The Impact of Actuation Force on Droplet Size Distribution and Spray Duration of Three Commercially Available Nasal Sprays

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INTRODUCTION

• Rhinitis is effectively treated by administration of intranasal corticosteroids (ICSs) generally delivered as aqueous suspension nasal sprays.

• Droplet size distribution (DSD) and spray duration are important parameters of nasal spray atomization that may affect deposition in the nose [1].

• Actuation forces for nasal sprays used by adults may vary widely among individuals [2].

• In this study, the impact of actuation force on DSD and spray duration was investigated for three commercially available ICS suspension nasal sprays:

- Nasonex® (Merck & Co., Inc., Kenilworth, NJ)
- Rhinocort Aqua® (AstraZeneca LP, Wilmington, DE)
- Flonase® (GlaxoSmithKline, Research Triangle Park, NC)

METHODS

• Individual actuations of nasal sprays (Nasonex, Rhinocort Aqua, and Flonase) were characterized by laser diffraction using the Sympatec Helos system with the Sympatec sprayer attachment and the force actuation unit (Sympatec GmbH, Clausthal, Germany).

• Each nasal spray was oriented upright and the nozzle was placed 3.25 cm from the center of the laser beam.

• The shot weight of each spray was determined by weighing each device before and after each actuation.

• Three actuation forces were selected for each spray to span a range of actuation forces measured clinically among adults [2]:

- Nasonex and Flonase: 34.3, 56.9, and 84.3 N
- Rhinocort: 36.8, 56.9, and 84.3 N

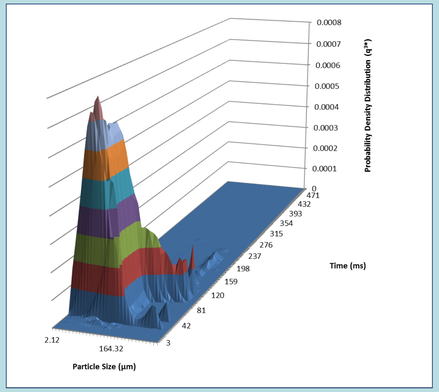
• Data were recorded every 3 ms starting 100 ms before the optical concentration was ≥ 0.5%. These data were then weighted based on optical concentration to interpolate the corresponding X_{10}, X_{50}, X_{90} and the GSD over the life of the spray. Each configuration was evaluated 5 times.

• The average transmittance, defined as 100% - optical concentration, provides an indication of the volume of the spray passing the lens and was used to determine spray duration.

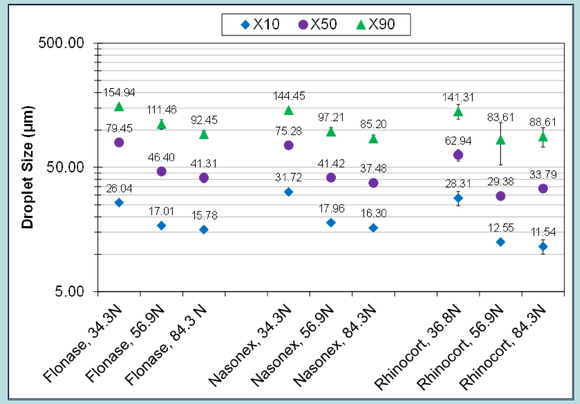
RESULTS

For all three formulations, the shot weights were representative of the package labeling.

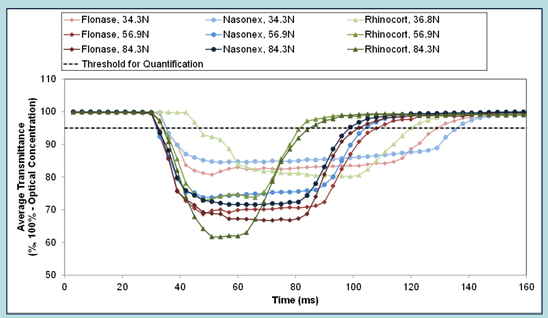
	Target Shot Weight (mg)	Actual Shot Weights (mg) 34.3N	56.9N	84.3N
Flonase®	100	96.5	108.0	101.0
Nasonex®	100	97.6	99.8	100.1
Rhinocort®	50	49.8	51.9	50.3



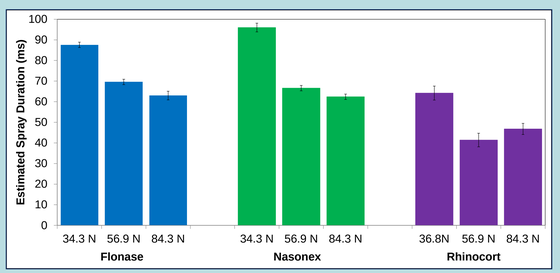
Plume DSD over time for Flonase at an actuation force of 56.9N.



Droplet sizes for the three products at each actuation force. GSDs ranged from 1.8-2.1.



Average transmittance profiles of the nasal sprays using three different actuation forces.



Estimated spray durations for the nasal spray products using three different actuation forces.

DISCUSSION

• The DSDs were similar for the three products at each actuation force, with the droplet sizes for Rhinocort Aqua being slightly smaller than Flonase and Nasonex.

• Generally, droplet sizes decreased with increasing actuation force.

• The higher two actuation forces produced sprays of similar intensity. The maximum intensity at the lowest actuation force was significantly reduced.

• The transmittance profiles for Rhinocort were different than the other two products. This may be a function of the shot weight, pump design, or formulation differences (e.g., viscosity, density).

• Shorter spray durations were observed at higher actuation forces.

• Spray duration, shot weight, and nozzle orifice area can be used to estimate spray velocity.

• DSDs and spray velocities can be used in computational fluid dynamics studies of nasal spray deposition to study the effects of actuation force on regional deposition from nasal sprays (see poster by Kimbell et al.).

REFERENCES

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ACKNOWLEDGMENTS

This study was funded by the U. S. FDA grant number 1U01FD005201. Views expressed in this presentation do not necessarily reflect the official policies of the FDA, nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.