

In Vitro Inhaled Aerosol Comparison of a Conserver Nebulizer (Circulaire® II) vs a Breath-Actuated Nebulizer (AeroEclipse® II)

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1. Background ...

Two different aerosol drug delivery systems claim to enhance Inhaled Aerosol (IA) and shorten treatment time. The Westmed Circulaire® II relies upon the 'conserver' principle, incorporating a flapper valve and reservoir bag that stores aerosol generated during the patient's exhalation phase, which would otherwise be wasted, and delivers it on the subsequent inhalation. Conversely, the Monaghan Medical AeroEclipse® II Breath Actuated Nebulizer (BAN) powers the nebulizer jet during inspiration only, to reduce waste during exhalation. Our RT department was already using the BAN and wished to decrease treatment time to comply with stricter corporate productivity standards. Acquisition cost differential favored a switch to Circulaire® II but we needed to determine if treatment time could be deliberately shortened without negatively affecting Inhaled Aerosol. **Although the treatment time for the BAN could be shortened by using concentrated albuterol, that option is not available for other inhalation drugs and limits the usefulness of the BAN.** So, the study questions became: (1) how does the Inhaled Aerosol of the Circulaire® II compare to that of the BAN during adult and pediatric breathing patterns and (2) can the Circulaire® II deliver equivalent Inhaled Aerosol in less time than the BAN?

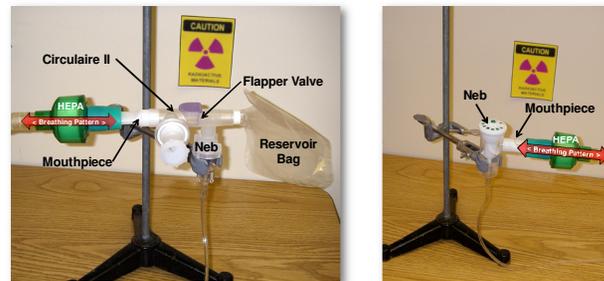
2. Methods ...

I bench tested 2 new samples each of Circulaire® II and BAN taken from hospital stock. Each device was charged with 2-8 mCi of radiolabeled (^{99m}Tc) unit-dose albuterol (2.5 mg / 3 mL 0.9% NaCl). An adjustable piston ventilator created 4 customized sinusoidal breathing patterns with a constant 7.5 L/min \dot{V}_{min} :

Pattern #	f	V _T	\dot{V}_{min}	I-time
1	15	500 mL	7.5 L/min	50%
2	15	500 mL	7.5 L/min	30%
3	30	250 mL	7.5 L/min	50%
4	30	250 mL	7.5 L/min	30%

The objective of using 4 different breathing patterns was to explore how rapid respiratory rates (f), smaller tidal volumes (V_T) and shorter inspiratory time fractions (I-time) influence aerosol delivery between the 2 different delivery systems. Because the BAN is internally mechanized (moving parts), we were concerned its performance would diminish at higher respiratory rates. Minute volume (\dot{V}_{min}) was kept constant in order to eliminate it as a source of variability in determining Inhaled Aerosol delivery.

Both devices were run on wall air at 50 psig & 8 L/min. Inhaled Aerosol was captured on HEPA filters coupled to the mouthpiece and connected to the piston ventilator. Each test was run up to 12 minutes and fresh filters were exchanged every 2 minutes. Exposed filters were measured in a radioisotope counter and the Inhaled Aerosol fraction (radioactivity on filter / radioactivity of initial nebulizer charge) was calculated for all filters. Cumulative IA, expressed as mass of albuterol, in mg, delivered to the HEPA filters, was determined by multiplying the IA fraction at any point in time by 2.5 (mass of albuterol in mg in the Initial Charge).

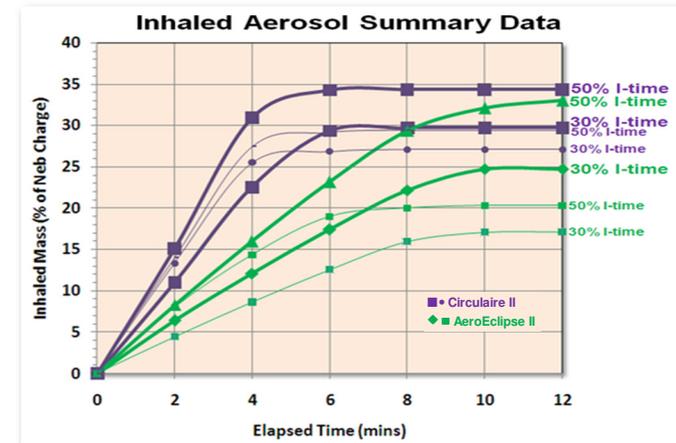


Test setups (ordinarily operated in a lead-lined exhaust hood): Circulaire® II (left) and the AeroEclipse® II (right) showing the HEPA filter at the 'mouth' that captures Inhaled Aerosol. Radioactivity of initial nebulizer charge and captured aerosol on filters is measured by a nearby radioisotope calibrator (not shown) and expressed as % of nebulizer charge.

3. Results ...

Device (note color code for graph on right)	Breathing Pattern (f/V _T /I-time)	Inhaled Aerosol at ...			
		4 minutes		8 minutes	
		%	mg	%	mg
BAN	15/500/50%	15.98	0.40	29.36	0.73
BAN	15/500/30%	12.11	0.30	22.19	0.55
BAN	30/250/50%	14.34	0.36	19.99	0.50
BAN	30/250/30%	8.64	0.22	15.96	0.40
Circ II	15/500/50%	30.88	0.77	34.34	0.86
Circ II	15/500/30%	22.53	0.56	29.69	0.74
Circ II	30/250/50%	27.46	0.69	29.38	0.73
Circ II	30/250/30%	25.50	0.64	27.09	0.68
Paired t-test for Circ II vs BAN:		P = 0.0021		P = 0.0416	

The Inhaled Aerosol data, shown in the table as well as graphically, depicts the mass of albuterol delivered against treatment time for the 4 breathing patterns and 2 nebulizer systems. The mean (±SD) IA for the Circulaire II at 4 mins was 0.66 (±0.09) mg compared to 0.55 (±0.14) mg for the BAN at 8 mins. Note that Inhaled Aerosol for the rapid/shallow breathing pattern is greater and more consistent for the conserver system than for the breath-actuated system, demonstrating that performance of the BAN falls off during rapid/shallow breathing.



4. Conclusion ...

The bench data clearly demonstrate that the Circulaire® II outperforms the AeroEclipse® II BAN inasmuch as equivalent or greater Inhaled Aerosol was delivered in half the time (4 vs 8 minutes), even with the more challenging rapid/shallow breathing pattern representative of children or acute asthmatics. Using equivalent aerosol drug delivery as the performance standard for acceptability, it can be concluded that the conserver system, embodied by the Circulaire® II, significantly increases drug delivery and allows treatment times with the Circulaire® II to be deliberately shortened to about 2-4 minutes while accomplishing the same or greater inhaled drug mass typically achieved with the BAN. The Circulaire® II can be used in this manner with a multitude of different drugs, besides albuterol, that are not available in high concentration unit doses. The Circulaire® II, on the basis of this performance, coupled with the favorable cost differential, met our requirements for an aerosol drug delivery system for routine and emergency therapy and justified a product switch.