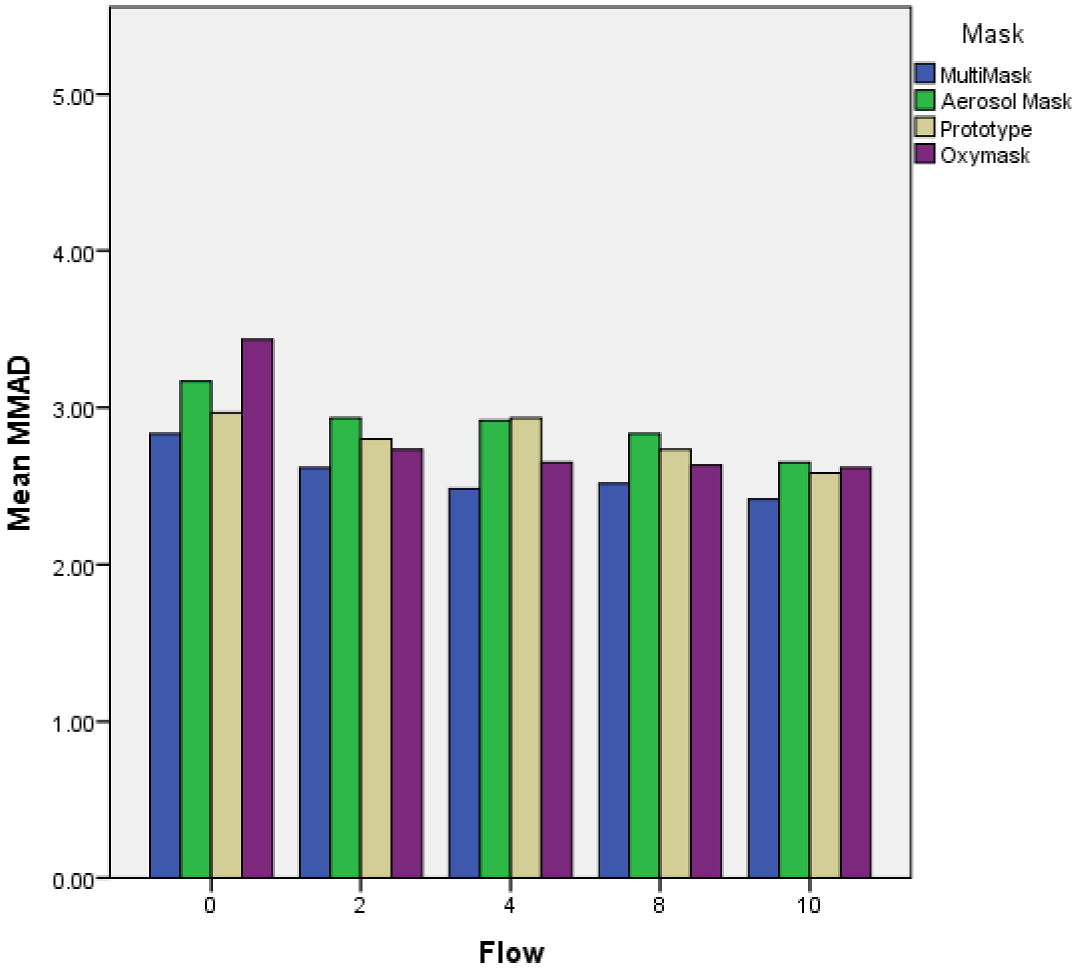
Dependent Variable	(I) Mask	(J) Mask	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
MMAD	MultiMask	Aerosol Mask	-.32593*	.07291	.000[a]	-.5220	-.1298
		Prototype	-.24074*	.07291	.008[b]	-.4368	-.0446
		Oxymask	-.20000*	.07291	.043[c]	-.3961	-.0039
	Aerosol Mask	MultiMask	.32593*	.07291	.000[a]	.1298	.5220
		Prototype	.08519	.07291	1.000	-.1109	.2813
		Oxymask	.12593	.07291	.523	-.0702	.3220
	Prototype	MultiMask	.24074*	.07291	.008[b]	.0446	.4368
		Aerosol Mask	-.08519	.07291	1.000	-.2813	.1109
		Oxymask	.04074	.07291	1.000	-.1554	.2368
	Oxymask	MultiMask	.20000*	.07291	.043[c]	.0039	.3961
		Aerosol Mask	-.12593	.07291	.523	-.3220	.0702
		Prototype	-.04074	.07291	1.000	-.2368	.1554
GSD	MultiMask	Aerosol Mask	-.08148*	.02465	.008[d]	-.1478	-.0152
		Prototype	-.04074	.02465	.609	-.1070	.0256
		Oxymask	-.01111	.02465	1.000	-.0774	.0552
	Aerosol Mask	MultiMask	.08148*	.02465	.008[d]	.0152	.1478
		Prototype	.04074	.02465	.609	-.0256	.1070
		Oxymask	.07037*	.02465	.031[e]	.0041	.1367
	Prototype	MultiMask	.04074	.02465	.609	-.0256	.1070
		Aerosol Mask	-.04074	.02465	.609	-.1070	.0256
		Oxymask	.02963	.02465	1.000	-.0367	.0959
	Oxymask	MultiMask	.01111	.02465	1.000	-.0552	.0774
		Aerosol Mask	-.07037*	.02465	.031[d]	-.1367	-.0041
		Prototype	-.02963	.02465	1.000	-.0959	.0367

* The mean difference is significant at the 0.05 level.
a. MultiMask MMAD significantly smaller than Airlife™ aerosol mask.
b. MultiMask MMAD significantly smaller than Prototype OxyMulti Mask.
c. MultiMask MMAD significantly smaller than Oxymask™ Aerosol.
d. MultiMask GSD significantly smaller than Airlife™ aerosol mask.
e. Oxymask™ Aerosol GSD significantly smaller than Airlife™ aerosol mask.
Aerosol Mask = Airlife™ aerosol mask
Oxymask = Oxymask™ Aerosol
Prototype = Prototype OxyMulti Mask

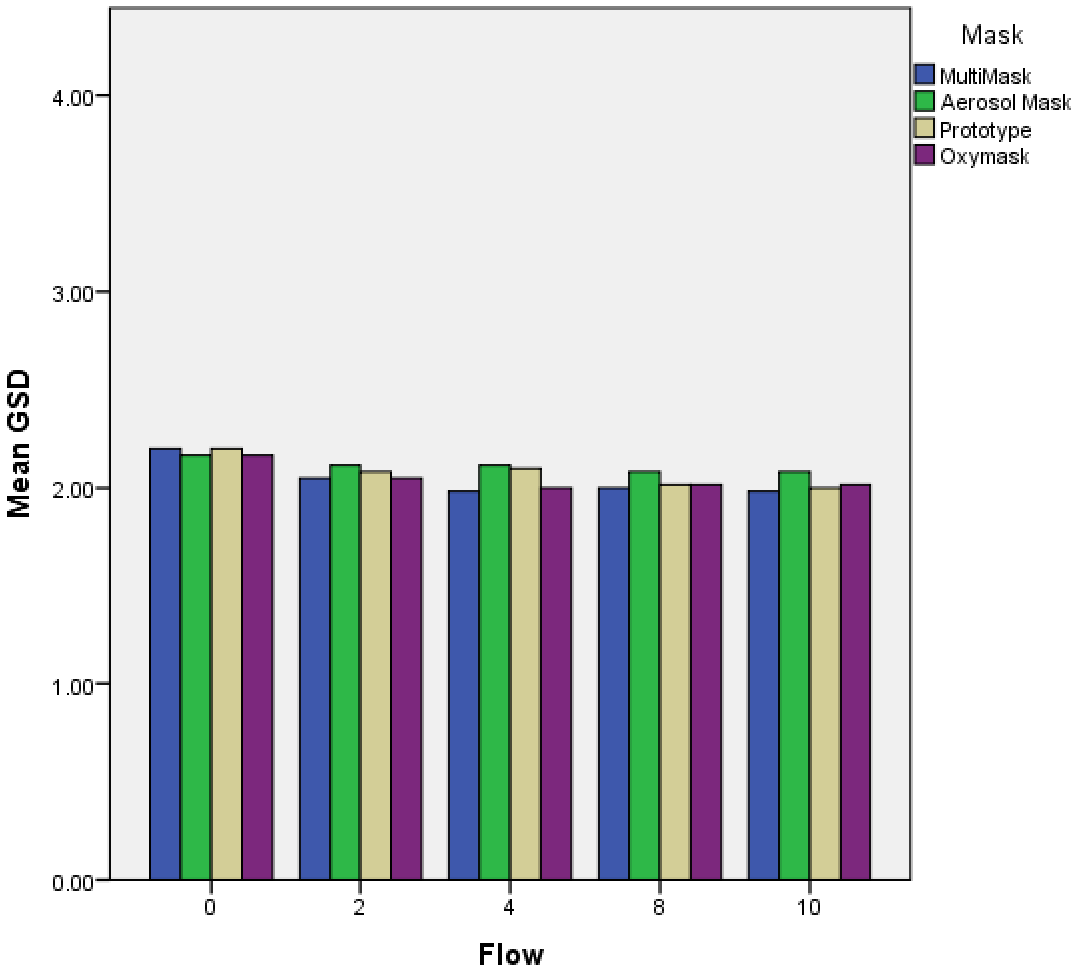
*Table 10. **Mean MMAD / GSD for each aerosol mask at flows found significant.*** *(μm)*

Flow (n)	**MMAD Mean (SD)**	**GSD Mean (SD)**
0 L/min (12)	3.10 (0.38)	2.18(0.10)
2 L/min (24)	2.77 (0.26)	2.07 (0.09)
4 L/min (24)	2.75 (0.26)	2.05 (0.19)
8 L/min (24)	2.68 (0.20)	2.03 (0.07)
10 L/min (24)	2.57 (0.22)	2.02 (0.07)

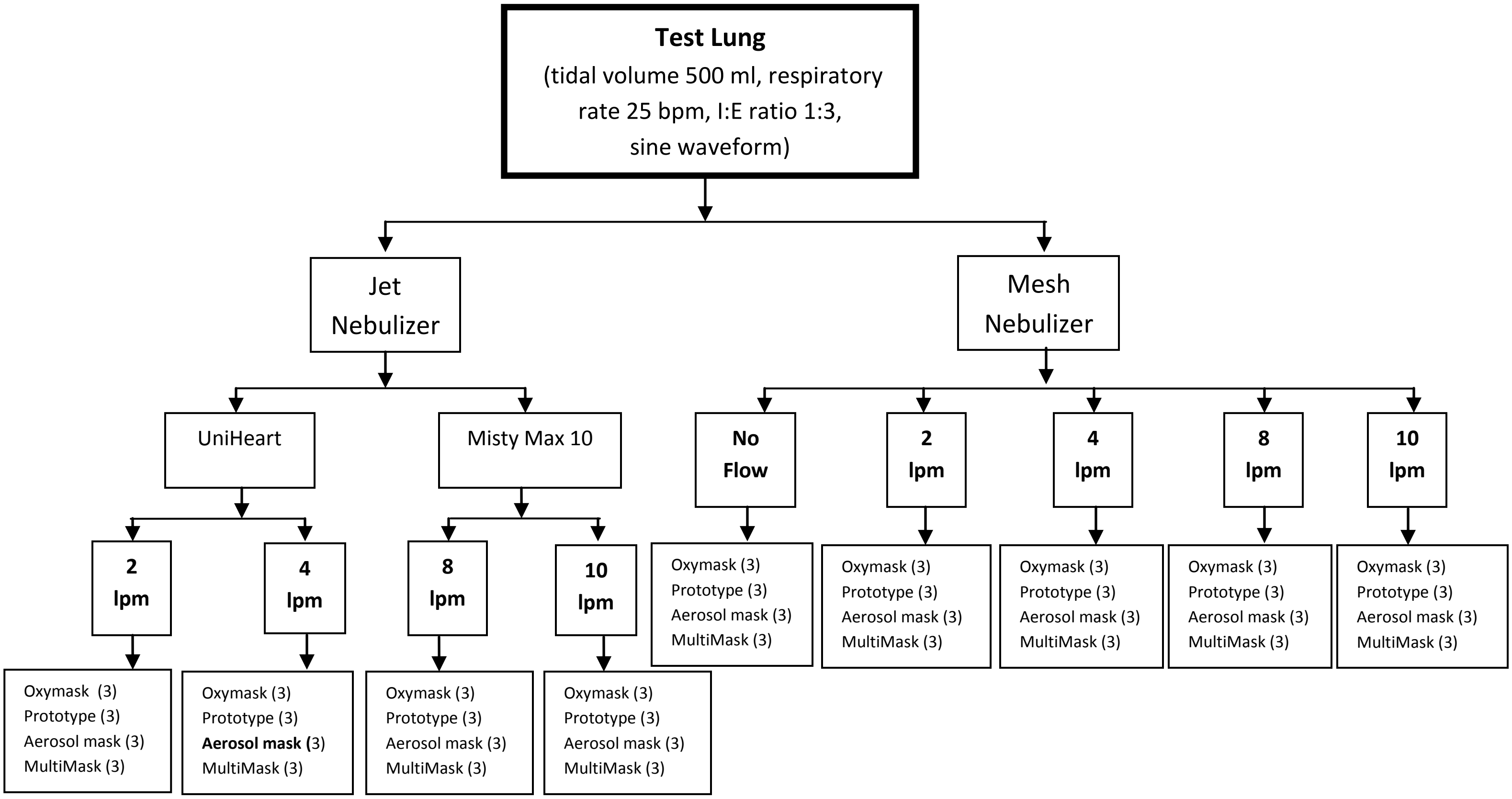
Graph 2. Mean MMAD *(μm)*



***Graph 3. Mean GSD** (µm)*



Appendix A



Test Lung
(tidal volume 500 ml, respiratory rate 25 bpm, I:E ratio 1:3, sine waveform)
Jet Nebulizer
Mesh Nebulizer
UniHeart
Misty Max 10
No Flow
2 lpm
4 lpm
8 lpm
10 lpm
2 lpm
4 lpm
8 lpm
10 lpm
Oxymask (3)
Prototype (3)
Aerosol mask (3)
MultiMask (3)

Appendix B

Dose Deposition Equipment

	Tracking	**Manufacturer**	**Notes**
Spectrophotometer		SPECTRA Max Plus	
Adult OxyMask Aerosol	Ref: OMN-4025-8	Southmedic www.southmedic.com	Aerosol mask only equipment used from mask/neb kit
Adult Oxy Multi-Mask Prototype		Southmedic	
Adult MultiMask	Ref: OHH-1425-8	Southmedic http://southmedic.com/products/oxy-multi-mask/	
Adult AirLife™ Aerosol Mask	001206	Carefusion www.carefusion.com/pdf/Respiratory/Respiratory_Consumables/AirLife_Catalog_082211.pdf	
AirLife™ Nonconductive Respiratory Therapy Filter	Ref: 001851	Carefusion www.carefusion.com/pdf/Respiratory/Respiratory_Consumables/AirLife_Catalog_082211.pdf	
AirLife™ brand Misty Max 10™ disposable nebulizer	Ref: 002430	Carefusion www.carefusion.com/pdf/Respiratory/Respiratory_Consumables/AirLife_Catalog_082211.pdf	
Laerdal® Airway Management Trainer		Laerdal http://www.laerdal.com/doc/92/Laerdal-Airway-Management-Trainer	
Dual Adult Training and Test Lung		Michigan Instruments http://www.michiganinstruments.com/dual-adult-lung	
Uniheart Nebulizer	100850	Westmed Heart® Nebulizers http://www.westmedinc.com/linesheets/Heart%20Nebs%20Rev.09.pdf	
Aeroneb Solo Nebulizer	AG-AS3000-US	Aerogen http://aerogen.com/aeroneb-solo.html	
Novametrix CosmoPlus Respiratory Profile Monitor		Phillips Respironics	

Appendix C

Particle Size Equipment

	Tracking	Manufacturer	Notes
Anderson 8 Stage Cascade Impactor	Serial #1372	Westech www.westechinstruments.com	Induction port & inlet cone inspection report certification (06.13.2012) on file in Rush University Aerosol Lab, Chicago, IL.
Vacuum Pump Assembly	Part #10709APB	Westech www.westechinstruments.com	28.3 LPM applications w/ flow meter and control valve. Rotary vane w/ sampling range 5-30 LPM
Spectrophotometer		SPECTRA Max Plus	
Adult OxyMask Aerosol	Ref: OMN-4025-8	Southmedic www.southmedic.com	Aerosol mask only equipment used from mask/neb kit
Adult Oxy Multi-Mask Prototype		Southmedic	From Southmedic
Adult Airlife™ Aerosol Mask	001206	Carefusion www.carefusion.com/pdf/Respiratory/Respiratory_Consumables/AirLife_Catalog_082211.pdf	
Uniheart Nebulizer	100850	Westmed Heart® Nebulizers http://www.westmedinc.com/linesheets/Heart%20Nebs%20Rev.09.pdf	
Aeroneb® Solo Nebulizer	AG-AS3000-US	Aerogen http://aerogen.com/aeroneb-solo.html	

References

1. Ari, A., Hess, D., Meyers, T. A guide to aerosol delivery devices for respiratory therapists. American Association for Respiratory Care, Dallas, Texas 2009.
2. Beecroft JM, Patrick JH. Comparison of the Oxymask and Venturi Mask in the Delivery of Supplemental Oxygen: Pilot Study in Oxygen Dependent Patients. Respir Care 2006; 13(5):247-252.
3. Ari A, Robert JH, Meryl MS, James BF. An In Vitro Evaluation of Aerosol Delivery Through Tracheostomy and Endotracheal Tubes Using Different Interfaces. American Association Respir Care 2012;57(7):1066-70.

Rush University
Aerosol Lab Contact Information

Meagan N. Dubosky, MS, RRT-ACCS, NPS, AE-C
Research Coordinator, Department of Respiratory Care
Rush University, College of Health Sciences
Meagan_dubosky@rush.edu
Tel: 312-942-3345

David L. Vines, MHS, RRT, FAARC
Program Director, Chair
Associate Professor, Department of Respiratory Care
Rush University, College of Health Sciences
David_vines@rush.edu
Tel: 312-942-4408