Influence of the Position on the *In Vitro* performances of a new spacer for pediatric use in a mechanical ventilation circuit.

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▪ Introduction

The efficiency of drug delivery in mechanical ventilation depends on multiple factors as for example the position of the device in the mechanical ventilation system [1; 2]. One of our recent study evaluate the influence of the position of the device in an adult mechanical ventilation circuit as a function of the volume [3]. The results show that the higher volumes (>100 mL) have a higher aerosol deposition when located in the inspiratory linb, before the Y piece compared to when the device is located after the Y piece, but the position seem to have no influence on in vitro performance of lower volume devices (60mL). The aim of this study was to evaluate the in vitro performance of a prototype spacer (MinimHal®, Laboratoire OptimHal-ProtecSom) with low volume (60mL), which allows the use of both a pressurized metered dose inhaler and a vibrating mesh nebulizer, at two different positions on the breathing circuit : before and after the Y piece. The prototype spacer was evaluated with both adult and paediatric settings.

▪ Material and methods

A ventilator (Evita 2 Dura, Dräger) was used in volume controlled mode connected to the test lung model (SmartLung Adult, IMT Medical). An endotracheal tube (7,5mm ID for the adult model and 4 mm ID for the pediatric model) and a right-angle elbow adapter were inserted between the Y-piece and the Test Lung. The delivered dose was collected on a filter inserted between the ETT and the test lung model. Measurements were performed at two different location on the mechanical ventilation circuit, before and after the Y piece.

Two different measurements were performed ;

- **Use with a pMDI** : 10 doses containing 100 µg of Salbutamol (Ventolin® 100µg, GlaxoSmithKline) were actuated in the prototypes during inspiration.
- **Use with a vibrating mesh nebulizer (VMN)** : A solution containing 5 mg of Salbutamol (Salbutamol Mylan, 2,5 mg/2,5 mL) was nebulized with the vibrating mesh nebulizer Aeroneb® Pro (Aerogen).

Measurements were performed with adult settings (Tidal volume = 450 mL, frequency = 15 cycles/min, Positive End Expiratory Pressure (PEEP) = 5cmH_2O, ratio between inspiratory and expiratory time = ½ and a flow rate of 21 L/min) and pediatric settings which corresponds to a child of 15kg weight (tidal volume = 150 mL, frequency = 25 breaths/min, ratio between inspiratory and expiratory 1/1, PEEP = 5 cm H_2O and flow rate of 13 L/min).

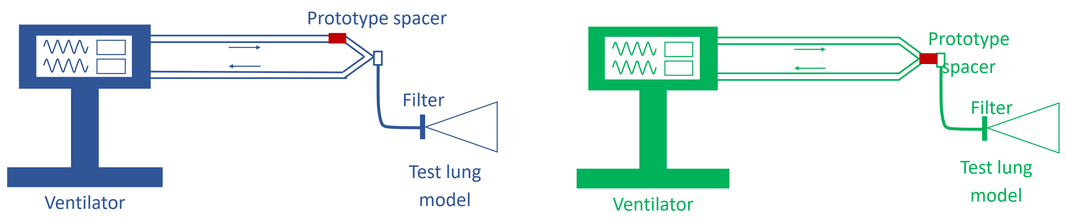


Fig 1: Schematic drawing of the bench model used for the experiments with the prototype inserted before the Y piece (left) and after the Y piece (right).

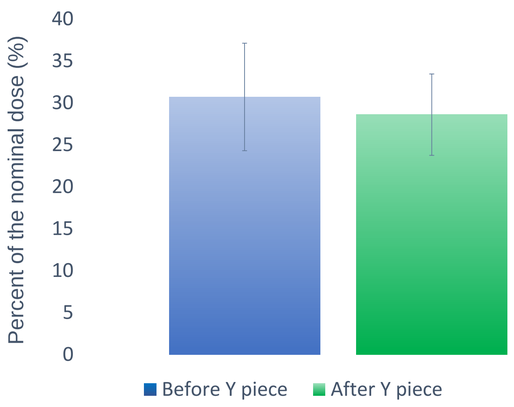
The filter and each component of the mechanical ventilation circuit were recovered with a NaCl solution (0,1M) and quantified by UV spectrophotometry. Each measurement was performed five times. Results are expressed as means ± standard deviation.

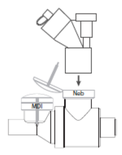
Statistical analyses were performed using GraphPad Prism 6.01 (GraphPad Software, CA) and consisted of multiple t-tests. A p-value < 0,05 was considered significant.

▪ In vitro aerosol delivery

Adult model

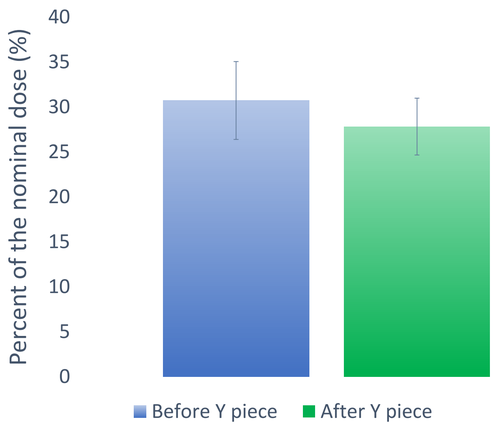
With vibrating mesh nebulizer

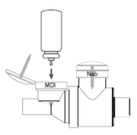




The percent of the nominal dose collected on the filter is similar when the device is located before or after the Y piece when using with the vibrating mesh nebulizer (30,70 ± 6,40 % vs 28,58 ± 4,84 %) (p > 0,05).

With pMDI





The percent of the nominal dose collected on the filter is similar when the device is located before or after the Y piece when using with the pMDI (30,71 ± 4,33 % vs 27,80 ± 3,16 %) (p > 0,05).

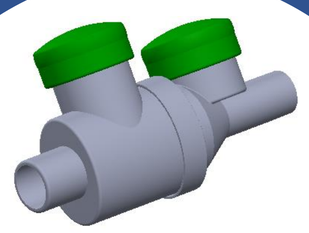
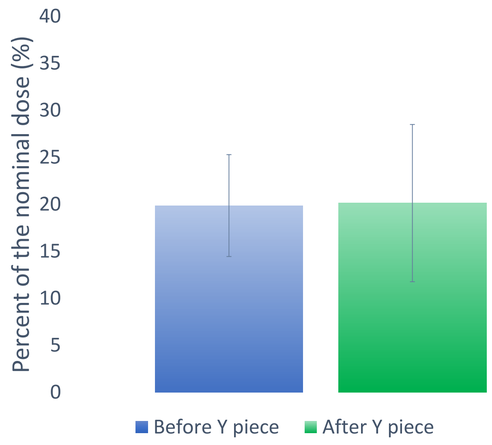


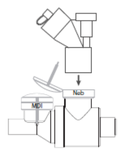
Fig 1: Drawing of the prototype (Solidworks, France)

The prototype was created with Solidworks (Dassault System) and 3D print with a PLA material. The prototype has an internal volume of 60 mL.

Pediatric model

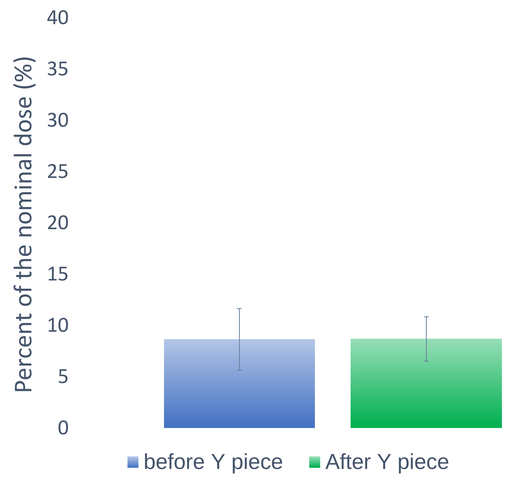
With vibrating mesh nebulizer

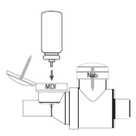




The percent of the nominal dose collected on the filter is similar when the device is located before or after the Y piece when using with the vibrating mesh nebulizer (19,85 ± 5,42 % vs 20,12 ± 8,36 %) (p > 0,05).

With pMDI





The percent of the nominal dose collected on the filter is similar when the device is located before or after the Y piece when using with the pMDI (8,64 ± 3,00 % vs 8,67 ± 2,16 %) (p > 0,05).

▪ Conclusion

The results show that the in vitro performances of the prototype spacer (60 ml) are not influenced by the position of the device in the mechanical ventilation breathing system when used with a vibrating mesh nebulizer or with a pMDI. And this, wether using pediatric respiratory parameters or adult respiratory parameters. This study is consistent with the previous one [3] which showed that for volumes becoming lower (<100mL), the location of the device had a fewer influence on the aerosol deposition with mechanical ventilation.

▪ References

[1] : Ari A, Aerabi H, Fink JB: Evaluation of Aerosol Generator Devices at 3 Locations in Humidified and non-humidified Circuits During Adult Mechanical Ventilation, *Respir Care* 2010, 55: 837-844.
[2]: Dugernier J, Wittebole X, Roeseler J, Michotte JB, Sottiaux T, Dugernier T, Laterre PF, Reychler G : Influence of Inspiratory Flow Pattern and Nebulizer Position on Aerosol Delivery with a Vibrating-Mesh Nebulizer During Invasive Mechanical Ventilation: An In vitro Analysis*, J Aerosol Med Pulm Drug Deliv* 2014, 27: 1-8.
[3] Eckes M, Porée T, “Effect of spacer volume on drug delivery using mechanical ventilation: An in vitro study”, Poster presentation, RDD 2019, Estoril.