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Novel Eye Drop Delivery Aid Improves Outcomes and Satisfaction

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Purpose: To compare a nose-pivoted drop delivery device (NPDD) with traditional eye drop delivery in glaucoma subjects.

Design: Repeated-measures case series.

Participants: Fifty glaucoma subjects (100 eyes) who reported difficulty self-administering eye drops.

Methods: We compared eye drop delivery using a NPDD against traditional delivery techniques at baseline (baseline traditional) and after standardized teaching (post-teaching traditional). Subjects used a 1-to-10 scale (10 being easiest) to rate the ease of delivery with each technique and completed a satisfaction survey. Two graders used digital video to independently review eye drop delivery and recorded: (1) accurate placement: the eye drop reached the ocular surface; (2) no contact: no bottle tip contact against the ocular or periocular surface; and (3) number of eye drops dispensed. We defined primary success as accurate placement and no contact; secondary success as primary success with only 1 drop dispensed.

Main Outcome Measures: We used logistic-transformed generalized estimating equation (GEE) regression to compare technique satisfaction, accuracy, no contact, and primary and secondary success. Number of drops dispensed was compared using a Cox model.

Results: Forty-seven of 50 subjects (94%) preferred the NPDD over traditional eye drop delivery. The mean score for ease of use was higher for the NPDD (8.9 ± 1.1) than baseline traditional (6.7 ± 2.1; $P < 0.001$) and post-teaching traditional (7.0 ± 2.0; $P < 0.001$). Forty-nine of 50 (98%) subjects thought the NPDD was comfortable to use and would recommend the device. The eye drop reached the ocular surface in a similar percentage of subjects (>90%) with each method. The bottle tip contacted fewer eyes with the NPDD (10 eyes) than baseline traditional (33 eyes; $P < 0.001$) and post-teaching traditional (25 eyes; $P = 0.009$). The number of drops dispensed was lower with the NPDD (1.7 ± 1.2) than baseline traditional (2.2 ± 1.6; $P = 0.017$) and post-teaching traditional (2.4 ± 1.8; $P = 0.006$). The NPDD increased primary and secondary success of eye drop delivery (86% and 54%, respectively) compared to baseline traditional (66% [$P = 0.001$] and 28% [$P < 0.001$]) and post-teaching traditional (70% [$P = 0.005$] and 40% [$P = 0.018$]).

Conclusions: Eye drop users preferred the NPDD over traditional eye drop delivery. The NPDD improved eye drop delivery success, reduced bottle tip contact, and decreased the number of eye drops wasted. *Ophthalmology Glaucoma 2021;4:440-446 © 2021 by the American Academy of Ophthalmology. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).*

Glaucoma affects more than 60 million people worldwide.[1] Eye drop medications are the most common method of treating glaucoma.[2] Poor adherence to prescribed eye drop medications can result in glaucomatous vision loss.[3–7] Eye drop adherence for all ocular diseases has 2 requirements: (1) possession and regular use of the medication as prescribed and (2) successful delivery of the medication to the eye. Most glaucoma patients struggle at self-administering eye drops.[8–11] Patients who struggle with eye drop self-administration could benefit from delivery aids.[12–19]

Prior studies indicate that up to 90% of glaucoma subjects instill their eye drops incorrectly, with 7% to 30% of patients missing the eye with the drop and 29% to 80% contacting the eye or eyelids with the bottle tip.[8–10,20] Poor eye drop instillation also wastes valuable medication, which can worsen adherence further if a bottle empties prematurely.[7–9] Self-administering eye drops can be challenging for patients, who may fear bottle tip contact against the eye, wasted medication, or vision loss resulting from poor delivery.[21] Although useful, existing delivery aids have not been adopted widely, possibly because they are not user friendly.[19]

We aimed to test whether a novel eye drop delivery aid would improve eye drop instillation success in patients with self-reported difficulty placing eye drops and whether they preferred such an aid over their traditional, unassisted technique. One of the authors (R.M.K.) developed a nose-pivoted drop delivery device (NPDD; GentleDrop [Bedo Solutions LLC]). The NPDD rests on the bridge of the nose

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to position a stable bottle tip over the ocular surface without obstructing the visual axis (Fig 1). Patients and clinicians may benefit from a user-friendly delivery aid that improves eye drop instillation.

Methods

We enrolled 50 glaucoma eye drop users at the Devers Eye Institute, Portland, Oregon, between April 2018 and September 2019. Participants were recruited if they reported having difficulty with eye drops in response to waiting room posters and/or interactions with eye care providers. The Legacy Health Institutional Review Board approved the study. Participants provided written informed consent before they underwent any study-related testing. All aspects of the study adhered to the tenets of the Declaration of Helsinki.

Inclusion and Exclusion Criteria

Inclusion criteria were: (1) existing diagnosis of perimetric or preperimetric glaucoma or ocular hypertension; (2) bilateral self-administration of 1 or more type of intraocular pressure-lowering eye drops with at least 6 months of prior usage; and (3) any self-perceived difficulty instilling eye drops. Exclusion criteria were: (1) cognitive or physical limitations interfering with eye drop administration; (2) current use of an eye drop delivery aid; or (3) allergy to preserved artificial tears.

Demographic Data

We collected demographic data including age, gender, ethnicity, diagnosis, visual acuity, visual field mean deviation, number of ocular hypotensive medications prescribed, prior incisional glaucoma surgery, years using glaucoma eye drops, level of education, and hand dominance. We tracked whether subjects instilled eye drops with the dominant hand and if they were standing, seated, or supine at each self-administration.

Nose-Pivoted Drop Delivery Device

The NPDD is a single-piece silicone eye drop alignment aid with a sleeve portion that fits around an eye drop bottle and an extending portion that rests on the bridge of the nose. The device balances on the bridge of the nose to position a stable eye drop bottle tip ergonomically over the ocular surface without covering the visual axis (Fig 1). When upright, the device is approximately 55 mm tall and 30 mm wide. The sleeve portion can accommodate any regularly shaped 5-ml, 10-ml, or 15-ml eye drop bottle with a 25-mm diameter. The device was designed to fit a wide range of pupillary distances with an average of 60 mm. The flexible silicone does not alter significantly the squeezing force required to instill an eye drop.

Study Procedure

We brought each subject to a room with a mirror, upright chair, reclining chair, and 2 digital video cameras. We then recorded 3 video sessions per subject from 2 different angles as they instilled propylene glycol 0.6% artificial tears (Systane Balance; Alcon). This artificial tear was chosen because of its milky white appearance, which is easily visible on video review. In the first videos, we recorded all subjects self-administer artificial tears into both eyes using their traditional techniques as performed routinely at home. Subjects then received standardized, 1-minute teaching sessions guided by handouts on the recommended traditional eye drop administration according to Glaucoma.org[22] and on the use of the NPDD. Subjects were allowed to practice with each technique for up to 2 minutes. During a 5-minute pause between video recordings, we measured the pupillary distance of each subject. We randomly determined the order of NPDD and post-teaching traditional testing. The second and third videos consisted of subjects self-administering artificial tears using the post-teaching traditional technique and the NPDD. We included a teaching session for both techniques (traditional delivery and NPDD) because previous studies have shown that teaching sessions alone can have a positive impact on the success of eye drop administration.[23,24] We documented subjects' self-perceived ease of use on a scale from 1 to 10 (10 being easiest) after each administration. At the end of the study, subjects completed a 5-point Likert scale satisfaction survey and chose their preferred method of instilling eye drops (i.e., traditional method or NPDD).

Figure 1. Photographs showing the nose-pivoted drop delivery device (NPDD; GentleDrop™; Bedo Solutions LLC) in use. The silicone sleeve balances on the bridge of the nose to position a stable eye drop bottle tip ergonomically over the ocular surface. The NPDD was designed to be nonintrusive by stabilizing the bottle while not (1) covering the eye, (2) touching the skin around the eye, or (3) pointing the bottle tip straight at the eye (i.e., obliquely angled, not perpendicular).

Video Recording

A research assistant held 1 camera at an oblique angle to the eye, and 1 camera directly to the side of the eye. We downloaded and saved the paired recordings in a unique local folder under a patient identification.

Video Analysis

Two reviewers (F.G.S. and Y.K.) masked to subject and visit order independently examined each video pair (50 subjects × 2 eyes × 3

Table 1. Demographic Characteristics of 50 Subjects in the Study

Characteristic	Data
No. of eyes (subjects)	100 (50)
Age, yrs	
Mean ± SD	68.8 ± 9.23
Range	54-92
Female gender, no. (%)	23 (46)
Ethnicity, no. (%):	
Non-Hispanic White	31 (62)
Black	8 (16)
Hispanic/Latino	6 (12)
Asian or Pacific Islander	4 (8)
Arabic	1 (2)
Education, no. (%)	
Less than high school	6 (12)
High school diploma	6 (12)
Some college	2 (4)
College degree	26 (52)
Graduate degree	10 (20)

SD = standard deviation.

Table 2. Medical Characteristics of 50 Subjects in the Study

Characteristic	Data
No. of eyes (subjects)	100 (50)
Diagnosis, no. (%)	
POAG	39 (78)
PACG	5 (10)
PXFG	3 (6)
NVG	2 (4)
Other	1 (2)
Mean no. of years using drops	
Mean ± SD	7.5 ± 7.8
Range	0.5–35
History of incisional surgery, no. (%)	7 (14)
Pupillary distance, mm	
Mean ± SD	64.5 ± 3.95
Range	57.0–73.0
BCVA, decimal (SD)	
Right eye	0.84 (0.32)
Left eye	0.81 (0.30)
VF MD, dB (SD)	
Right eye	−5.29 (7.15)
Left eye	−6.63 (9.05)
Total no. of medications	
Right eye	
Mean ± SD	1.9 ± 1.0
Range	0–5
Left eye	
Mean ± SD	1.8 ± 0.9
Range	0–4

BCVA = best-corrected visual acuity; dB = decibels; MD = mean deviation; NVG = neovascular glaucoma; PACG = primary angle-closure glaucoma; POAG = primary open-angle glaucoma; PXFG = pseudoexfoliation glaucoma; SD = standard deviation; VF = visual field.

self-administrations = 300 pairs) in a random fashion. They graded each video based on the report of Tatham et al[11] as follows: (1) did an eye drop reach the ocular surface (yes or no), (2) did the bottle tip touch the ocular or periocular surface (yes or no), and (3) the number of eye drops dispensed (total number). The graders discussed any discrepancies and tried to reach an agreement. If they could not reach an agreement, a third masked reviewer (S.L.M.) was available to adjudicate the discrepancy.

Statistical Analysis

We compared baseline scores against the post-teaching traditional and NPDD scores. Primary analysis included generalized estimating equation (GEE) logistic regression analyses of preintervention versus postintervention scores for each intervention: (1) eye drop reached the ocular surface versus drop did not reach the ocular surface, (2) bottle tip contacted the ocular or periocular surface versus no contact, and (3) only 1 drop dispensed versus multiple drops. Successful outcomes were defined as follows: a primary success was achieved when the drop reached the ocular surface without bottle tip contact, and a secondary success was achieved when the drop reached the ocular surface without bottle tip contact and only 1 drop was dispensed. We also analyzed (1) the number of eye drops dispensed per instillation attempt (Cox proportional hazards model) and (2) subject satisfaction scores and self-perceived difficulty of self-administration (logistic-transformed GEE regression).

Secondary analysis of demographics and baseline characteristics included age, gender, ethnicity, education, hand dominance, previous training by a health care worker, position when delivering eye drops (sitting, standing, laying down), and pupillary distance. We used logistic regression to determine the association of these variables with eye drop instillation success. Two researchers independently performed the masked grading of each video, and their agreement was assessed with Cohen's κ test. We performed all analysis using R software version 3.5.0 (R Foundation for Statistical Computing) and defined a P value smaller than 0.05 to denote statistical significance.

Results

Table 1 shows subjects' demographics, and Table 2 shows their medical characteristics.

Survey Analysis

Forty-seven of 50 subjects (94%) preferred the NPDD over traditional eye drop delivery. On a 5-point Likert survey, 49 of 50 subjects (98%) "agreed a little" or "agreed a lot" that the NPDD was comfortable to use, and 49 of 50 subjects (98%) would recommend the device to a family member or friend who uses eye drops (Fig 2). Subjects' ease-of-use scores (i.e., 1–10 rating after each administration) were significantly higher in the NPDD group (mean ± standard deviation [SD], 8.9 ± 1.1), than in the baseline group (mean ± SD, 6.7 ± 2.1; $P < 0.001$) or the post-teaching traditional (mean ± SD, 7.0 ± 2.0; $P < 0.001$; Fig 3A). On 5-point Likert surveys, subjects likewise were significantly more confident in their ability to deliver eye drops successfully with the NPDD (mean ± SD, 4.6 ± 0.7; $P < 0.001$) compared to baseline (mean ± SD, 3.5 ± 1.4; $P < 0.001$) and post-teaching traditional (mean ± SD, 3.3 ± 1.3; $P < 0.001$; Fig 3B). Subjects also believed the bottle tip was less likely to touch the eye with the NPDD (mean ± SD, 4.9 ± 0.2; $P < 0.001$) than baseline (mean ± SD, 3.9 ± 1.3; $P < 0.001$) and post-teaching traditional (mean ± SD, 3.3 ± 1.5; $P < 0.001$; Fig 3C).

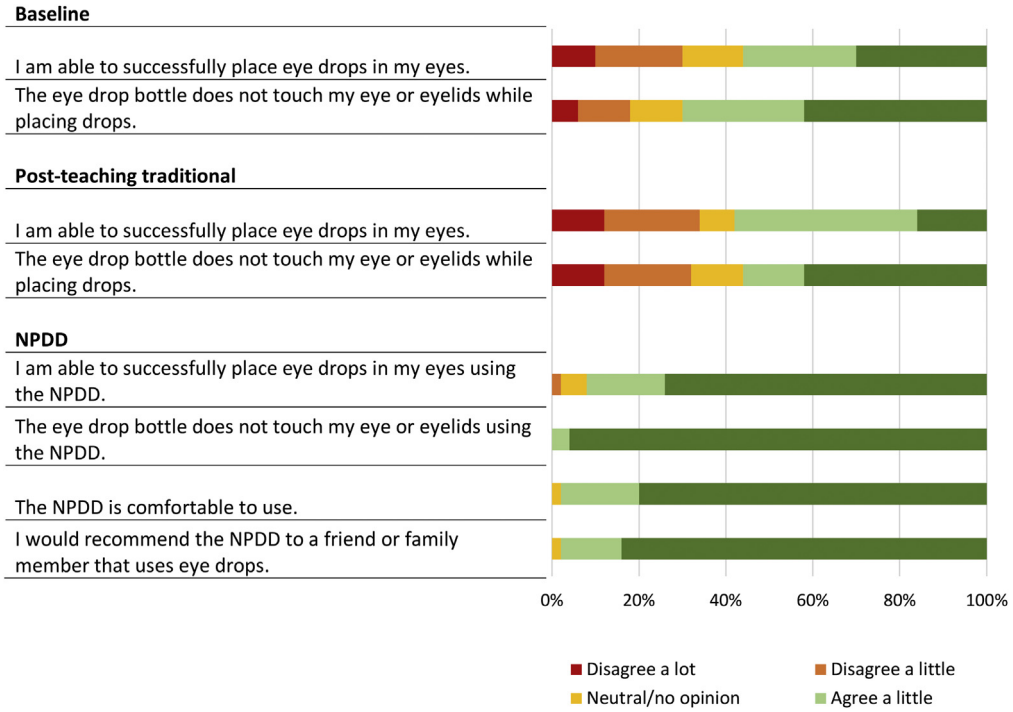

Figure 2. Diagram showing the 5-point Likert survey at baseline and conclusion of the study.

Video Analysis

The interreviewer agreement was 90.0% ($\kappa = 0.736$; $P < 0.001$). After the 2 original reviewers discussed the discrepancies, agreement was achieved in 100% of eyes. The eye drop reached the eye in a similar percentage in each method (baseline, post-teaching traditional, and NPDD), with no statistically significant difference among them (94%, 96%, and 94%, respectively; $P > 0.1$).

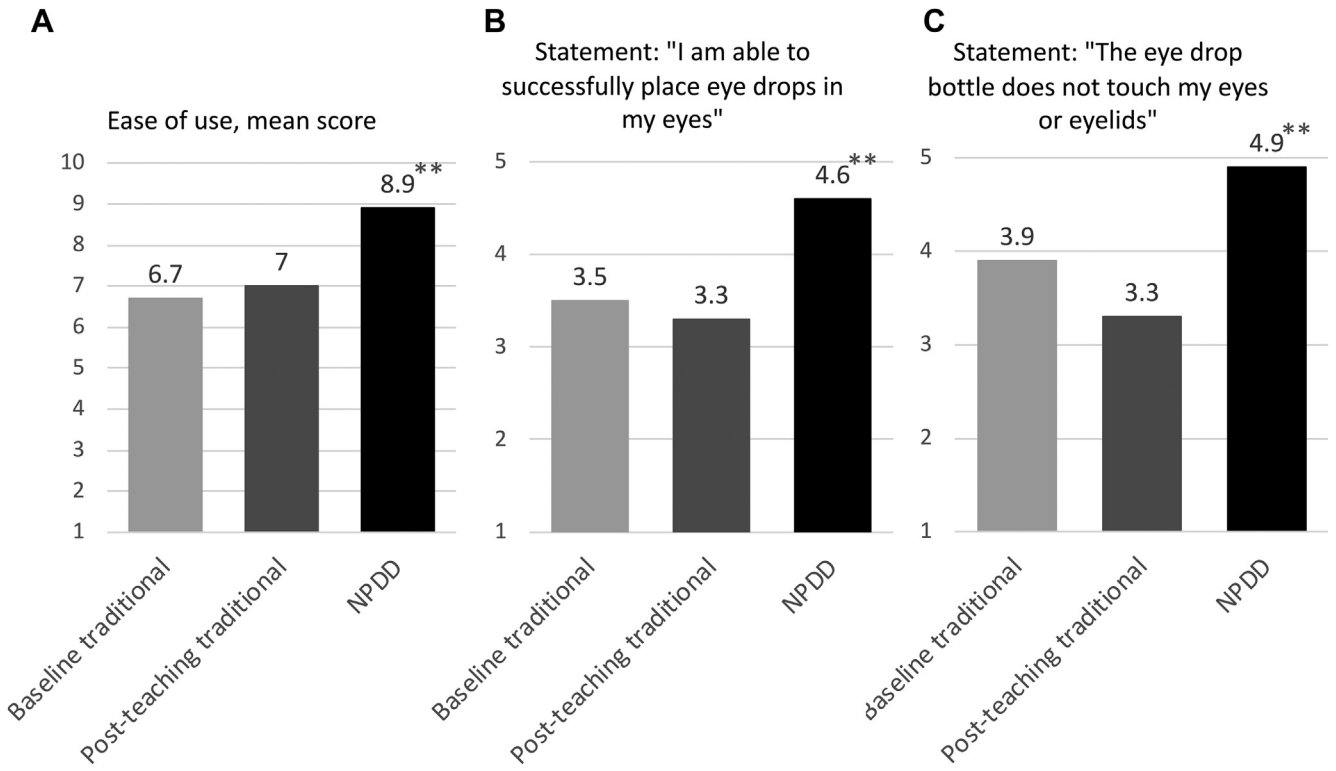

Figure 3. Bar graphs showing patient-reported ease of administration: (**A**) ease-of-use scores on a 1-to-10 scale and (**B** and **C**) survey scores on a 1-to-5 Likert scale. **$P < 0.001$. NPDD = nose-pivoted drop delivery device.

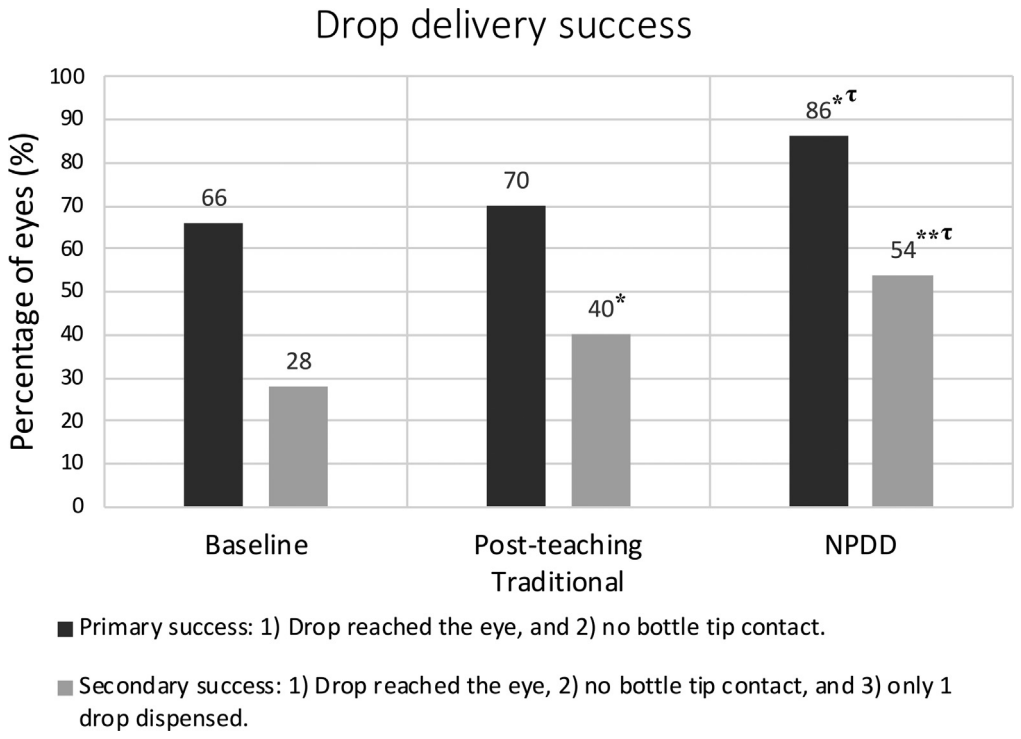

Figure 4. Bar graph showing success of eye drop administration: primary success (black bars) and secondary success (gray bars). *$P < 0.05$ **$P < 0.001$ compared with baseline. τ$P < 0.05$ against the post-teaching traditional. NPDD = nose-pivoted drop delivery device.

However, the bottle tip contacted fewer eyes with the NPDD (10 eyes) than baseline (33 eyes; $P < 0.001$) or post-teaching traditional (25 eyes; $P = 0.009$). The mean number of eye drops dispensed was 2.2 ± 1.6 at baseline, 2.4 ± 1.8 in the post-teaching traditional, and 1.7 ± 1.2 with the NPDD ($P = 0.017$ vs. baseline and $P = 0.006$ vs. post-teaching traditional, Cox proportional hazards model).

Primary success of eye drop delivery (i.e., drop reached eye with no contact between bottle and eye or lid) was 66% at baseline, 70% with post-teaching traditional, and 86% with the NPDD. Post-teaching traditional was not significantly more successful than baseline ($P = 0.45$). Primary success with the NPDD was higher than baseline ($P = 0.001$) and post-teaching traditional ($P = 0.005$). Secondary success of eye drop delivery (i.e., primary success plus only 1 drop dispensed) was 28% at baseline, 40% with post-teaching traditional, and 54% with the NPDD (Fig 4). Secondary success was higher with post-teaching traditional and the NPDD compared with baseline ($P = 0.033$ and $P < 0.001$, respectively), and the NPDD remained more successful than the post-teaching traditional ($P = 0.018$).

Demographic and individual characteristics (i.e., age, gender, ethnicity, education, hand dominance, previous training by a healthcare worker, position when delivering eye drops, and pupillary distance) were not associated with success rates in any of the techniques ($P > 0.1$ for all).

Discussion

We were interested in comparing eye drop instillation with a novel delivery aid against the traditional technique before and after instruction in experienced glaucoma eye drop users. This study showed that: (1) experienced glaucoma eye drop users preferred the NPDD over the traditional technique and found that the device made eye drop delivery easier and (2) the NPDD improved success of eye drop delivery.

In our study, 94% of subjects preferred the NPDD over traditional eye drop delivery. Previous studies evaluating satisfaction with eye drop delivery aids reported a 29% to 89% satisfaction rate.[14,15,18] In a literature review, Davies et al[19] found that delivery aids were useful in improving eye drop delivery success; however, they were an underused resource with limited patient adoption. The authors concluded that patients could benefit from future innovations designed around the eye drop user. The NPDD was designed to be nonintrusive by (1) not covering the visual axis (therefore, subjects see only the tip of the bottle, and not a large device over the eye), (2) not contacting the periocular skin including the eyelids and eyebrow, and (3) positioning the tip of the bottle at an oblique angle, not directly perpendicular to the eye. We believe that these design features contributed to our subjects' high satisfaction rates: 98% of subjects agreed that the NPDD is comfortable to use and 98% would recommend the device to a friend.

Subjects' ease-of-use scores (i.e., 1−10 rating after each administration) were significantly higher with the NPDD than baseline or post-teaching traditional (8.9, 6.7, and 7.0, respectively). On 5-point Likert surveys, subjects likewise were significantly more confident in their ability to deliver eye drops successfully (4.6, 3.5, and 3.3, respectively) and to avoid bottle tip contact against the eye (4.9, 3.9, and 3.3, respectively) while using the NPDD. Several other studies

using delivery aids also report positive ratings for ease of use. The Eyedrop (Vanguard Design) received an ease of use score higher than baseline use (7.6 ± 1.6 vs. 6.2 ± 1.8 on a 1−10 scale; $P < 0.01$).[13] The Opticare (Cameron-Graham Ltd) reduced difficulty in bottle squeezing from 60% to 33%.[25] In contrast, only 26% of subjects found eye drop instillation to be easier with the Inverted Funnel-Shaped Guide (Merck Frosst Canada), and no change in subjective ease of use was found with the Mirror-Hat device (developed by John Beck).[15,16] Subjects reported more difficulty placing eye drops with the Xal-Ease (Pfizer Ophthalmics) compared with a standard eye drop bottle (30% vs. 21%; $P = 0.03$) after 1 week of use, but they reported higher favorability of the device after 1 month's practice.[18]

The NPDD improved success of eye drop delivery from a baseline of 66% to 86% with the primary success definition and from 28% to 54% with the secondary definition. Two previous studies used similar definitions as our secondary success criteria and reported similar success rates (10%−28%).[8,9] Prior instillation aids have been able to increase accuracy, reduce contamination, or both. The Easidrop (Quoteforce) increased the proportion of subjects instilling an eye drop on the first attempt from 20% (6/30 subjects) at baseline to 87% (26/30) with the device.[12] The Mirror-hat device decreased contamination from 37% (11/30 subjects) to 13% (4/30 subjects; $P = 0.02$),[16] and other devices eliminated contamination by using extensions that separate the bottle tip from the eye.[18,19] Other instillation aids have been designed to reduce required grip force,[14,25−28] neck extension,[17,19,27] and delivery time (Upright Eyedrop Bottle) during eye drop administration.[19]

The NPDD reduced the average number of drops dispensed per self-administration from 2.2 at baseline to 1.7 ($P = 0.017$). Sharma et al reported a similar decrease in drops dispensed (from 2 to 1.6) using drop application strips (FDC Ltd).[29] Lazcano-Gomez et al[23] reached a significant reduction in drops dispensed (from 1.5 to 1.2) after a video-based personalized teaching intervention. Our shorter teaching intervention did not decrease the number of drops dispensed. Other studies using delivery aids found no difference[16] or even an increase[18] in the number of drops delivered.

This study has several limitations. Subjects had only a few minutes to practice with the NPDD and post-teaching traditional technique before undergoing testing. A longer teaching intervention and longer practice time may have improved outcomes further in both of these groups. No follow-up visits took place; therefore, we could not evaluate the retention of the effects over time. The artificial tears used during testing may have had a different consistency or bottle shape than subjects' glaucoma eye drops. Subjects may have been biased toward the device because it was developed by a physician at the testing institute. Finally, a Hawthorne effect may have occurred because the subjects knew they were being observed and recorded, and although this would affect results by all 3 techniques, the magnitudes of the effect could differ.

In summary, we found that experienced glaucoma eye-drop users preferred the NPDD over the traditional delivery technique. The NPDD improved successful eye drop delivery and reduced medication waste. The NPDD also increased subjects' self-perceived eye drop administration accuracy and ability to avoid bottle tip contact with the eye. The NPDD may provide glaucoma patients with an easier and more effective alternative to place eye drops successfully.

Footnotes and Disclosures

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No animal subjects were included in this study.

Author Contributions:

Conception and design: Sanchez, Mansberger, Kung, Gardiner, Burgoyne, Cunningham, Rees, Jones, Kinast

Analysis and interpretation: Sanchez, Mansberger, Kung, Gardiner, Burgoyne, Cunningham, Rees, Jones, Kinast

Data collection: Sanchez, Mansberger, Kung, Gardiner, Burgoyne, Cunningham, Rees, Jones, Kinast

Obtained funding: Kinast; Study was performed as part of the authors' regular employment duties. No additional funding was provided.

Overall responsibility: Sanchez, Mansberger, Kung, Gardiner, Burgoyne, Cunningham, Rees, Jones, Kinast

Abbreviations and Acronyms:
NPDD = nose-pivoted drop delivery device; **SD** = standard deviation.

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Adherence, Aid, Delivery, Device, Eye drops, Glaucoma, Guide, Medication, Satisfaction, Self-administration.

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