

Usability and Tolerability Study in Human Subjects with a Novel Precision Olfactory Delivery (POD) Device. John Hoekman, Alan Brunelle, Michael Hite, Paula Kim, Chris Fuller. *Impel NeuroPharma, Inc.*

PURPOSE

Summary

- To compare the usability and tolerability of the Impel Precision Olfactory Delivery (POD) device to a reference conventional pump nasal spray device (CNS) in the administration of a saline dose.

Background and Objectives

The specific objectives of this study were to identify:

- How well participants tolerated nasal saline administered by each of the devices;
- Whether participants could readily use each of the devices; and
- Whether participants encountered any problems or errors of use that would indicate a potential need for change in device design, device-use instructions, and/or labeling of the Sponsor's device.

METHODS

Study Structure

Thirty-one participants ranging in age from 24 to 59 years each completed 2 sessions where they were asked to perform a series of tasks with each of the nasal-delivery devices. Each session lasted 45 minutes. Each participant used one of the nasal delivery devices during each session. During each session, participants answered a series of questions. The participants received an explanation of the purpose of the study, its planned activities, and its requirements, and had an opportunity to have their questions answered before undergoing any study-related procedures. This study employed a within-participant design where all participants used both of the devices. The presentation order of the devices was systematically varied to account for any potential order effects. Thus, each participant used either the POD or CNS device during their first session and the other device during their second session. Sessions occurred at least 1 day apart to provide enough time for any residual effects/sensations to subside following the use of the first device.

Treatment Each device was prefilled with sterile saline. The participants self-administered 0.1mL sterile isotonic saline twice to each nostril during each session, for a total volume of delivery of 0.4mL/session and a total of approximately 0.8 mL over the course of the entire study. The devices were rated in 8 categories.

Videotaping Four (4) video cameras recorded each session, for a left side, right side, overhead and frontal view.

Table 1: Age and Race/Ethnicity of study participants by Gender

Age (years)	Female	Male	Race/Ethnicity	Female	Male
20-29	5	2	African American	6	4
30-39	2	4	Caucasian	10	9
40-49	5	4	East Indian	0	1
50-59	4	5	Other	0	1

CONCLUSIONS

- The Impel POD outperformed the reference device in overall preference, saline deposition, accurate positioning for administration, impact on nasal conditions and priming before use.
- The POD matched the reference device for tolerance to saline, and administration of saline.

RESULTS

The POD outperformed in terms of:

- Overall preference;
- Saline deposition;
- Positioning for administration;
- Impact on nasal conditions; and
- Priming before use.

The POD matched the CNS in terms of:

- Tolerance of saline;
- Preparation for priming; and
- Administration of saline.

- Two-thirds of the participants (21/31, 67%) preferred the POD to the reference device, with nearly 50% of the participants having greater confidence that the dose was sufficiently delivered. This result was corroborated with the participant's assessment of superiority to the POD with regards to each device's ability to deposit the saline to the olfactory region of the nasal cavity. This mirrored the related assessment for the perception of the saline loss into the throat or coming out of the nose.
- Participants rated both devices comfortable to use and tolerated well the delivery of saline with both devices.
- It was found that participants were better able to prime, aim and actuate the POD versus the reference pump spray.
- In addition, 100% of participants were able to successfully actuate the POD on first attempt, while 9/31 had difficulty with the reference device. Eventually all users were able to use both devices.



Impel's Pressurized Olfactory Delivery (POD) device 1.0



Conventional Nasal Spray (CNS)



Example of POD positioning for dosing.

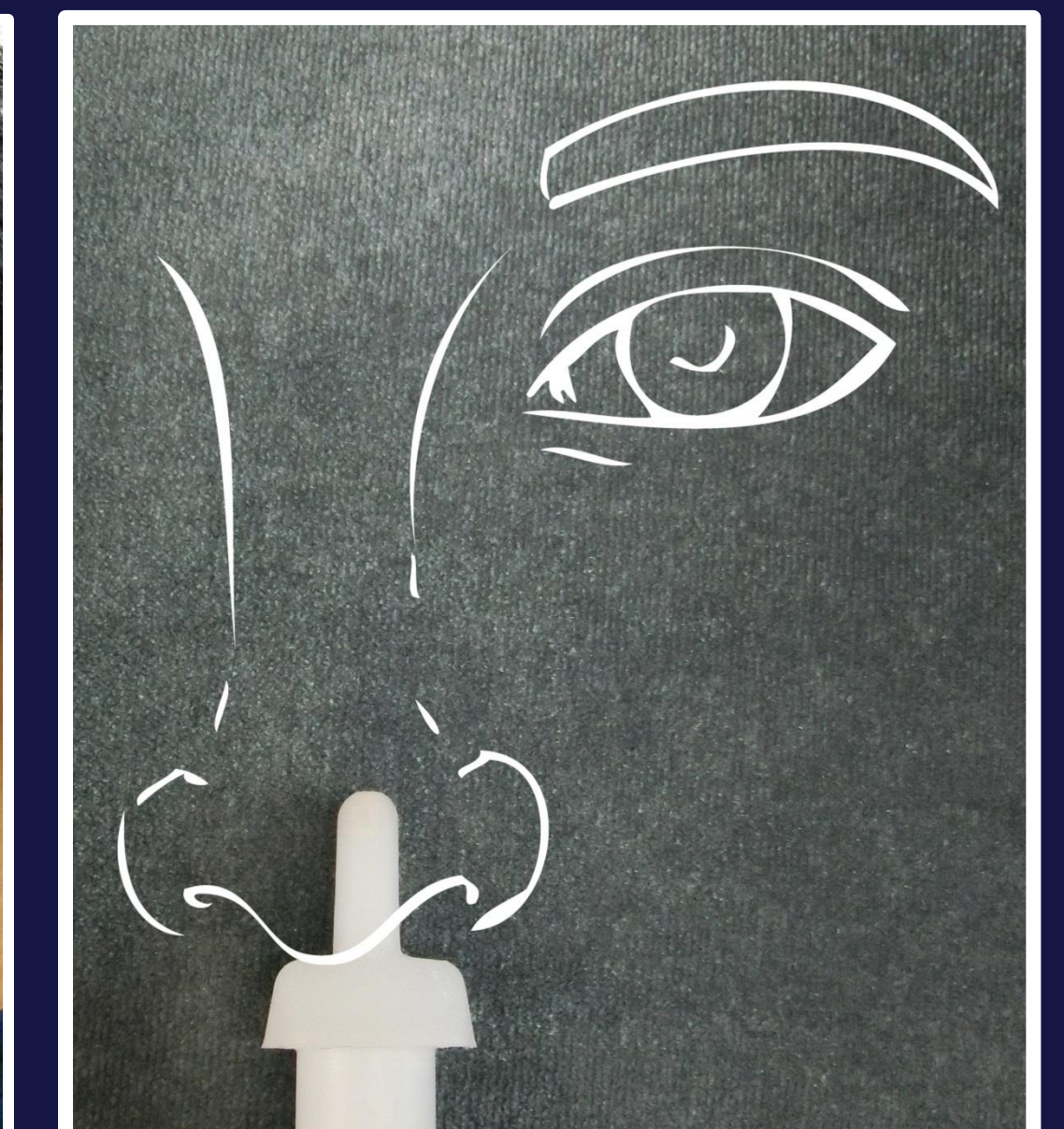


Diagram given to participants showing correct positioning for use.