Eye Drop Aid for Improved Quality of Care

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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 81% of users preferred the assistive device over traditional methods. These findings suggest that the assistive device offers a viable solution for improving the 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, 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 the 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 involve 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. According to Karki et al., 2011, proper eye drop technique follows these steps:

1. The patient must tilt their head back and look up.
2. With one hand, the patient should pull their lower eyelid down and away from their eyeball.
3. With the other hand, the patient should hold the eye drop bottle upside down with the tip above the pocket.
4. The patient should squeeze the prescribed number of eye drops into the conjunctival sac, which is the eyelid pocket.
5. For at least one minute, the patient should close the eye and press their finger lightly on their tear duct to prevent the eye drop from draining into their nose.

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.

The 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 applications experienced by individuals with reduced manual dexterity. Therefore, 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 apply force on the bottle. Additionally, The device offers two stabilizing mechanisms, an eyebrow rest or a nose bridge rest. These mechanisms allow for stability and precision while administering eye drops and allowing for prevention of bottle tip contamination.

In this study, the team investigated two things. First, a quantitative approach was taken to ensure the device promotes the release of a single drop of medication. Second, a qualitative study was performed in which patients 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

This testing had previously been completed with participants who were the six design team members. This testing can be referenced in Appendix B. To eliminate any potential biases, this testing was redone with participants outside of the design team. These participants were thirteen students from UW-Madison in the biomedical engineering department.

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. This study was conducted 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: 15 mL bottle without the device, 15 mL bottle with the device, 2.5 mL bottle without the device, and 2.5 mL bottle with the device. If there is less variability in the drop size administered from the bottle while using the device than the variability in 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

To analyze the variability in drop size, an F-test was used. Two F-tests were performed, one for the data using the large eye drop bottle and one for the data using the small eye drop bottle. An F-test is a statistical test used to compare the variances of two sets of data. The two sets of data compared are using the device to dispense the drops compared to not using the device. The null hypothesis is that the variances of the two sets of data are equal. The alternative hypothesis is that the variances of the two sets of data are not equal. A significance level of 0.05 was applied to interpret the statistical significance of this result. If the p-value is less than 0.05, it indicates that the observed result would occur by chance less than 5% of the time if the null hypothesis were true. Therefore, if the p-value is less than 0.05, the null hypothesis is rejected, in favor of the alternative hypothesis.

Study 2: Preference Testing

This study's purpose was to determine if the proposed device should be commercially distributed and available to consumers. This testing was conducted to determine the effectiveness of the eye drop assistant in making the administration of eye drops easier, compared to the traditional eye drop bottle.

Participants

This study focuses on the elderly population due to the heightened prevalence of ophthalmic diseases and the limited dexterity associated with aging. The research specifically focuses on the opinions of this demographic as the eye drop assistant aid is designed for their use. Participants were recruited at the Oakwood Village University Woods retirement community via a flyer post and then screened to ensure that they met the study's inclusion criteria. 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. The final inclusion criteria is that 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 to improve administration. Next, the potential participant needed to be able to hold and manipulate a handheld 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. Following the screening procedure, all participants will provide verbal informed consent. 37 participants met the inclusion criteria and were enrolled in the study.

Study Procedures

A recruitment flyer was posted at the retirement community stating the room, date, and time of the study. The research team asked interested subjects to meet in that room on the designated day and time. Subjects interested in participating in the study were identified at Oakwood Village University Woods Retirement Community. The study team screened the subjects using the screening document submitted with the IRB application to determine their eligibility. 37 subjects were recruited from Oakwood Village University Woods Retirement Community site in Madison, Wisconsin. Once participants were enrolled, the research team demonstrated how to use the eye drop assistant device. Then, study participants experimented using the eye drop assistive device and dispensed the drops onto a cloth. They were given about ten minutes to do so. Next, study participants dispensed eye drops from the conventional eye drop bottle onto a cloth. Finally, study participants completed the survey to evaluate the device's usability compared to the traditional eye drop bottle. They also provided their opinion on whether they preferred the nose bridge or the platform on the eye drop assistive device. The subjects provided feedback on design changes and other general opinions related to the device and its use.

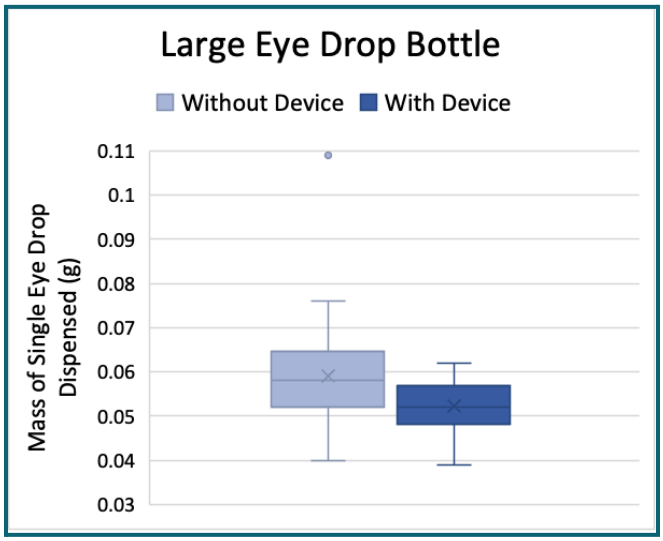
Thematic analysis of qualitative data:

To analyze the qualitative data received from the preference test survey, the team performed a thematic analysis of the responses to the final survey question. Subjects were verbally asked "What changes, if any, would make the eye drop assistant easier to use? Consider how it would feel to use this device while dispensing eye drops into your lower eyelid pocket." Then subjects provided a verbal response to the researcher and this response was recorded on the survey sheet. Based on the responses provided by the subjects, codes were created to identify and group common concepts between all of the responses. After the codes were generated, similar codes were grouped into a broader theme. Based on the codes generated from the

responses, the team identified five common relevant themes that highlighted the feelings toward the current device. The five themes will be thoroughly addressed in the preceding results section.

Results

Study 1 Results: Single drop



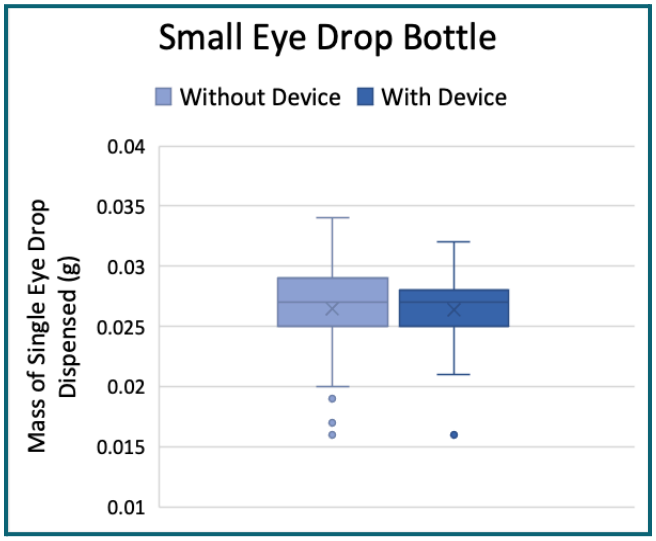


Figure 1. Box plots displaying the mass of a single drop dispensed without the device compared to the device for a large eye drop bottle and a small eye drop bottle.

Starting with the F-test for the large (15 mL) eye drop bottle, the F-value was 4.1533. The p-value for this was less than 0.001. For the small (2.5 mL) eye drop bottle, the F-value was 2.0004. This corresponds to a p-value of 0.004. Because both of the p-values are less than the significance level of 0.05, the results are statistically significant. This signifies that the use of the device reduces the variability in drop size compared to not using the device.

Study 2 Results: Preference Testing

Quantitative Results

The first two questions on the survey (Appendix D) ask for participants to rate the ease of dispensing a single drop out of the eye drop bottle without the assistive device compared to the assistive device. Participants provided ratings on a scale of 1-10 with 1 being very difficult and 10 being very easy. A t-test was used to compare the average ratings without the device compared to with the device. The null hypothesis was that the average rating for dispensing a single drop with the device was the same as the average rating without the device. The alternative hypothesis was the average rating for dispensing a single drop with the device is higher than without the device. The t-value was -3.29, which yields a p-value of 0.0007765. Because this p-value is less than the significance level of 0.05, the result is statistically significant. This indicates that the use of the assistive device made eye drop administration significantly easier for the participants. Additionally, the last question on the survey explicitly asked whether or not participants would prefer to use the assistive device. 81% of participants responded that they would prefer to use the device to administer eye drops over using just the eye drop bottle.

Qualitative Results

Based on the responses provided to the preference testing survey, five themes were identified:

1. Increased Ergonomics While Using the Device as Compared to the Bottle

This theme involves the attitude towards enhanced user experience during eye drop administration from the device, compared to just using the eye drop bottle alone. Subjects expressed a sense of enhanced accuracy, control, and stability while using the device. Codes such as “increased accuracy with the use of the device”, “user noticed increased control with the device”, and “user noticed increased stability with the device” were identified and grouped under this theme.

2. Issues with Eye drop Administration with just the bottle

This theme highlights that current eye drop users struggle with administering eye drops from the bottle by themselves. Subjects reported various difficulties and frustrations associated with the use of the traditional eye drop bottle. Two key codes that were identified to fall under this theme are "issues with the use of the current bottle" and "issues with releasing a single drop from the current bottle." These codes reflect subjects' struggles with the usability and functionality of the current eye drop bottles.

3. Interest in Using the Device

This theme involves the subjects' feelings towards using the eye drop assistive device. Many subjects reported strong interest in acquiring one of the devices for themselves and expressed interest in the components of the device. The three codes that define this theme include: "interest in purchasing the device", "overall positive feedback surrounding the device", and "positive feedback on the stabilization mechanisms of the device."

4. Suggestions Regarding Device Components

This theme covers feedback and suggested changes regarding the handle, the nose bridge, and the platform design aspects. Codes such as "Suggested improvements to handle", "Suggested improvements to nose bridge", and "Suggested Improvements to platform" were included in this theme.

5. User Experience and Adaptation

Challenges and Limitations Resulting from Testing

This theme incorporates instances where participants expressed general troubles of using the device without ideas for changes to improve the design. This theme also highlights the notion that the participants felt as though they could not provide feedback based on the testing procedure. Codes such as "Struggle with ease of Use" and "Cannot comment without using the device to administer eye drops" were included in this theme.

Discussion

The statistical results from Study 1 confirm that the use of the assistive device yields a more consistent drop size during eye drop administration. This increased consistency translates to reduced eye drop waste, which is one of the primary goals of the use of an eye drop assistive device. Moving on to Study 2, the assistive device was significant in easing eye drop administration for the participants in the retirement community. Because the objective of the device is to ease eye drop administration for those over the age of 65, this result is validating.

From the thematic analysis conducted in study 2, several themes have emerged, highlighting the study subjects' attitudes, experiences, and suggestions regarding the eye drop assistive device. Collectively, these themes provide valuable insights that will inform the implementation of the device to enhance user satisfaction and adherence to eye drop treatments. Themes 1 and 3 highlight the potential benefits of the eye drop assistive device in improving the patient experience while administering eye drops, potentially leading to increased adherence to eye drop treatments. Theme 2 emphasizes the need for an eye drop assistive device. Lastly, themes 4 and 5 will be the basis for future research and modifications to the device design, such that future testing procedures will allow subjects to administer eye drops into their own eyes. This provided feedback will guide future research into potential design changes.

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 device's effectiveness 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 consistently decreased the average drop size and decreased the variability in the amount of medicine consumed. Based on initial consumer preference surveys, users feel there are shortcomings in current eye drop administration methods, and users also feel as if the proposed device provides an increase in ergonomics and ease of administration. 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. Although the device shows promising results, there are highlighted areas of improvement that will serve as a guide into further design research.

Disclosure Statement

No potential conflict of interest was reported by the authors.

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Appendix A - Single Drop Test Protocol

Single Drop Testing Protocol

Date of testing: 4/2/2024 and 4/3/2024

Scope

To perform testing to quantify the amount of eye drop solution released from the bottle for each squeeze of the handles.

Purpose

To understand the effectiveness of the eye drop assistive device in minimizing eye drop waste per use and delivering a consistent dosage of medication.

Test Samples

Multiple subjects will perform trials, so that the data collected is more representative of a variety of users, such as male and female.

Materials and Equipment

- Eye drop assistant devices
- Scale
- Weight Boats
- 15 mL eye drop bottle
- 2.5 mL eye drop bottle

Methods

- 13 total subjects will participate in the testing
- Each subject will perform two tests with 10 trials each:
    - 15mL without the device
    - 15mL with the device
- ***or***:
    - 2.5mL without the device
    - 2.5mL with the device

- For each trial, the weight boat will be set on top of the scale and the scale will be zeroed out. After the scale reads zero, the user will handle the bottle either with or without the device and hold it above the weight boat. Next, the user will dispense a single drop into the weigh boat. If using the device, the subject will squeeze the handles of the eye drop assistant device together to administer one drop. Once there is a visual indication that a drop has dropped, the user will set the device down away from the scale. Then the scale measurement will be recorded. Ten trials are performed, so there are ten measured drops for the use of the eye drop assistant device. Each test participant will complete these ten trials.

Data Analysis and Documentation Requirements

The weight of eye drop solution dispensed per trial will be recorded for each of the four tests. For each individual subject, the average and standard deviation of the ten trials will be calculated for each of the two tests they completed. These will be used to create box plots of each individual subject's data to visually compare use of the device with not using the device for both of the bottle sizes. Then, the averages and standard deviations will be combined to calculate the overall average and overall standard deviation across subjects for each of the four tests. These overall averages and standard deviations will be used for a statistical test.

- A t-test will be run to compare the overall average eye drop size when using the device compared to not using the device for both the 15 mL bottle size and the 2.5 mL bottle size.
    - The goal is for the average drop size when using the device to be statistically significantly lower than without using the device. This result will indicate that the device effectively minimizes eye drop waste compared to regular eye drop bottles.
- A f-test will be run to compare the overall variance in eye drop size when using the device compared to not using the device for both the 15 mL bottle size and the 2.5 mL bottle size.
    - The goal is for the variance in drop size when using the device to be statistically significantly lower than without using the device. This result will indicate that the device delivers a more consistent dose of eye drop medication than regular eye drop bottles.

Appendix B - Initial Single Drop Test Data

Participants

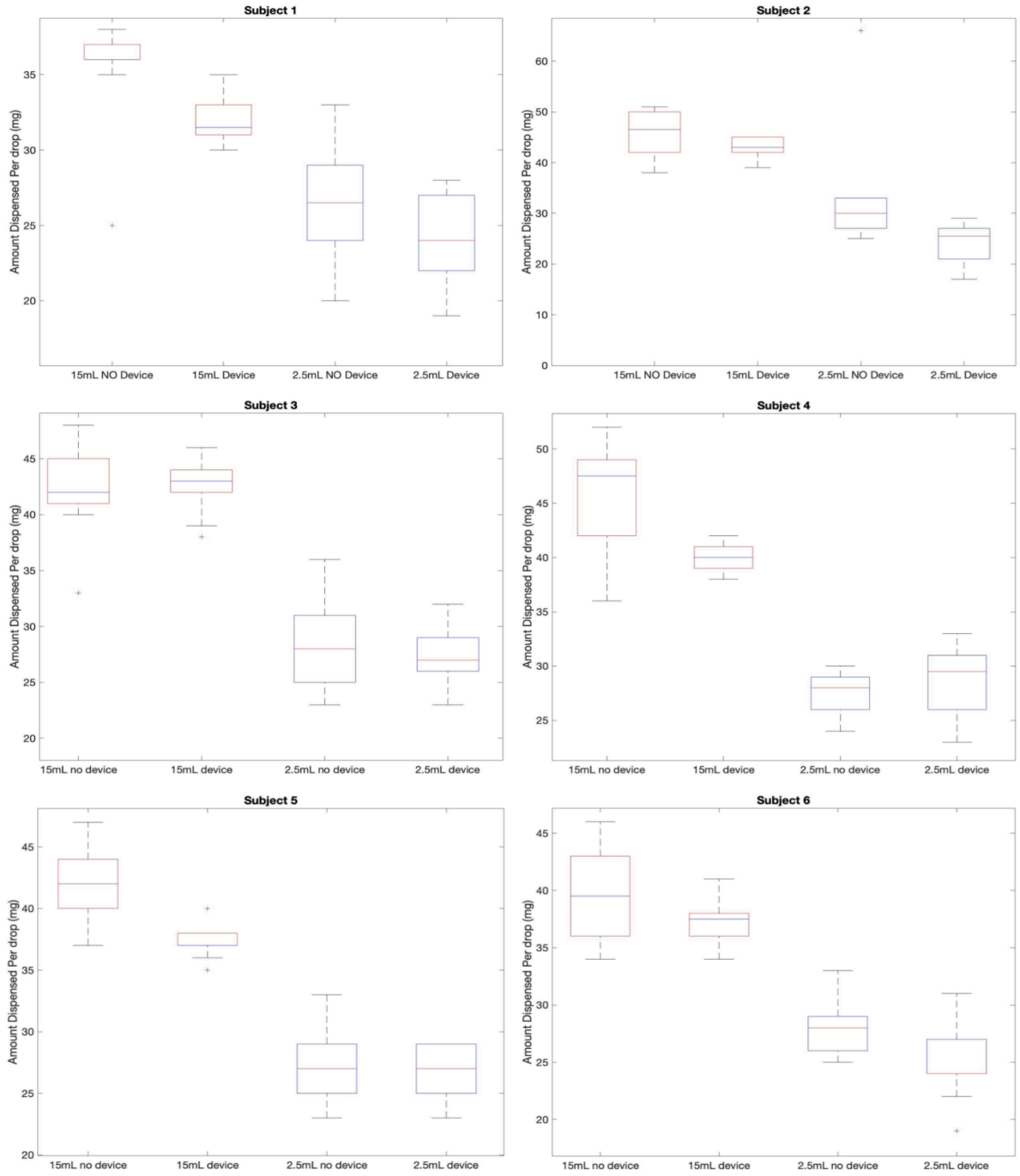
The participants of the study were the design team which consisted of six young adults, both male and female. Its purpose was to evaluate the device's effectiveness in consistently delivering one drop of solution per use.

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: 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 the 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	

Results

The box and whisker plots 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 15 mL 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 compared 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 drops 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.

Appendix C - Preference Test Protocol

Preference Testing Protocol

Date of testing: 3/7/2024 & 3/15/2024

Scope

To perform testing to evaluate the effectiveness of the eye drop assistant device in making the administration of eye drops easier than the traditional eye drop bottle.

Purpose

The purpose of this study is to determine if the proposed device should be commercially distributed and available to consumers.

Test Samples

Residents of the Oakwood Village University Woods Retirement Community, located in Madison, Wisconsin.

Materials and Equipment

- Eye drop assistive device
- Lubricating eye drop solution bottles
- Cloth to dispense eye drop solution onto
- Post-test survey

Methods

The participants of the study will be shown a demonstration by a lead investigator on how to use the device. Once the participant receives this demonstration, the device will be handed to the participant and the participant will have 5-10 minutes to handle the device and try using the device to administer eye drops. It should be noted that the participant should not administer eye drops into their own eyes, rather they should hold the device above a cloth and administer the eye drop solution onto the cloth. The participant will then be asked to dispense the eye drops without the assistive device. Finally, the participant will be instructed to complete a survey about the difference in difficulty between the two methods.

Acceptance Criteria

- Adults with ophthalmic conditions are treated with eye drops.
- Experience difficulties when using the conventional eye drop bottle.
- Ability to hold and manipulate a handheld device with one hand.
- English-speaking (able to provide consent and complete questionnaires).

Data Analysis and Documentation Requirements

The participants will be given a survey that will record how they felt the device affected their ability to distribute the eye drop solution compared to dispensing without the assistive device.

Appendix D - Preference Test Survey Template

Survey:

On a scale from 1-10, with 1 being extremely difficult and 10 being extremely easy, rank the following:

Dispensing a singular drop out of the eye drop bottle **without** the assistive device: _____

Dispensing a singular drop out of the eye drop bottle **with** the assistive device: _____

Ease of handling and holding the assistive device: _____

How easy was it to understand how to use the device?: _____

Which of the two versions of the prototype shown do you prefer?: _____

Based on your experience, would you prefer to dispense your eye drops with or without the assistive device? _____

What changes, if any, would make the eye drop assistant easier to use? Consider how it would feel to use this device while dispensing eye drops into your lower eyelid pocket.

_____
_____
_____

Appendix E - Product Design Specifications

Project Name: Eye Drop Assistant

Client: Dr. Beth Martin

Team Members: Co Team Leaders: Anabelle Olson, Kasia Klotz, Communicator: Eva Coughlin, BWIG: Jenna Krause, BSAC: Thomas Kriewaldt, BPAG: Tevis Linser

Function:

Eye drops play a crucial role in managing many ophthalmic diseases and conditions. For example, glaucoma can result in vision loss if not controlled by regular use of medicated eye drops. As essential as these eye drops are, many patients are not able to administer them in an efficient manner. These difficulties could be attributed to the size of the eye drop bottle and the risk of bottle tip contamination. The small size of the eye drop bottles can pose challenges, especially for individuals with reduced dexterity. This often results in the administration of too many drops, which leads to wasting the medication. Furthermore, hovering the dropper bottle above the eye while dispensing the solution is difficult for many and can result in the bottle tip coming into contact with the surface of the eye, causing contamination and potentially compromising the effectiveness of the medication. These limitations can deter consistent eye drop use, often resulting in treatment failure and disease progression. The team must design a device to assist patients in squeezing the eye drop bottle, while releasing a consistent amount of solution per drop.

Client Requirements:

1. The device must be compatible with the proper technique of eye drop administration.
    a. The device must not dispense the eye drops directly into the center of the patient's eye.
2. The device must allow that the eye drop bottle be inserted into it for patient use.
3. The device must be adjustable to fit various bottle sizes and shapes in order to be compatible with any patient's eye drop bottle.
4. The device must adjust to meet the position of the patient's eye.
5. The device must make it easier for elderly patients and those with arthritis or other limiting diseases to grip the bottle.

a. The portion of the device that the patient grips to dispense the eye drops must have a larger diameter than the eye drop bottle itself.
b. The device must incorporate a non-slip material surface to increase the grip for the patient and ease the squeezing of the bottle.

6. The device must minimize eye drop solution waste by ensuring that a single drop of eye drop solution is dispensed.
7. The team must not exceed a budget of $500 for the creation of the device and other project needs.

Design Requirements:

1. Physical and Operational Characteristics:
    a. *Performance Requirements:*
        i. The device will be compatible with eye drop bottles intended to treat glaucoma and age related macular degeneration.
        ii. The device will rest comfortably on the bridge of the user's nose.
        iii. The device will be easily adjustable so that the user can place the bottle directly over the eyelid pocket [1].
        iv. The device will be fitted with some material or extruded pieces to allow for a better grip of the bottle.
        v. The device will allow for the steady administration of a singular drop of medicine.
    b. *Safety:*
        i. In order to avoid growth of bacteria or other contaminants, the device will ensure that the bottle does not come into contact with the patient's eye during its use [1].
        ii. The device's design will not include sharp or pointed edges to avoid injury during use.
    c. *Accuracy and Reliability:*
        i. The design will consistently and reliably administer 1 drop per squeeze.
            1. Drop size is regulated in the design of the dropper bottle, typically administering between 25 and 70 μL [2].
            2. The force needed to administer a single drop must not exceed 5 N [3].

d. *Life in Service:*
    i. The device will withstand the administration of 180 drops [4].
        1. A 2.5 oz bottle of generic Latanoprost, used to treat glaucoma, typically lasts for 45 days with correct usage, which amounts to 90 drops or 180 drops with a factor of safety of 2.
e. *Shelf Life:*
    i. The current design will consist of 3D printed PLA plastic. With no exposure to sunlight and in conditions with less than 60% humidity, the device will last around 15 years [5].
        1. Total shelf life may vary depending on change in material or the addition of other materials included in the device.
f. *Operating Environment:*
    i. The device will be designed to be used outside of a hospital setting.
    ii. Patients with arthritis will be able to easily control the device.
    iii. The product will function normally under ambient temperature conditions.
        1. 18 - 28°C (62.4 - 82.4°F) per FDA guidelines [6].
    iv. The device will function after exposure to various eye drop solutions.
g. *Ergonomics:*
    i. The device will be comfortable for an arthritic patient to hold.
    ii. The device will not be stressful for an arthritic patient to squeeze.
    iii. All users of the device will be able to functionally administer eye drops.
    iv. The tip-to tip (thumb to pointer finger) grip force required to administer one drop will not be more than 8 N of force [3].
h. *Size:*
    i. The product will be applicable to the hand size and shape of any user.
        1. No wider than 7 cm at the grip point of the squeezing mechanism, to ensure the device is inclusive of all prospective users [7].
    ii. The circular shapes of eye dropper bottles should fit snugly into the device.
    iii. The device will be able to fit many different sizes of eye dropper bottles.
        1. Internal radius will be larger than 1 cm, and smaller than 2 cm [8].
        2. The device will be able to hold different eye dropper bottles which have a height between 4 and 10 cm [8].
i. *Weight:*

i. The design will be lightweight so that the device can be easily moved to different positions without additional stress to arthritic patients.
ii. A minimum of two fingers will be able to hold the device.
iii. The device will weigh no more than 0.2 lbs.

j. Materials:

i. A rigid material, such as hard plastic or resin, will be used as the material of the final device to minimize the device's patient-to-patient costs and weight.

k. Aesthetics, Appearance, and Finish:

i. The finish of the device will not have protruding edges that could cause harm to the user's eye.
ii. The surface of the device will incorporate a non-slip material to increase the grip for the user.

2. Product Characteristics:

a. Quantity:

i. There will be one finalized prototype for the client.
ii. During development there will be multiple, testable prototypes.
1. Different sizes and shapes to compensate for the various sizes and shapes of people's anatomy.
2. Ideally, the final prototype will have an adjustable function to fit the various sizes and shapes of people's anatomy.

b. Target Product Cost:

i. The device will be as cheap as possible to compete with current eye drop assistants on the market and reach a wide consumer base.
ii. The total materials cost for a potential product will be relatively cheap.
1. FormLabs resins can be printed at the MakerSpace for under $0.30 per gram [9].
iii. The target cost for sale is $10-$15 per unit, based on prices of existing devices. The target cost of production of the product is therefore under $5 per unit.

3. Miscellaneous:

a. Standards and Specifications :

i. FDA approval will be needed to grant this device as safe to use in a medical setting.
    1. The FDA's Center for Devices and Radiological Health (CDRH), will be responsible for the regulation of the manufacturing process [10].
ii. This device has a specialized setting in which it is used, which means it is a Class I device by FDA classification standards [11].
    1. A Class I medical device is a low-risk medical tool with a simple design, presenting minimal risk to patients and users.
    2. Class I devices have general controls and Requires a 510(k) Premarket Notification as stated by FDA guidelines.
iii. ISO 291: Plastics — Standard atmospheres for conditioning and testing [6].
iv. ISO 14971: Medical devices - Application of risk management to medical devices [12].
v. ISO 7886-4: Sterile hypodermic syringes for single use — Part 4: Syringes with re-use prevention feature [13].

b. Customer:

i. The targeted consumers for this device will be the elderly population, specifically anyone with dexterity issues *stemming from arthritis*.

c. Patient-Related Concerns:

i. The device will allow for easy and concise distribution of eyedrops. Use of excessive force may cause patients to distribute the incorrect amount of eye drops which is wasteful and could impact treatment time. The device will also be easily stabilized. Without this aspect, patients could accidentally touch eye dropper tip to eye which would lead to contamination and possibly infection.

d. Competition:

i. There are many competing devices on the market currently. However, none of them cover all of the aspects that the team hopes to cover in the design. Some of the downfalls to current devices include: incompatible with different sized eye droppers, cannot properly secure eyedropper, difficult to use, and does not allow for proper eye drop technique.

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