USER TESTING: CRITICAL FOR TRULY UNDERSTANDING PATIENT NEEDS

Here, Fanny Sellier, Global Category Manager, Ophthalmic Products, Nemera, presents a trio of comparative user studies between Nemera's Novelia® preservative-free, multidose eyedropper and similar products from competitors, highlighting the need for user studies in addition to standard *in vitro* tests when assessing the quality of an ophthalmic drug delivery device.

INTRODUCTION

Ophthalmic pathologies include eyesight threatening conditions (diabetic retinopathy, glaucoma, cataract, age-related macular degeneration and retinal detachment) and, relatively speaking, less serious eye conditions (dry eye, red eye, etc), all of which are treated by ocular injections, eyedrops or surgery. Eyedrops are primarily used for glaucoma, dry eye disease (DED), conjunctivitis and allergy. For chronic diseases, when daily treatments are needed, preservative-free formulations are key to protecting the patient's ocular surface, as preservatives can cause allergic reactions, irritations and can even damage patients' eyes.[1] Thus, preservative-free formulations are needed for glaucoma and DED.

At present, two options are available for dispensing preservative-free ophthalmic formulations: unit-dose systems or preservative-free, multidose systems. Unit-doses are generally considered to be not patient-friendly, and are often costly and bulky, making them unsuitable for home use for chronic conditions.[2] Therefore, in order to improve patient compliance and limit waste, the preferable solution is to use preservative-free formulations with the convenience of a multidose bottle. Two main types of preservative-free, multidose (PFMD) systems exist today:

- **Pump systems** – These use either an airless container or a filter technology to allow air to enter back into the bottle. The advantage of pump systems is that the dose is controlled and consistent, however priming is needed before delivering the first dose.
- **Squeeze bottles** – These dispense drops using either a non-return valve or a filtering system. Most of them also rely on an air filtering system to stop bacteria entering the bottle when it is open to the air. There is no priming with squeeze bottles, but the dose is less controlled.

Eyedropper performance is mainly evaluated by *in vitro* tests, such as the dose variability against shelf life, the sterility of the content and the delivered drop. Despite these important *in vitro* tests, the usability aspects of the drug delivery system are not fully considered. Therefore, also conducting a user test evaluation is key because, even if it is successful according to the *in vitro* tests, an eyedropper may not necessarily be appreciated by patients due to poor usability. Consequently, a device with good *in vitro* test performance could be clinically inefficient.

In this article, we report on three user tests that have been conducted to evaluate the level of difference in terms of usability characteristics and user preferences for different PFMD systems.

COMPARATIVE USER STUDY 1: NOVELIA® BOTTLE & 3K®

A randomised study was conducted at the end of 2017 at the Department of Ophthalmology, Kuopio University Hospital (Kuopio, Finland), interviewing 30 patients over 50 years old with either glaucoma or ocular hypertension, with a majority of female participants (77%).[3] The patients used safety glasses and instilled eyedrops from two different PFMD systems: the Novelia® bottle from Nemera and the

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3K®-System pump from Ursatec (St Wendel, Germany). The participants were asked to rate several parameters from -5 (extremely difficult) to +5 (extremely easy):

- Opening of the container
- Squeeze force needed for drop administration
- Targeting the eye
- Drop control
- Removal of the residual drop
- General usability of the container.

In addition, the users were also asked about their preference between the two eyedrop containers.

According to the results, Novelia® outperformed 3K® in the tasks of opening, squeezing, targeting the eye and removing the residual drop, as well as having better general usability (Figure 1). 100% of users were able to open the Novelia® bottle and deliver a singular drop onto the protective glasses. Five participants did not succeed in opening the 3K® system and seven out of the remaining 25 were not able to instil a singular drop onto the safety glasses. 97% of users named Novelia® as their first choice container over the 3K® system, with only one participant in favour of 3K®.

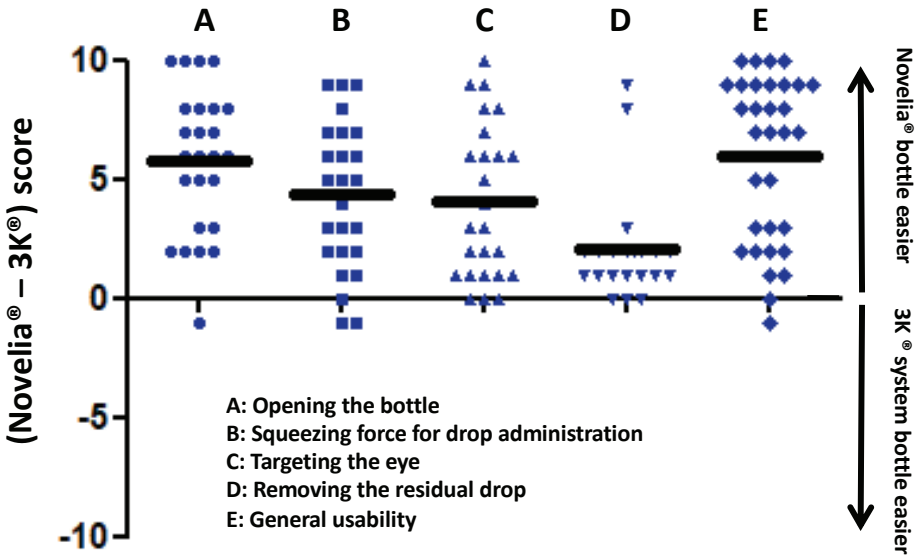

Figure 1: The difference between scores given by 30 patients with glaucoma or ocular hypertension for Novelia® and 3K®-System bottles (Novelia® - 3K®) . Adapted from Figure 1 of the study "Preferences and ease of use of preservative-free IOP-lowering eyedrop containers: A comparison of two multidose bottles" with the permission of Clinical Investigation journal.

COMPARATIVE USER STUDY 2: NOVELIA® BOTTLE & OSD

A second randomised study was performed for Nemera by the independent user studies consultancy GfK (Suresnes, France).[4] This study comprised 90 patients (40 in Europe and 50 in the US). 75% of them were over 60 years old. 40% of the participants had glaucoma, 40% were regular users of eyedrops (primarily for DED) and 20% were occasional users (for example for conjunctivitis). The interviews happened at the respondents' homes or in GfK's offices, where patients instilled eyedrops (using safety glasses) with different eyedroppers and rated these systems on nine attributes from 1 (very poor) to 5 (very good). Both ophthalmic systems were PFMD bottles: The Ophthalmic Squeeze Dispenser (OSD) from Aptar Pharma (Radofzell, Germany) and Novelia® from Nemera.

Based on the results, Novelia® was found to display superior usability characteristics, with the exception of the grip of the bottle, where both devices were considered to be the same (Figure 2).

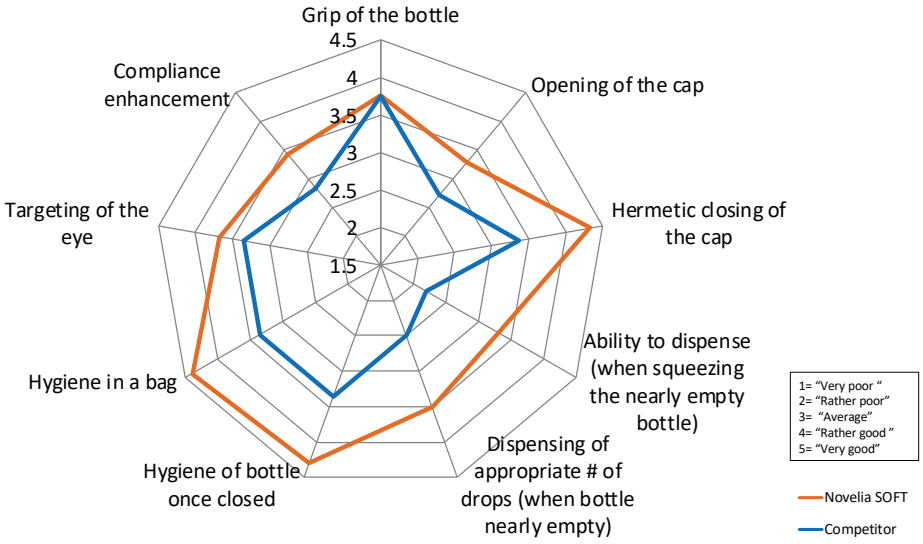

Figure 2: Mean scores across different parameters given by 90 patients with glaucoma, dry eye or conjunctivitis using Novelia® and OSD.

First of all, the screw cap on Novelia® proved intuitive, as it is a similar mechanism to that found on regular, preservative-containing three-piece eyedroppers, whereas the OSD cap opening was not perceived as obvious or easy. Patients are not used to snap-on caps with their current bottles, and so found opening the OSD confusing. Additionally, some patients found it too loose after repeated use, meaning it ceased to seal hermetically and could come off when carried in a purse or bag. The robustness of the Novelia® screw cap made patients feel more comfortable when carrying it in a bag as it felt more secure.

The biggest difference between both systems was seen when the bottle was nearly empty at the end of use, at which point the participants found squeezing the OSD bottle harder than the Novelia® one.

Additionally, participants appreciated the Novelia® blue tip as it helped them target their eyes.

Overall, 68 out of 90 users (76%) preferred Novelia® over the OSD.

COMPARATIVE USER STUDY 3: NOVELIA® BOTTLE & 3K®

The third randomised study sponsored by Nemera was conducted early in 2018 in Marketing Espace's office (Lyon, France).[5] Out of the 20 users interviewed, 60% were regular users of eyedrops (including seven with glaucoma) and 40% were occasional users. The participants were asked to administer drops onto protective glasses with

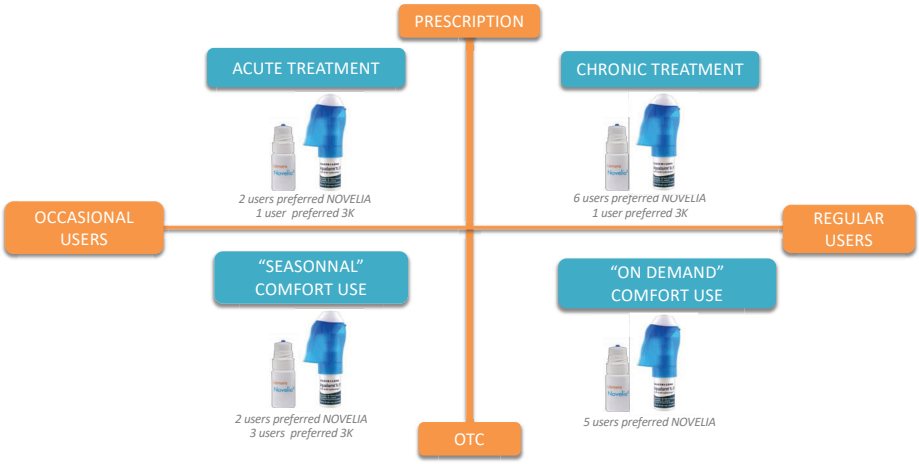

Figure 3: User preference segmented by user type (regular/occasional) and treatment type (medical with prescription/comfort) on 20 patients.

the same two PFMD containers as the first study: Novelia® and the 3K®-system. They also selected their preferred system overall and rated them from 1 (very poor) to 5 (very good) on several individual parameters:

- Cap opening
- Ease of first time use
- One drop at a time
- Targeting the eye
- Hermetic sealing
- On-the-go use
- Ease of treatment adherence.

Overall the 3K®-system was rated at 3.4/5 (average/good) and Novelia at 4.2/5 (good). Patients reported that Novelia® was easy to use and ideal for an on-the-go use. Novelia® also outperformed 3K® by 0.6 or 0.7 points on cap opening, hermetic sealing and eye targeting. Both systems performed equally (3.7/5) on one drop at a time. 75% of users preferred Novelia® over 3K® for these reasons.

Another interesting finding was that regular and occasional users don't have the same preferences for eyedrop containers and value them differently. On the one hand, both systems were appreciated similarly by occasional users, four of eight occasional users preferred Novelia® and the same number preferred 3K®. On the other hand, regular users demonstrated a very strong preference for Novelia®, with 11 of 12 regular users preferring Novelia®. This would suggest that chronic users are more sensitive to easy-to-use features.

CONCLUSION

The three studies demonstrated a significant difference between PFMD systems in terms of usability, which can have an impact on patient adherence and treatment efficacy. The studies were conducted in hospitals, patients' homes and offices. Participants had glaucoma, ocular hypertension, DED, conjunctivitis and allergies. The studies did however have some limitations due to the low number of participants and two of them being sponsored by Nemera. However, they all point towards a patient preference for the same PFMD system, Novelia®, highlighting the difference between the ophthalmic systems tested.

The third study highlighted a difference in patient preference according to the frequency with which they use the eyedropper. Notably, patients with chronic diseases, such as glaucoma and DED, show a strong preference for a product that is easy to use daily and easy to carry. Glaucoma patients are often elderly people and have difficulties using eyedroppers but still need to administer eyedrops every day, sometimes twice daily. Nearly nine out of 10 glaucoma patients are unable to instil eyedrops correctly,[6] and therefore an easy-to-use system that is appreciated by patients could contribute to improving their compliance to a treatment.

In conclusion, drug delivery systems should be assessed not only in terms of *in vitro* performance (drop consistency, leachables, etc) but also in terms of patient usability.

ABOUT THE COMPANY

Nemera is a world leader in the design, development and manufacture of drug delivery devices for the pharmaceutical, biotechnology and generics industries. Nemera's services and products cover several key delivery routes: ophthalmic; nasal, buccal, auricular; inhalation; parenteral; and dermal and transdermal.

Nemera always puts patients first, providing the most comprehensive range of devices in the industry, including innovative off-the-shelf systems, customised design development, and contract manufacturing.

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Fanny Sellier is responsible for ophthalmic products at Nemera, including the preservative-free technology, Novelia®. She joined the company in 2011. A graduate from the ISEG business school in Strasbourg and the IUT de Chimie (chemical sciences) in Besançon, France, Ms Sellier worked for seven years for Rhodia (now Solvay) in the US in marketing, Lean enterprise and business development. She was then with BASF in a marketing position managing products for the home care industry.

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