Eye Drop Aid for Improved Quality of Care

Kasia Klotz, Anabelle Olson, Eva Coughlin, Jenna Krause, Tevis Linser, & Thomas Kriewaldt

28 February, 2024

Abstract

Individuals with reduced dexterity often face difficulties dispensing eye drops, leading to waste and failed treatments. This study introduces and evaluates an assistive device designed to provide mechanical advantage, thereby facilitating easier and more controlled eye drop dispensation. The objective was to compare both the effectiveness and user preference between the assistive device and traditional eye drop bottles. Methods included quantitative tests measuring the volume of solution dispensed and a survey capturing user preference. Results from the single drop test show that the device significantly reduces the amount of eye drop solution dispensed. Preference test results showed that [percentage]% of users preferred the assistive device over traditional methods. These findings suggest that the assistive device offers a viable solution for improving self-administration of eye drops for individuals with reduced dexterity, potentially enhancing medication adherence and reducing waste. Future research should explore long-term usability and the device's impact on adherence to eye drop regimens.

Introduction

Eye drops are the leading therapeutic option for the treatment of ophthalmic diseases. The prevalence of such diseases increases with increasing age, such that by the age of 65 it is estimated that one in three people have a vision-reducing disease such as glaucoma, cataract, and age-related macular degeneration (Quillen D. A., 1999). Glaucoma, which is the second leading cause of blindness worldwide, can result in vision loss if not controlled by regular use of medicated eye drops (*Don't Let Glaucoma Steal Your Sight!,* 2020). . Although such eye drops are often essential for treatment of ophthalmic diseases, many patients, particularly among the older population where reduced manual dexterity is a common issue, cannot administer them efficiently. The challenges faced by individuals with reduced manual dexterity involves limitations of force generation and precision during the administration of eye drops. This difficulty often results in solution wastage and poses the risk of bottle tip contamination, which further complicates the management of ophthalmic diseases.

Reduced manual dexterity is associated with limitations in fine motor skills and precise movements. These patients have difficulties dispensing the desired amount of eye drops due to the quantity of force required to dispense a single drop from a bottle. On average, about 15 N of force is required to dispense a single drop from a standard eye drop bottle, however patients with arthritis can only apply about 5 N of force (Dedeoğlu, M., 2013). Often, patients will try to overcompensate by squeezing the bottle harder, potentially leading to unintended dispensing of a larger amount of eye drop solution than is necessary, resulting in solution waste. Furthermore, the difficulty in achieving stability and accuracy while squeezing the bottle often results in a lack of precision, with it being reported that up to 37.3% of patients miss the eye target with eye

drops (Davis et al., 2018). These difficulties lead to wastage of eye drop solution, ultimately causing the eye drop solution to run out prematurely to prescription refill. If patients run out before the refill date, they face out-of-pocket costs, causing financial strain and potentially disrupting their treatment. Failing to adhere to eye drop therapies can often lead to ophthalmic disease progression, causing further harm to the patient.

While addressing eye drop administration, it is important to understand the proper eye drop technique. The proper eye drop technique includes first the patient must tilt their head back and look up. With one hand, the patient should pull their lower eyelid down and away from their eyeball. With the other hand, the patient should hold the eye drop bottle upside down with the tip above the pocket. Then, the patient should squeeze the prescribed number of eye drops into the conjunctival sac, which is the eyelid pocket. For at least one minute, the patient should close their eye and press their finger lightly on their tear duct to prevent the eye drop from draining into their nose (Karki et al., 2011). Failing to follow proper eye drop technique can result in unwanted side effects, such as fainting following the administration of glaucoma eye drop solution directly into the center of the eye. This is due to the presence of beta-blockers in glaucoma eye drop solution, and when entered into the tear ducts, causes blood pressure to drop rapidly, resulting in fainting. This emphasizes that proper administration of eye drops is essential to ensuring patient safety and maximizing the therapeutic effects of the eye drops.

Use of eye drop application aids by individuals has been identified as an approach to making eye drop application easier. However, few existing eye drop aids tackle all the issues with eye drop application experienced by individuals with reduced manual dexterity. The eye drop assist device

has been developed to improve these difficulties. The device includes two squeezable handles, allowing the user to use their whole hand, rather than just the pinching fingers to exhibit force on the bottle. Additionally, the device has a platform rest that allows the user to position the device on their face above their eye, allowing for stability and precision while administering the medication, and allowing for prevention of bottle tip contamination.

In this study we investigated two things. The first being a quantitative approach to ensure the device promotes the release of a single drop of medication. Second, a qualitative study, in which patient's were surveyed based on their experiences with the device compared to the traditional eye drop bottle.

Methods

A participant, cross-sectional study was used. Ethical approval was obtained from the local university's Institutional Review Board before starting recruitment.

Study 1: Single drop

The purpose of this test was to evaluate the ability of the assistive device to reduce the amount of eye drops being administered from the bottle.. One round of testing for each bottle size was done without the device, and one was done with the device. The participants were instructed to make the best effort to administer one eye drop into the weigh boat. The volume of the solution dispensed per-use was measured and directly compared for two different sized bottles. The

comparison was done independently for each subject due to each of the subjects having varying grip strengths that would affect the amount of solution released from the bottle.

Participants

The participants of the study were the design team which consists of six young adults containing both male and female. Its purpose was to evaluate the device's effectiveness in consistently delivering one drop of solution per use.

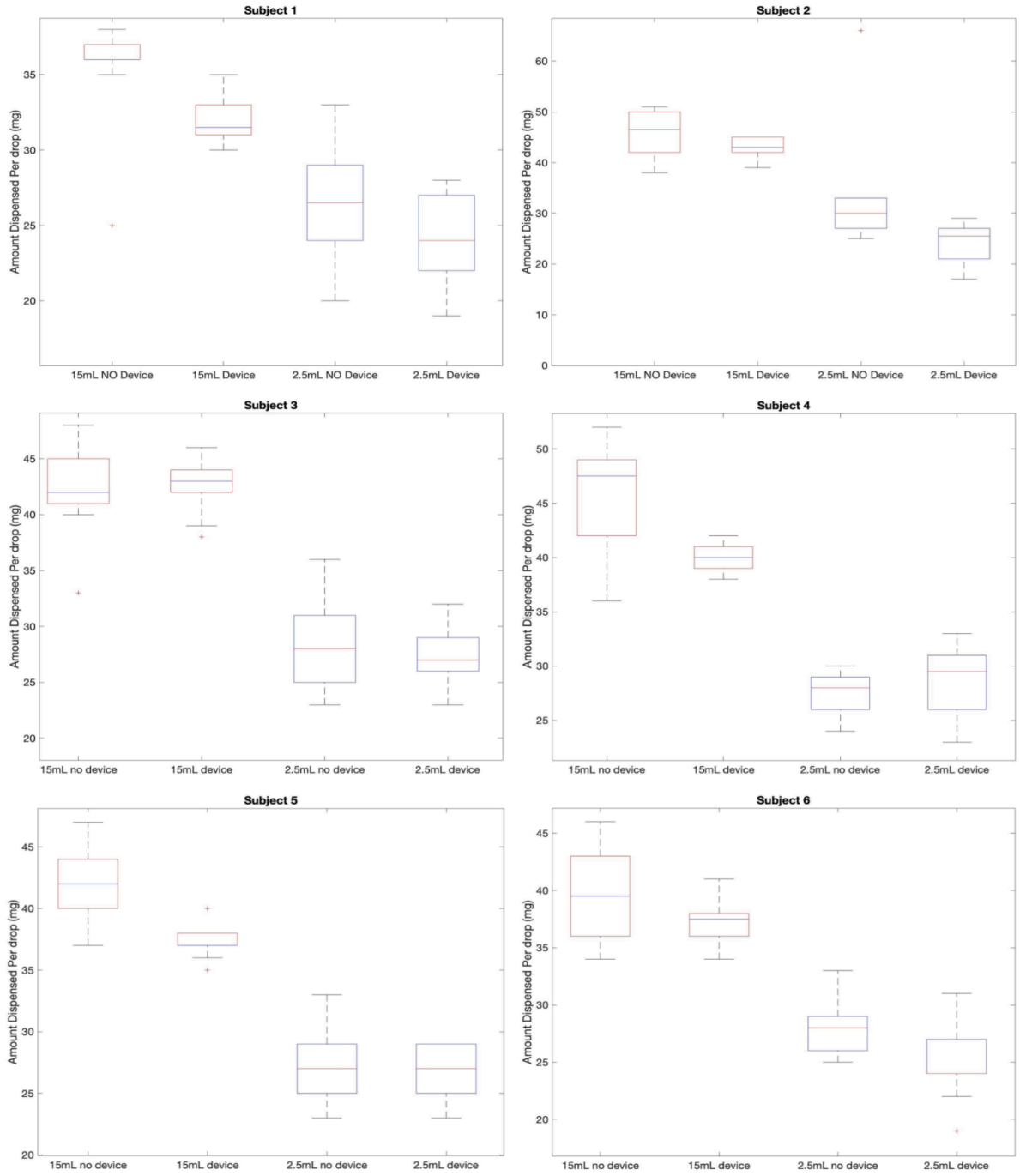
Study Procedures

To quantify the effectiveness of the device, the amount of eye drop solution administered from the bottle while using the device was compared to the amount of eye drop solution released from the bottle without the device. The team conducted the study in an engineering laboratory using a mass balance scale. The testing was done using a weigh boat, which was zeroed out before each drop was administered. Each of the participants listed above performed four tests each: 15mL without the device, 15mL with the device, 2.5 mL without the device, and 2.5mL with the device. If the drop size administered from the bottle while using the device is more consistent than the drop size administered using just the bottle, then the conclusion can be drawn that the device ensures a more consistent release of eye drop solution than the use of just the bottle.

Statistical Analysis of Quantitative Data

The following graphs are box and whisker graphs to compare the amount of eye drop solution dispensed per squeeze of the bottle. The first comparison, which can be seen as red boxes, is between the size of the drop dispensed from the 15mL bottle when the device is used and the control, being the use of an eye drop bottle without the device. The second comparison, which

can be seen as blue boxes, is the same two tests but with the 2.5mL bottle. There are 6 graphs, each corresponding to a different subject's data. These graphs compare the volume dispensed under the four conditions only among the trials done by the subject. Among these graphs, it is concluded that the standard deviation for the amount dispensed with the 15mL bottle decreased with the device when compared to the control for all six subjects. For the smaller 2.5mL bottle, the standard deviation of the drop size decreased with the device compared to the control for five out of the six subjects. These findings suggest that the device promotes less variability and more consistency in the size of the dispensed eye drops. Additionally, the data shows that the max size of the drop dispensed from the 15mL bottle decreased with the device in comparison to the control for all 6 subjects. For the smaller 2.5mL bottle, the max size of the drop dispensed with the device was smaller than the max drop size for the control trial for five out of six subjects. This data further shows that the device allows for a smaller size eye drop than the traditional bottle.



Note. MatLab box plots displaying difference between drop size when using the device compared to not using the device for each of the six test subjects.

The overall averages across test subjects were calculated for the following test groups: 15 mL no device, 15 mL with device, 2.5 mL no device, and 2.5 mL with device. There were a total of sixty data points used to compute the average of each test group. The average drop size when not using the device for the 15 mL bottle size was 0.04172 grams. The average drop size when using the device for the 15 mL bottle was 0.03872 grams. A t-test was run to determine whether there was a statistically significant difference between the average drop size for the 15 mL bottle when using the device compared to without the device. The p-value of the t-test was 0.000988, indicating a statistically significant result. This indicates that the average drop size for the 15 mL bottle when using the device is significantly lower than when using the conventional eye drop bottle on its own. This same t-test was performed to compare the average drop sizes for the 2.5 mL bottle. The average drop size for the 2.5 mL when not using the device was 0.02828 grams compared to 0.02598 grams when using the device. The p-value for this t-test was 0.009677, confirming that the average drop size for the 2.5 mL bottle is significantly lower when using the device. The results of these t-tests indicate that the eye drop assistant device effectively minimizes eye drop solution waste by decreasing the size of the drop that is dispensed with each use.

Similar to the analysis described above, the standard deviations across test subjects were calculated for all four test groups, yielding a total of sixty data points for each test group. The standard deviation across test subjects for the 15 mL bottle without the device was 0.005443 grams compared to 0.004187 grams with the device. A f-test was run to analyze if there was a statistically significant difference between the variance in drop size when using the device compared to not using the device for the 15 mL bottle. The p-value was statistically significant at

0.0461, indicating that the variance in drop size when using the device is significantly lower than the variance in drop size without using the device for the 15 mL bottle. For the 2.5 mL bottle, the standard deviation across test subjects without the device was 0.005843 grams compared to 0.003427 grams with the device. The p-value for this f-test was 0.00006598, indicating that the variance in drop size when using the device is significantly lower than without the device for the 2.5 mL bottle. The results of these f-tests suggest that the eye drop assistant device decreases the variability of eye drop size dispensed, therefore, increasing the consistency of eye drop administration. A summary of these computed values and statistical analyses are shown in **Table 1** and **Table 2**.

Table 1: The statistical analysis of the single drop testing for the 15 mL bottle.

	15 mL bottle	15 mL bottle with device
Mean (g)	0.04172	0.03872
SD (g)	0.005443	0.004187
t-test p-value	0.000988	
f-test p-value	0.04601	

Table 2: The statistical analysis of the single drop testing for the 2.5 mL bottle.

	2.5 mL bottle	2.5 mL bottle with device
Mean (g)	0.02828	0.02598
SD (g)	0.005843	0.003427

t-test p-value	0.009677
f-test p-value	0.00006598

Study 2: Preference Testing

The purpose of this study is to determine if the proposed device is one that should be commercially distributed and available to consumers. This testing will evaluate the effectiveness of the eye drop assistant device in making the administration of eye drops easier than the traditional eye drop bottle.The participant of the study will be shown a demonstration by a lead investigator on how to use the device. Then, the participant will have about twenty minutes to handle the device and try using the device to administer eye drops onto a cloth. The participant will then be asked to dispense the eye drop without the assistive device. Next, the participant will be instructed to complete a survey about the difference in difficulty in the two methods. Finally, the participant will also provide feedback on whether they prefer the device to be attached securely via a nose bridge or to a freely movable eyebrow platform.

Participants

Given that approximately 5% of those over 65 have glaucoma and 10% of those over 80 have glaucoma, this study is focused on the elderly population (*Causes of Glaucoma,* n.d.). Most ophthalmic diseases like glaucoma increase in prevalence with age and are treated with eye drops, so it is important to obtain the opinions of the elderly on the device. The research team was able to conduct this study at Oakwood Village University Woods retirement community. The

research team recruited participants from the retirement community by posting flyers advertising the study with a scheduled date and time.

Participants were screened to ensure that they meet the inclusion criteria of the study. First, participants must be able to understand an informed consent document and be willing to comply with study procedures. The research team needed to ensure that potential participants wanted to be in the study and knew the expectations for participation. As mentioned earlier, the research team's main focus is the elderly population, so potential participants need to be over the age of 65 and have ophthalmic conditions treated by eye drops. The research team also wanted to ensure that these potential participants had experienced difficulties with using the conventional eye drop bottle. In order to be interested in an assistive device, there must be a need for that device in improving administration. Next, the potential participant needed to be able to hold and manipulate a hand held device with one hand. This ability is necessary to operate the device and therefore, must be required. Those unable to use a hand for the use of the eye drop assistant device must be excluded from participation in the study. Finally, for communication purposes, potential participants must be English speaking and possess the mental capacity to give informed consent. Because this study involves direct communication with the research team and the research team is limited to English speakers, it is necessary to ensure all participants can fluently speak English to avoid a language barrier. Additionally, potential participants must possess the mental ability to understand instructions from the research team and coherently communicate feedback verbally and via survey. Those who are not able to communicate via English or do not have the mental capacity to consent, must be excluded from participation in the study. Following the screening procedure, all participants will provide verbal informed consent.

Study Procedures

There will be a recruitment flyer for the study posted at the retirement community stating the room, date, and time that the study will take place. The research team will ask interested subjects to meet at that room on the designated day and time. Potential subjects that are interested in participating in the study will be identified at Oakwood Village University Woods Retirement Community. The study team will screen the subjects using the screening document submitted with the IRB application to determine their eligibility. About thirty subjects will be recruited from Oakwood Village University Woods Retirement Community site in Madison, Wisconsin. Individuals from populations who are underrepresented in clinical research (e.g., racial and ethnic minorities, women, individuals from rural and underserved communities, older individuals, federally recognized nations and tribes) will be enrolled with a goal of ensuring that all eligible patients are given the opportunity to participate in research and that research findings can be generalizable to the entire population. Once participants have been enrolled, the research team will provide a demonstration on the use of the eye drop assistant device. Then, study participants will experiment with using the eye drop assistant device and dispense the drops onto a cloth. They will be given about ten minutes to do so. Next, study participants will dispense eye drops from the conventional eye drop bottle onto a cloth. Finally, study participants will complete the survey to evaluate the device usability compared to the traditional eye drop bottle. They will also provide their opinion on whether they prefer the device with the nose bridge or the device with the eyebrow platform.

Thematic analysis of qualitative data:

- Address the themes
    - Describe how they came up, describe what they mean

        - Include examples from data
- Explain the takeaways/ show how analysis answers the research question

Results

Study 1: Single drop

The graphs shown in figure x are box and whisker plots that compare the amount of eye drop solution dispensed per squeeze of the bottle. The first comparison, which can be seen as red boxes, is between the size of the drop dispensed from the 15mL bottle when the device is used and the control, being the use of an eye drop bottle without the device. The second comparison, which can be seen as blue boxes, is the same two tests but with the 2.5mL bottle. There are 6 graphs, each corresponding to a different subject's data. These graphs compare the volume dispensed under the four conditions only among the trials done by the subject. Among these graphs, it is concluded that the standard deviation for the amount dispensed with the 15mL bottle decreased with the device when compared to the control for all six subjects. For the smaller 2.5mL bottle, the standard deviation of the drop size decreased with the device compared to the control for five out of the six subjects. Additionally, the data shows that the maximum size of the drop dispensed from the 15mL bottle decreased with the device in comparison to the control for all 6 subjects. For the smaller 2.5mL bottle, the maximum size of the drop dispensed with the device was smaller than the maximum drop size for the control trial for five out of six subjects. Single drop testing results yielded a statistically significant decrease in variance and size of eye drop administered after the device was employed for both bottle sizes. This suggests that the device provides a fix for users that previously dispensed too much liquid in the form of multiple

drops or single larger drops, and allows for those same users to consistently perform successful drops.

Study 2: Preference Testing

The research team has received IRB approval for this study and will be completing the testing in the beginning of March. The results will be analyzed by comparing the ratings between the traditional eye drop bottle administration and the eye drop assistant device. This will also help the research team in determining the attachment portion of the device. Following this study, the research team will create an addendum to the IRB to include the administration of eye drops in the patient's eyes.

Discussion

There are several limitations of the studies mentioned. Firstly, in Study 1, the team measured the size of the solution drops released using their weight on top of a scale and a weight boat. Employing a more precise scale and ensuring its calibration before each new subject may yield more accurate results. Additionally, the study only involved six participants to evaluate the effectiveness of the device in releasing a single drop. This was a preliminary study to test the efficacy of early prototypes, but further testing with a larger sample size and improved measuring procedures is necessary. This would confirm that the device meets its specifications, testing results, and therefore any future claims about the product, on a much wider scale.

The second study has not been conducted, however, there are potential limitations in the recruitment and screening process. The team needs to ensure that the inclusion and exclusion criteria are being consistently applied to establish a valid sampling pool. If not, results from this study on age and other criteria could prove to be inaccurate. Moreover, it should be noted that conclusions drawn from this study may only apply to the chosen inclusion population, as participants may show bias towards the device due to their medical condition or other influences.

Future testing should focus on the reliability and precision of the device, ensuring that it is designed to accommodate the squeezing capabilities of the target age ranges. Additionally, a cyclic loading study is planned to determine the material properties of the device, ensuring the device is suitable for its audience. Additional studies on medicated eye drop bottles used with the device should be carried out to ensure that specific bottles are compatible. Another potential limitation is that standardized bottles used in these studies may differ in shape, size, and squeezing force compared to what a participant may use for their personal use. In addition, during future studies, subjects should be given adequate time to comprehend and use the device, minimizing misuse of the device during testing. Human trials with the final device will assess its efficacy, ease of use, and other relevant factors in a real-world setting, confirming that the device is capable of meeting the requirements of its target population.

Conclusion

The device has consistently decreased the average drop size and decreased the variability in the amount of medicine consumed. Based on initial consumer preference surveys […] This device

successfully addresses current issues faced by eye drop users. The device enables users to adhere to eye drop regimens by reducing waste and increasing administration success. The device [is received by the main consumer group in this way].

Disclosure Statement

No potential conflict of interest was reported by the authors

Funding

The work was supported by University of Wisconsin, School of Pharmacy Professor Beth Martin.

Bibliography

Causes of Glaucoma | American Geriatrics Society. (n.d.). *HealthInAging.org*. Retrieved February 29, 2024, from https://www.healthinaging.org/a-z-topic/glaucoma/causes

CDC. (2020, November 24). Don't let glaucoma steal your sight! *Centers for Disease Control and Prevention*. https://www.cdc.gov/visionhealth/resources/features/glaucoma-awareness.html

Davis, S. A., Sleath, B., Carpenter, D. M., Blalock, S. J., Muir, K. W., & Budenz, D. L. (2018). Drop instillation and glaucoma. *Current Opinion in Ophthalmology*, 29(2), 171–177. https://doi-org.ezproxy.library.wisc.edu/10.1097/ICU.0000000000000451

Dedeoğlu, M. (2013). The relationship between hand grip and pinch strengths and disease activity, articular damage, pain, and disability in patients with rheumatoid arthritis. *Turkish Journal of Rheumatology*, 28(2), 69–77. https://doi.org/10.5606/tjr.2013.2742

Karki, R., Meena, M., Prakash, T., Rajeswari, T., Goli, D., & Kumar, S. (2011). Reduction in drop size of ophthalmic topical drop preparations and the impact of treatment. *Journal of Advanced Pharmaceutical Technology & Research*, 2(3), 192. https://doi.org/10.4103/2231-4040.85540

Quillen, D. A. (1999). Common causes of vision loss in elderly patients. *American Family Physician*, 60(1), 99–108.