Eye Drop Assistant

BME 400, Fall 2023

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Abstract

Eye drops are the leading therapeutic option for the treatment of ophthalmic diseases. For example, glaucoma, the second leading cause of blindness worldwide, can result in vision loss if not controlled by regular use of medicated eye drops [1]. Although these eye drops are often essential for treatment, many patients cannot administer them efficiently, especially patients with limitations in their dexterity. These difficulties can stem from the size of the eye drop bottle and result in a risk of bottle tip contamination. Furthermore, many patients administer excessive drops, depleting their medication supply before the prescription refills. Therefore, this report presents an alternative method of administering eye drops using an eye drop assistant. The eye drop assistant proposed will be a hand-held medical device that ensures the release of a consistent dose of medication, allows for the proper eye drop technique, and improves the ease of administration for the user. To evaluate the device's efficacy in meeting these objectives, three prototype-based tests were conducted: single drop test, precision test, and squeeze force test. Results showed that the device decreased the average drop size, the variability in drop size, and the area over which drops were dispensed. Furthermore, the force required to squeeze the device is inclusive to most populations of users. The results led to the conclusion that the final prototype significantly improves upon current methods.

Table of Contents

Introduction

Motivation

Eye drops are the leading therapeutic option for the treatment of ophthalmic diseases such as Glaucoma. Ophthalmic diseases are most prevalent in the elderly population where reduced dexterity is also extremely common, posing significant challenges in administering eye drops. Pharmacists emphasize that effective treatment requires proper eye drop technique, involving the administration of a singular drop of medication directly into the lower eyelid pocket [2]. Patients with diminished dexterity have difficulties dispensing the desired amount of eye drops due to the quantity of force required to release a single drop from common eye drop bottles. On average, about 15 N of force is required to dispense a single drop from a standard eye drop bottle [3]. However, patients with arthritis can only apply about 5 N of force [3]. This difficulty results in poor stability and accuracy while attempting to squeeze the bottle, leading to eye drop waste. Between 6.8 and 37.3% of patients miss the target for eye drops which leads to eye drop waste and missed doses [4]. Additionally, about 25% of patients report missing eye drop doses due to administration difficulties [5]. This poses issues because eye drop prescriptions often have scheduled refills. If patients run out before the refill date, they face out-of-pocket costs, causing financial strain and potentially disrupting their treatment. Unsteadiness of hands also poses a risk of touching the bottle tip to the eye, which leads to contamination. Ultimately, these concerns can lead to health complications and a diminished quality of life.

Problem Statement

The eye drop bottle is difficult to use, especially for those with reduced dexterity, therefore the team proposes an eye drop assistant that ensures the release of a consistent dose of medication, allows for proper eye drop technique, and improves the ease of administration by decreasing the necessary manual force applied to the bottle.

Background

Biology and Physiology

Ophthalmic diseases are more prevalent in the elderly population, where other diseases such as hand tremors, arthritis, poor coordination, and peripheral neuropathy present further challenges to successful eye drop use [5]. This difficulty in administering eye drops can result in improper treatment of ophthalmic diseases and ultimately cause harm to patients. For example, improper eye drop technique can be very dangerous for patients who have glaucoma. Glaucoma is associated with optic nerve degeneration

that deteriorates vision and may lead to blindness [6]. More than 1 million Americans are being treated for glaucoma and 80,000 people are legally blind due to glaucoma. Glaucoma is prevalent in the elderly population as more than 9% of people over 80 years are diagnosed with it [7]. Prescription eye drops are the most common treatment for glaucoma and need to be used at least once every day to prevent vision from worsening. Glaucoma eye drops are topical beta-adrenergic antagonists that treat the patient's eyes by reducing aqueous humor formation. Topical medications may enter the systemic circulation via the nasolacrimal ducts, commonly known as the tear ducts. This is an issue because small amounts of systemically absorbed beta-blockers can produce significant adverse cardiovascular, pulmonary, and endocrine effects. Studies relate the use of topical beta-blockers to syncope, bradycardia, systemic hypotension, palpitations, and arrhythmias [7]. The client communicated to the team that she has witnessed patients administering glaucoma eye drops directly into the center of their eye, causing their blood pressure to rapidly drop, and eventually resulting in the patient fainting. This is because administering the eye drop directly into the center of the eye leads to the medication being absorbed into the tear ducts. This emphasizes that proper administration of eye drops is essential to ensuring patient safety and maximizing the therapeutic effects of the eye drops.

When administering eye drops, the patient must first 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 [2].

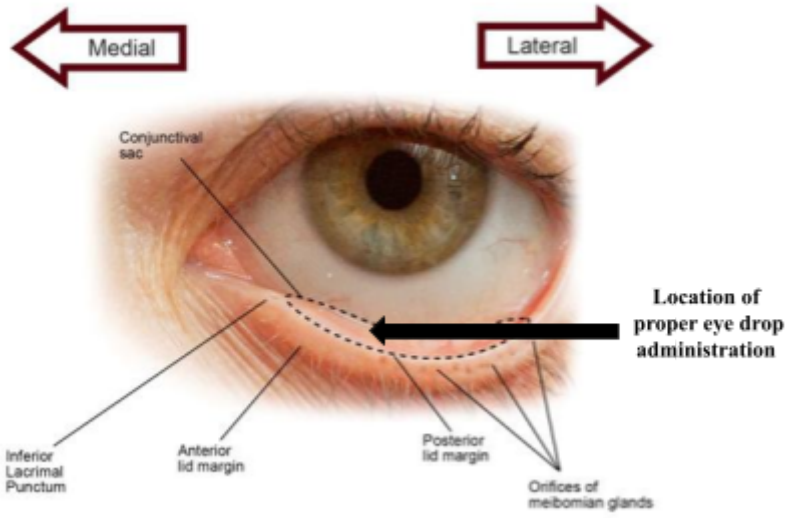

Figure 1: Anatomy of the eye, outlining the conjunctival sac (area enclosed by dotted line) where eye drops should be placed [8].

Improper eye drop administration technique, age-related physical difficulties, variable duration of use, and missing the eye during administration are potential causes for microbial contamination at the dropper tip [9]. A study tested glaucoma medications used by patients for at least three months and found an overall 28% rate of bacterial contamination [9]. This contamination is caused by contact with the eye dropper tip to the eye or ocular annexes. To prevent infection, patients should never touch the tip of the bottle with their hands or their eyes [2].

Client Information

The client, Dr. Beth Martin, is a pharmacist and professor in the UW-Madison School of Pharmacy's Pharmacy Practice and Translational Research Division. Dr. Martin is also the assistant dean for teaching and learning at UW-Madison School of Pharmacy. Dr. Martin's research involves improving pharmacist practice behaviors as well as studying patient learning. Her clinical practice setting is Oakwood Village University Woods Retirement Community, which is useful in her patient/provider studies. Dr. Martin is acclaimed, having won several awards in her field. Notably, she is an elected fellow of the American Pharmacists Association (APhA) Academy of Pharmaceutical Research and Science [10].

Existing Devices and Patents

A few devices that are aimed to assist in eye drop administration exist on the market. Notable devices that target similar issues to this project's problem statement are the Droppy Eye Drop Dispenser shown in **Figure 2** and the GentleDrop Eye Drop Guide shown in **Figure 3**. The Droppy Eye Drop Dispenser utilizes protruding wings to allow for extra mechanical leverage to decrease the force needed from the user to squeeze a drop out of the bottle. This design falls short because the location of the bottle tip is situated directly over the eyeball which does not allow for the drop to be placed properly in the conjunctival sac. The GentleDrop Eye Drop Guide features a stabilizing structure that rests on the user's nose to provide stability and placement assistance. Although this device aids the user's ability to target the conjunctival sac, there are no included features that improve squeeze capability or ensure only a single drop is being administered.

Figure 2: Droppy Eye Drop Dispenser [11].

Figure 3: GentleDrop Eye Drop Guide [12].

Patents surrounding current eye drop assistants that most closely fit the description of the project include a bandolier cartridge eye drop delivery system shown in **Figure 4** and an eye drop applicator shown in **Figure 5**. The bandolier works by including cartridges that revolve around and dispense solution with the push of a button. The patent protects the working mechanism and the eyelid retracting legs. This design does ensure correct dosage, but it does not directly address the proper eye drop technique or typical eye drop bottle compatibility. Next, the eye drop applicator requires the user to fill the retainer section and apply the drop directly to the pouch of the eye. The patent for this device protects design aspects of the anatomy and material used in the device. Although the eye drop applicator ensures a single drop and allows for hitting the correct application site, the method used increases the risk of contamination and injury to the patient as the device is likely to directly contact the patient's eye.

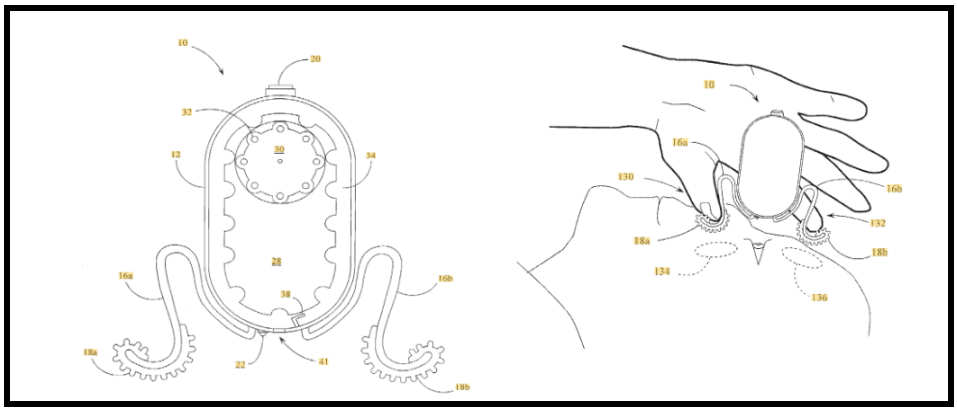

Figure 4: Bandolier Cartridge Sterile Eye Drop Delivery System With Eyelid Retracting Legs [13].

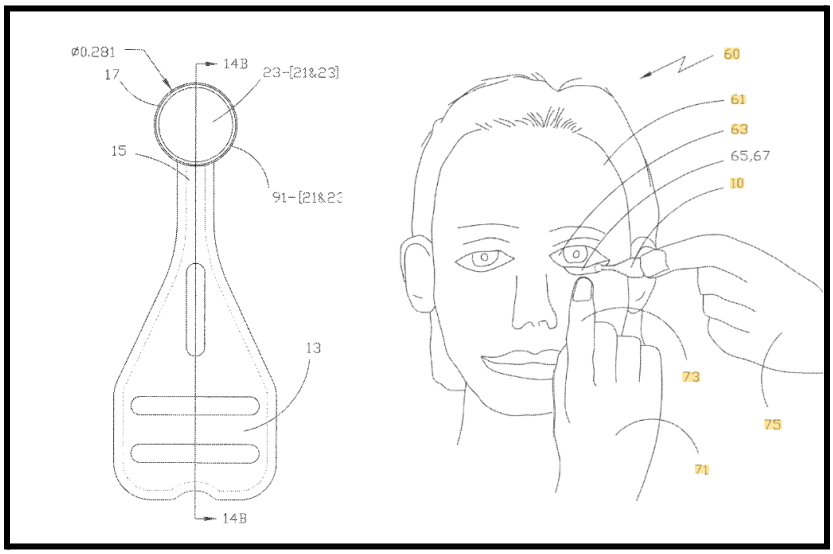

Figure 5: Eye Drop Applicator [14].

Design Specifications

The device design focuses on aligning with proper eye drop administration techniques. The proposed device ensures that the eye drops are dispensed into the ideal location of the bottom eye pocket, avoiding the center of the patient's eye. The device should also offer adjustability to fit the bottle sizes and shapes provided by the client. The eye drop bottles range from 4.7 to 8 cm in height, base to nozzle, and 1.8 to 2.5 cm in diameter at the bottle's widest point. The device must also address the grip challenges often faced by elderly patients or individuals with conditions like arthritis, which result in a reduced squeezing force capability (less than 5N) [3]. The maximum size between the handles of the device must not exceed 7 cm. The calculation to determine this length is based on anthropometric data of thumb and index finger sizes [15]. For the full calculation, please refer to Appendix A. Considering that a typical eye

drop bottle requires a squeezing force of up to 14.7 N to dispense a drop, the device must bridge the gap between the force required and the force applied by providing an enhanced grip and a non-slip material surface [3]. This design feature compensates for the disparity in force application, ensuring that the dispensing process remains smooth and efficient for individuals with limited hand strength. Furthermore, the device aims to minimize eye drop solution waste by ensuring the dispense of a single drop, aligning with the standard drop size range of 21.5 ul to 69.4 ul [16]. Lastly, the team must not exceed a budget of $500 for the creation of the device and other project needs. For the full Product Design Specifications, please refer to Appendix B.

Preliminary Designs

Design 1: The Eye Lash Dropper

The Eye Lash Dropper design contains four components to make the dispensing of an eye drop easier. First, the handles, which will be soft and shaped comfortably to fit the hand, provide a larger surface area to squeeze than the traditional dropper. The next component is the nose bridge rest. This rest provides support for the device and allows the user to position the device over their eye, such that the proper eye drop technique is used. The next component is the spring stopper mechanism, which will have a spring constant such that when the correct amount of force is applied to the handles, the spring will apply force against the user and the handles will separate. This ultimately ensures that only one drop of eye drop medication is dispensed, and the user does not willingly dispense too much. In the case that the medication dose requires two drops, the user will have to squeeze the handles a second time to dispense the second drop. The final component is the bottle insert, which can fit multiple bottle sizes, allowing this device to be more universal and reach a larger audience. The dimensions for the design are averaged facial measurement values for males and females used from the anthropometric data which can be referenced in Appendix C. Together, these components of the Eye Lash Dropper design allow for ease and accuracy of eye drop administration.

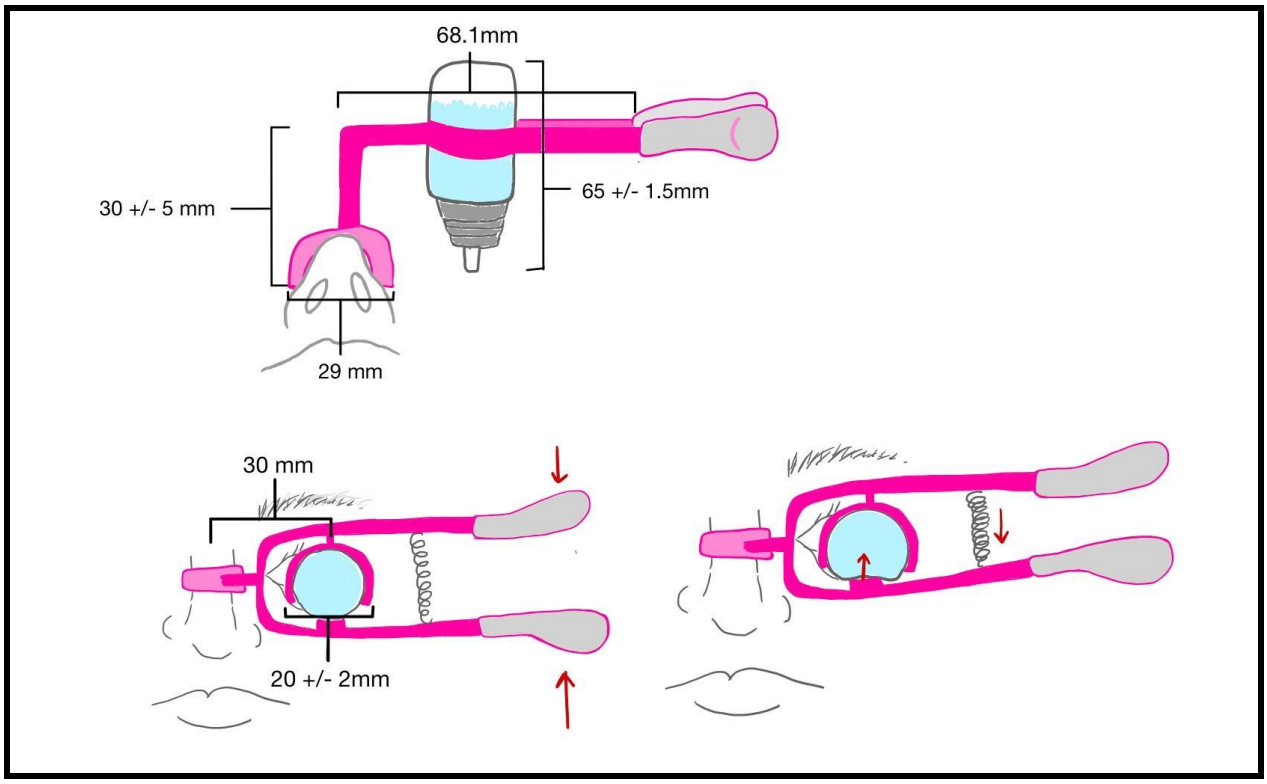

Figure 6: The Eye Lash Dropper Sketch.

Design 2: The Slider

The Slider design is an intricate device that allows patients to elicit a single eye drop by pushing a button. This device enables patients with diminished grip strength to administer medication without exerting pressure upon an eye dropper bottle. A plastic, half-conical central chamber allows the device to fit multiple bottle sizes and shapes while remaining lightweight. The Slider design also features two plastic extending arms that run vertically from the central chamber and parallel to the eye dropper bottle's sides. These extending arms house metallic pins that act as the mechanical fingers that squeeze the bottle. The extension arms have two cut finger slots that allow the patient to hold and stabilize the device. To further enhance stability, the motor control chamber at the base of the device is slightly curved to conform to the shape of the nose when in use. The squeezing mechanism of the Slider is controlled using an Arduino located in the side chamber, which is activated through buttons at the rear. Wires connect the controls to motors within the extension arms, which induce tension on internal cables. These cables, in turn, connect to the pins, causing them to move to the center of the device and squeeze the eye dropper bottle when tension is applied. The Slider is a complex device that empowers patients to use eye drops without physically squeezing the bottle.

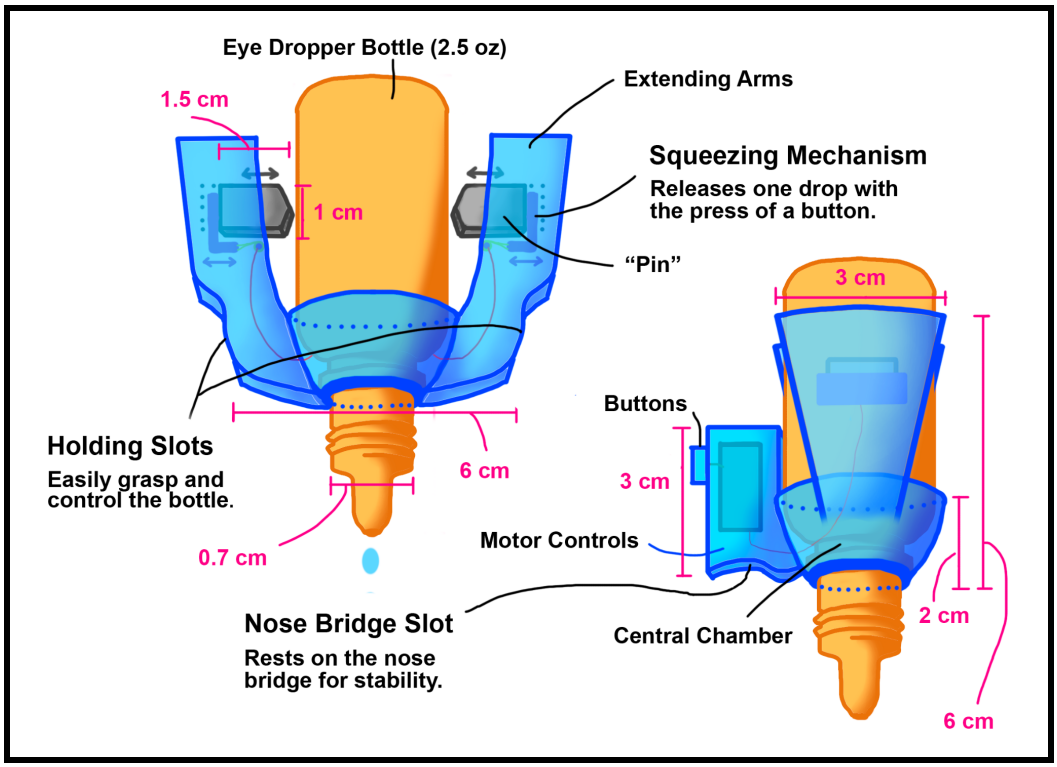

Figure 7: The Slider Design Sketch.

Design 3: Stopper Buddy

The Stopper Buddy design prioritizes ease and precision in administering eye drops. The device features a flexible nose bridge mechanism, ensuring a comfortable and secure fit, while accommodating a wide variety of individual anatomies. Adjustable wires allow for personalized positioning above the eye, adapting to individual preferences for optimal usage, crucial for ensuring the drop reaches the bottom eye pocket following the proper technique. A stopping mechanism is integrated, guaranteeing the precise administration of a single drop, minimizing waste, and ensuring an accurate dosage. When the device is squeezed together, the ball rod rolls down until it hits a wall designed as a stopping mechanism. While the rod is moving down, it is squeezing the bottle and administering a single drop. The design is user-friendly with an easy-to-squeeze mechanism, making it accessible and efficient for individuals with varying hand strengths, especially catering to the elderly and those with limited dexterity. Together, these elements create a comprehensive and adaptable eye drop administration device that significantly enhances the user experience.

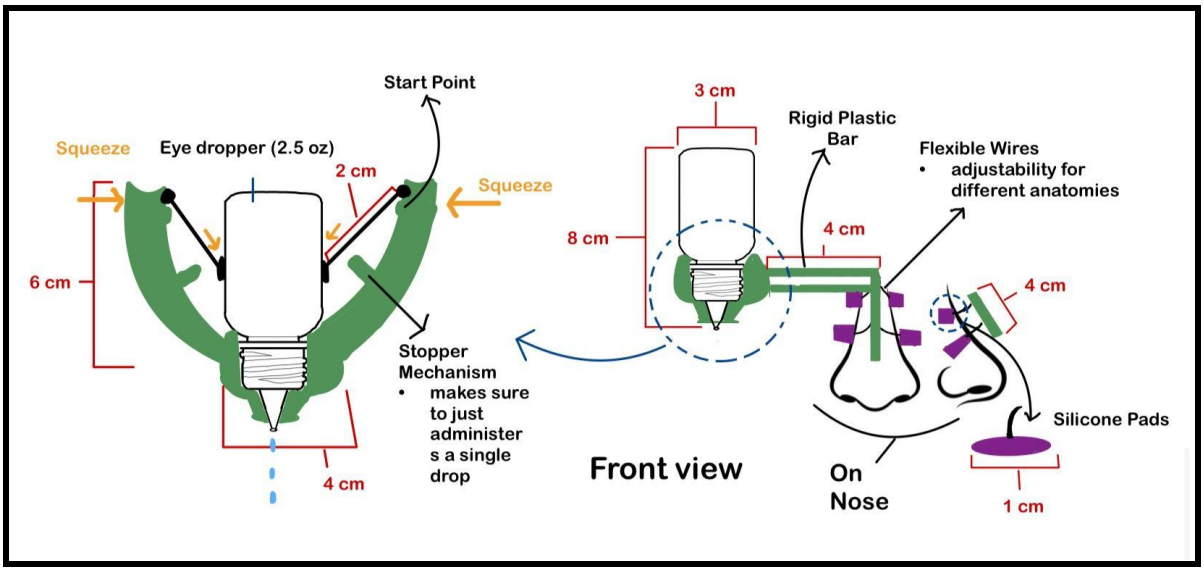

Figure 8: The Stopper Buddy Sketch.

Preliminary Design Evaluation

Design Matrix

Table 1: The Design Matrix comparing three preliminary designs

Design Categories (Weight)	**Design 1 - The Eye Lash Dropper**		**Design 2 - The Slider**		**Design 3 - Stopper Buddy**	
Injury & Contamination Risk (30)	5/5	30	3/5	18	3/5	18
Ease of Use (20)	4/5	16	5/5	20	3/5	12
Accuracy (20)	4/5	16	5/5	20	4/5	16
Compatibility (15)	4/5	12	3/5	9	3/5	9
Cost (10)	4/5	8	2/5	4	5/5	10
Ease of Fabrication (5)	3/5	3	1/5	1	4/5	4
Total Points:	**85**		**72**		**69**	

Design Category Descriptions

Injury & Contamination Risk:

The injury & contamination category assesses the potential for the device to cause harm to the patient. This category is weighted highest because the device is designed for patient use and involves the eyes, which are very delicate. First, the device must not injure the patient in any way. A patient needs to be able to safely use this device without the need to worry about the eye drop bottle coming loose from its position or other portions of the device scratching the facial area surrounding their eye. Second, the device must prevent contamination by ensuring that the tip of the eye drop bottle doesn't directly touch the eye. Lastly, it is imperative that the device is compatible with the proper eye drop technique because it can be dangerous for certain eye drops to be dropped directly into the center of the eye.

Ease of Use:

The design must be easier to use than the current eye drop bottle. This category encompasses multiple different aspects of the design. The insertion of the eye drop bottle into the device should be relatively smooth and the administration of drops from the device should be of more ease than the bottle pinch mechanism. The comfort level of the patient while using the device is also included in this category. The device should be easy to hold and operate with no exposed sharp edges or pinch points at the user interface surfaces. The device should not put any extra strain on the patient's face or hand while it is being used. This category is weighted relatively high because one of the points of this design is to make eye drop use easier.

Accuracy:

The accuracy category refers to the device's dependability on precisely releasing a single drop from an eye dropper bottle. Accuracy also describes the ability of the patient to consistently use the device to insert eye drops into the intended area of the eye. This category is weighted somewhat highly as it is vital that the device enables arthritic patients to consistently and correctly administer their medication, while also minimizing eyedrop waste to reduce patient expenses.

Compatibility:

Compatibility category encompasses the design's capability to accommodate a wide range of eye drop bottles and adapt to diverse patient anatomies. This ensures that the design can effectively and efficiently work with various types and sizes of eye drop bottles, catering to the specific needs and

anatomical differences of individual patients. This category received a medium weight because the client stated there is some variability in eye drop bottles; the majority of them on the market are the same size.

Cost:

This category includes the estimated cost of materials and processes included in the fabrication of the device. The cost should be relatively low as to ensure accessibility to patients of many different economic statuses. The team also has a budget of $500, so the overall associated costs need to stay under budget.

Ease of Fabrication:

Ease of fabrication evaluates how difficult the design will be to create based on time and resources available. This category was weighed the least because most of the designs will be able to be 3D printed. The other categories listed were more important as they pertain directly to the patients. Fabrication is the responsibility of the engineers, and therefore it is expected that the designs can be fabricated.

Design Matrix Evaluation

Injury & Contamination Risk:

The Eye Lash Dropper ranked highest at a 5/5 in the injury & contamination category because the device is stabilized with the nosepiece, which minimizes the risk of the device being dropped into the patient's eye. Additionally, the device is positioned at a height above the eye, preventing any contamination that could be caused by touching the eye drop bottle tip to the eye. The Slider and Stopper Buddy designs both scored a 3/5 in this category because they don't prevent the tip of the bottle from coming into contact with the eye. Therefore, The Slider and Stopper Buddy designs are not as stable and have a higher chance of being dropped by the patient.

Ease of Use:

The Slider design ranked highest of the three designs for this category because the eye drop bottle is easily inserted into the device and the dropper mechanism is electrically fueled, therefore, the user only needs to push the button on the device for the administration of a drop. The Stopper Buddy design ranked lowest in this category because the initial setup of the device is rather complicated, due to the required positioning of the nose bridge.

Accuracy:

The top-performing design in the accuracy category is the Slider. This score can be attributed to its dependability in releasing a single drop from an eye dropper bottle. The presence of the nose ridge on the motor compartment enables this design to consistently insert eye drops into the same part of the eye. While the Stopper Buddy and the Eye Lash Dropper also received favorable scores in this category, they will not release eye drops as consistently as the Slider. However, both designs feature a physical connection to the nose bridge, which will allow patients to reliably administer medication to a specific part of their eye.

Compatibility:

The Eyelash Dropper design excelled in accommodating both eye drop bottles and diverse nose anatomies, securing a higher rating in the compatibility category of 4/5. The ability to effectively cater to a wide spectrum of users and their unique needs played a significant role in the evaluations and rankings within this category. The Slider and Stopper Buddy were both rated 3/5 in this category because while they showed a reasonable level of compatibility with different nose anatomies, they demonstrated limited adaptability to varying eye drop bottles, which slightly hindered their overall score.

Cost:

The Stopper Buddy design scored the best in this category because the design includes the least amount of material. The materials it uses, including wire, 3D printer plastic, and silicone, are relatively inexpensive and easy to obtain. The Eye Lash Dropper is slightly more robust and special ordering springs to accommodate the forces needed could be expensive. Added cost from the electronics components in the Slider design leaves this design with the lowest score in this category.

Ease of Fabrication:

The Slider design ranked the lowest in this category, as it requires electrical components and possible coding which makes the design more complicated than the others. The Stopper Buddy ranked the highest in this category, as it is the simplest design of the three. This design could be 3D printed and assembled with existing materials like wire.

Proposed Final Design

Based on the evaluation of the design matrix, the team determined that the Eye Lash Dropper design will be the proposed final design, as it received the highest cumulative score as shown in **Table 1**. The design received the highest scores in the injury and contamination risk and compatibility categories.

The device scored highest in the injury and contamination risk category because of the nose bridge rest component. This component stabilizes the device on the nose and ensures that the device does not come in contact with the eye, preventing both injury to the patient and bottle tip contamination. The device also scored high in compatibility, accommodating various nose shapes and left/right-hand use, making it suitable for a wide user population. Overall, the Eye Lash Dropper best meets the defined needs of the client and will be fabricated into a working prototype.

Fabrication/ Development Process

Materials and Methods

The team decided to move forward with using PLA plastic printed at the UW Makerspace as the material for the prototyping process all the way through to the final prototype. Changes to the initial prototype versions throughout iterations were made in SolidWorks, and changes were based on shortcomings agreed upon by the team. Differing colors were used throughout iterations to help in design organization. Early iterations utilized Bambu Lab PLA and Bambu Lab 3D printers at default settings of 20% infill and grid pattern infill. The prototypes produced using these parameters weren't as rigid, and features of the design, such as the nose piece peg, sheared off with minimal force application. The final prototype was 3D printed as one complete part, so no assembly with other tools or materials was required. An Ultimaker printer with printer settings at normal resolution (0.2mm layer height) and 40% triangle infill was used for the final prototype. At 40% infill, PLA has an elastic modulus of 324 MPa and a yield strength of 11.1 MPa [17]. In addition, PLA has a density of 500 kg/m^3 [18]. These properties give the device enough deflection to transmit force to the eye drop bottle without inducing enough stress within the device to cause material failure. The high elastic modulus also ensures that the device remains rigid throughout use. PLA is also relatively cheap as each device costs around $2.00 to manufacture. A full list of expenses can be seen in Appendix D. Future work will include researching alternate methods and materials that allow for quicker and cheaper manufacturing while maintaining the material properties of a PLA part prepared with an Ultimake at 40% infill. Also, the team will consider adding material to or changing the nose piece material to increase ergonomics and increase usability for all nose shapes and sizes.

Fabrication Process

The inspiration for the final device was taken from an eyelash curler as well as a pliers. The idea was to create a device that used mechanical leverage to improve the ease of squeezing the eye drop bottle. The device was modeled using SolidWorks. Initially the device had long, thin, parallel handles. The

squeezing mechanism held the bottle loosely in place. The nose piece was printed separately and the device had to be assembled for use. There were vital changes made to this design throughout multiple iterations that lead to the final design. The mechanical advantage of the device was improved by increasing the diameter of the handles as well as adding a 6 degree angle to both sides. The nose piece was printed attached to the device so that there was no longer assembly required. This is ideal as assembly can be difficult for people with reduced dexterity. The team recognized that the neck size was consistent throughout the different types of eye drop bottles. A bottle neck support was added to the device to ensure that the bottle was placed at a consistent height. Lastly, the height of the device was reduced which allows the tip of the bottle to be closer to the eye. This helps to ensure that the eye drop is administered to the correct location.

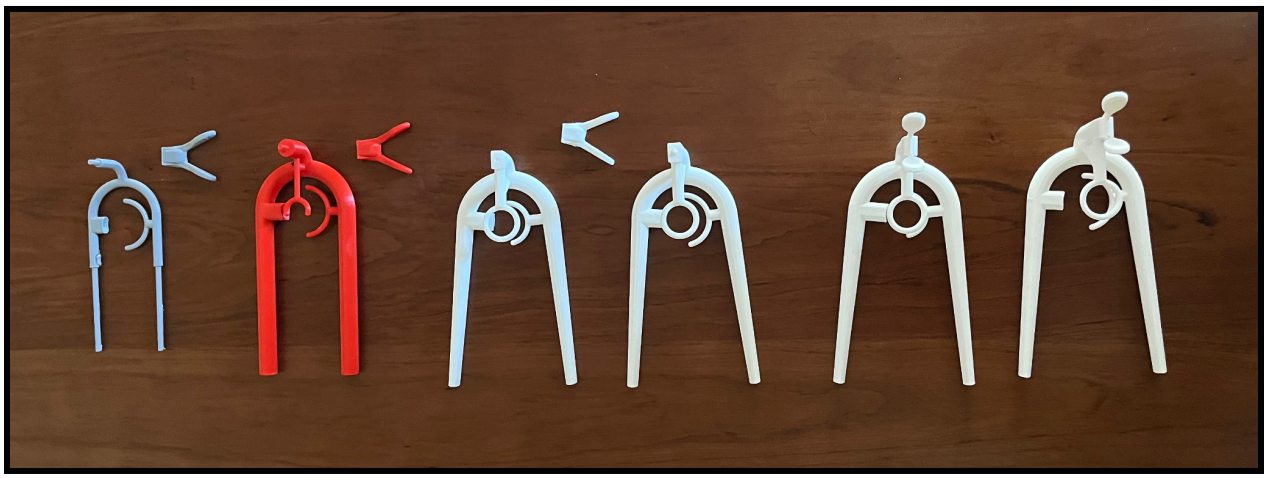

Figure 9: Series of prototype iterations from this semester, with the first print on the far left and the final devices on the far right.

Final Design

The final design consists of two different sized devices. The larger device accommodates large eye drop bottles that are typically used for lubricating eye drops. The smaller device accommodates small eye drop bottles that are commonly used for prescription medications that treat ophthalmic diseases such as Glaucoma. The team decided to create two different sized devices rather than one adjustable device to maintain the ease of use by not having any small moving parts that could be difficult to maneuver. Each of the devices has a nose piece that ensures stability during eye drop administration. The squeezing mechanism of the device is used to apply force to the bottle. Lastly, as mentioned previously, each device has a bottle neck support to ensure the bottle stays in place and is resting at a height that allows for proper eye drop technique. This aspect is designed in a way that still allows for the cap to be reapplied onto the bottle while in the device, reducing the chances of patients losing their eye drop bottles.

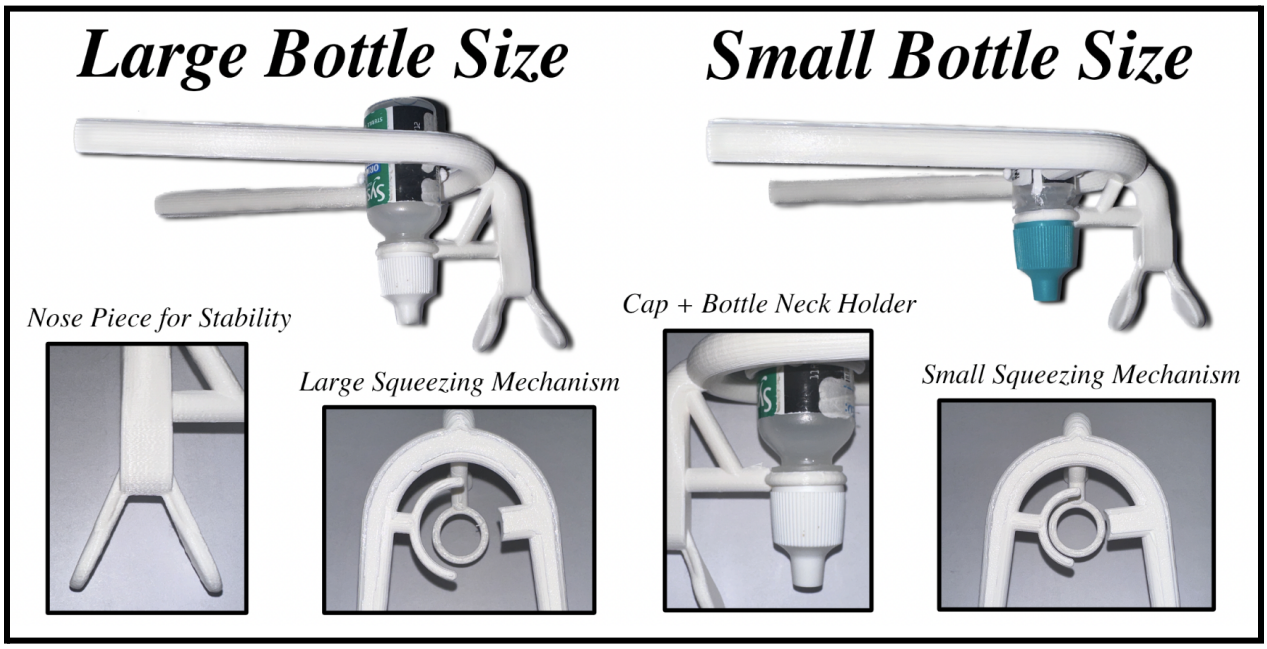

Figure 10: Breakdown of final devices highlighting key features.

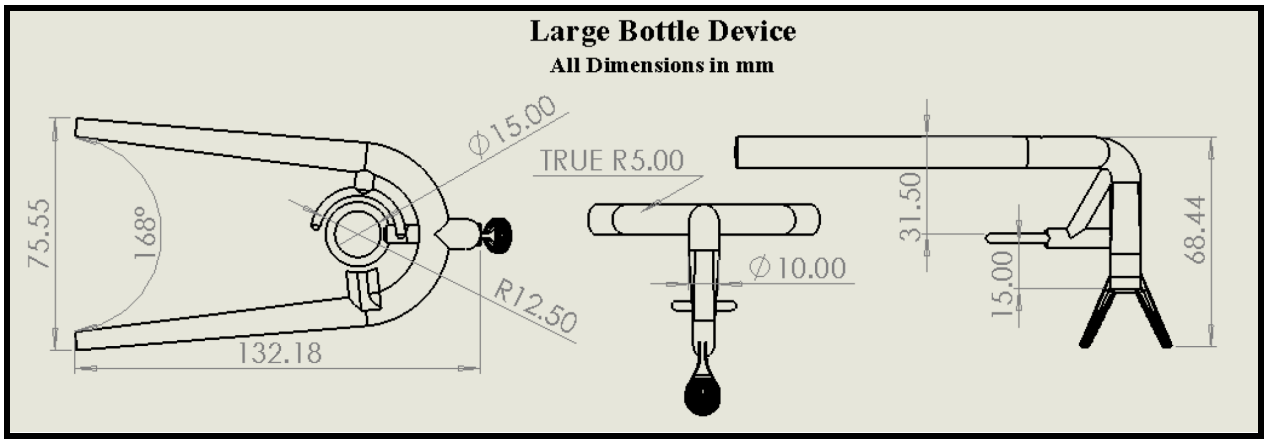

Figure 11: SolidWorks drawing showing dimensions of the Large Bottle Device.

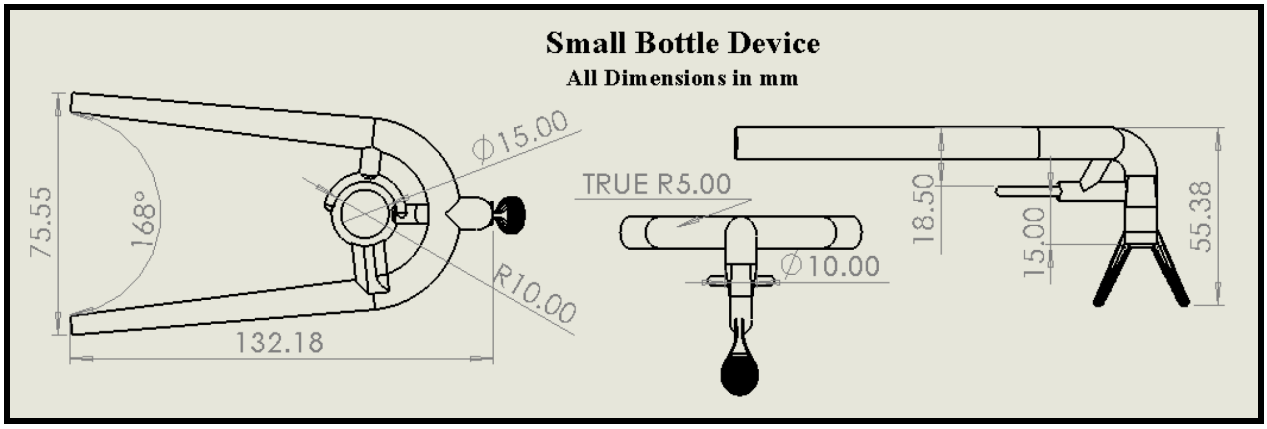

Figure 12: SolidWorks drawing showing dimensions of the Small Bottle Device.

Testing

Single Drop Test

Protocol:

This test was conducted to assess the efficacy of the device in consistently delivering one drop per use. To quantify this, 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. There were a total of six subjects that 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. For the full protocol, reference Appendix E.

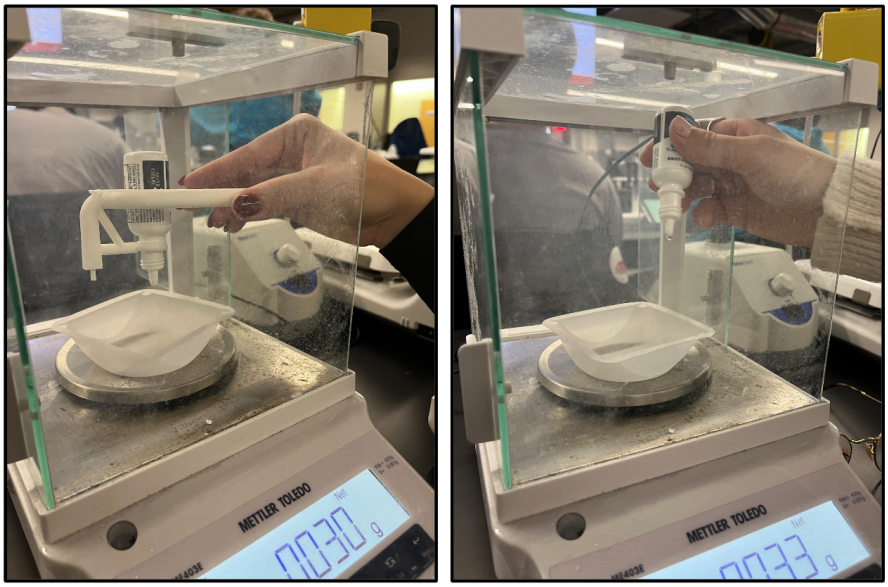

Figure 13: Experimental set up for single drop test.

Results:

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.

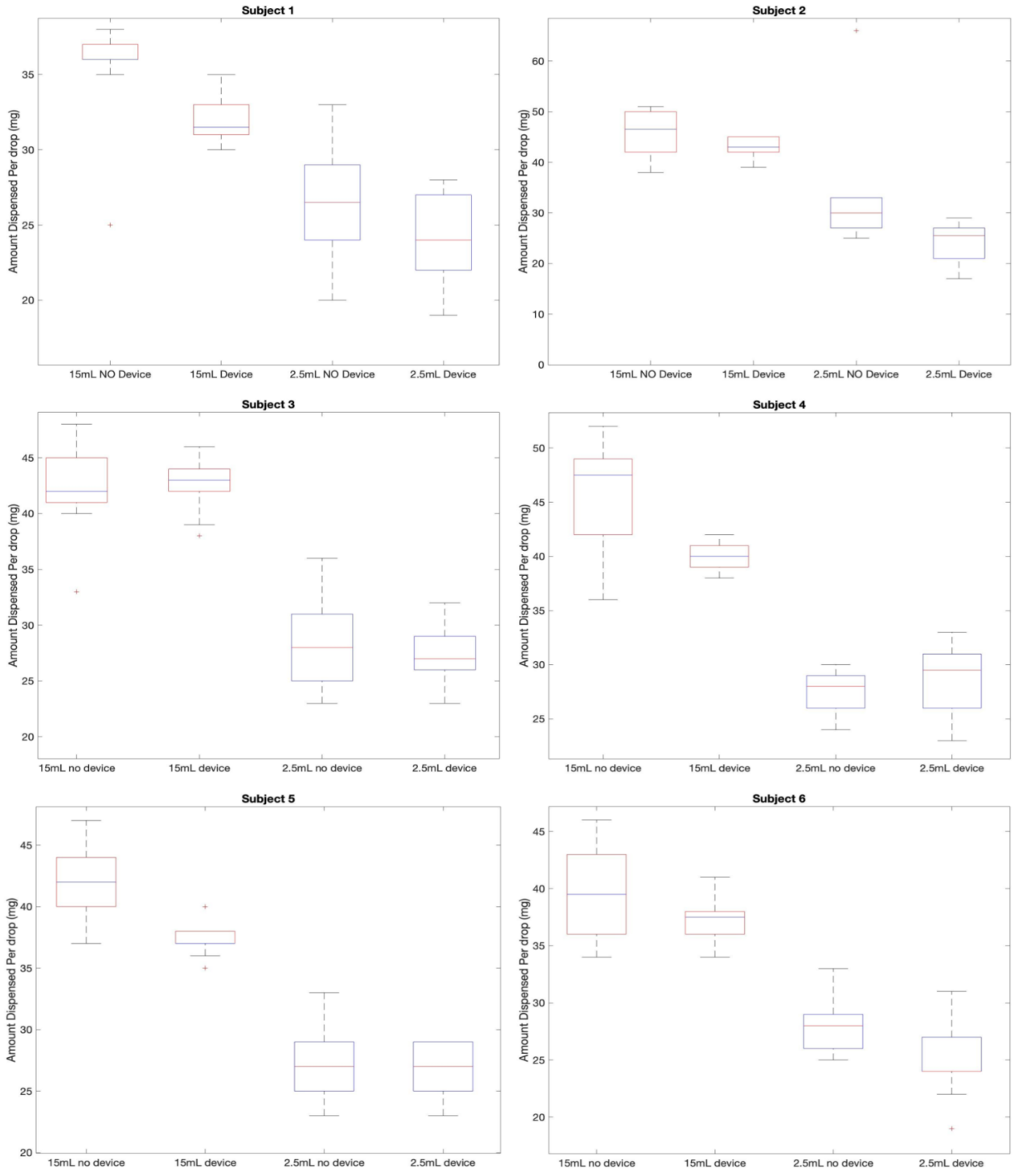

Figure 14: MatLab box plots displaying difference between drop size when using the device compared to not using the device for each of the six test subjects.

Statistical Analysis:

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 2** and **Table 3**.

Table 2: 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 3: 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	

Precision Test

Protocol:

A testing setup was established on a flat surface, incorporating a rolled-up tin foil to simulate a nose anatomy placed beside a piece of paper featuring a round circle with dimensions of 24.2 mm (transverse) × 23.7 mm (sagittal) [19]. The subject conducted four tests, each consisting of 10 drop trials under different bottle conditions: 15mL bottle without the device, 15mL bottle with the device, 2.5mL bottle without the device, and 2.5mL bottle with the device. During each trial, a single drop was dispensed onto a piece of paper, marked with a sharpie, and replaced, with this sequence repeated until ten drops were marked on ten different pieces of paper. Using a light, the ten marked papers were then transferred onto a single master page, capturing all drops from that trial. This standardized process was replicated across all listed conditions. In the case involving the device, the tin foil served as a stabilizing point, emulating the function of the nose in a typical human anatomy setup.

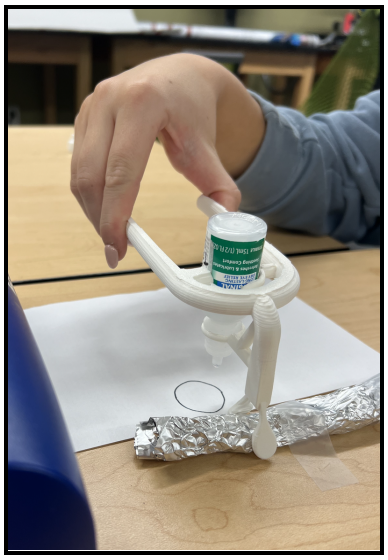

Figure 15: Experimental setup of precision test.

Results:

The team conducted a thorough analysis of the data using ImageJ on the master pages. Each piece of paper, featuring a calibrated line of 10.54 mm, was used for ImageJ calibration. Initially, the team measured the entire area of the circle, representing the eye, followed by measuring the areas covered by the 10 drops. To determine the total area covered by the drops, the team divided the area of 10 drops by the total circle area. The areas of each condition were depicted in **Table 4**. This process allowed the team to assess the precision difference between the device and no device. The precision differential was calculated by dividing the total area covered by drops for the device by the total area covered by drops for no device, multiplied by 100, providing the percentage difference in precision. The area coverage for the small bottle size decreased by 34.90% with the device, while the large bottle size area coverage decreased by 43.32% with the device.

Table 4: Comparison of the device's precision. Calculations taken from ImageJ.

15 mL Bottle	
Device Condition	**% of Area Covered**
NO Device	8.21%
Device	3.56%
2.5 mL Bottle	
Device Condition	**% of Area Covered**
NO Device	9.15%
Device	3.19%

Squeeze Force Test and Simulation

Protocol:

Force Test

Before conducting physical force testing on the final device using an MTS machine, the team designed a testing fixture made of PLA plastic. This fixture supports the device to ensure it cannot rotate, slip, or move during the performance of the test. This testing fixture is shown in **Figure 16**. The displacement of the handles required to release a single drop from the 2.5 mL and 15 mL bottles and respective small and large device sizes was measured and recorded. The small eye drop assistant device was placed in the testing fixture with the 2.5 mL bottle in place and oriented correctly. The MTS machine lowered to the point of first contact, and then a compressive test was started. The handles of the device were forced closer together until the displacement reached the previously calculated value of displacement. The MTS test recorded a graph of Force vs. Displacement. The graph generated on the MTS software was saved and exported to MATLAB. The MTS test was conducted six times, three trials for each bottle size. For the full protocol, please refer to Appendix G.

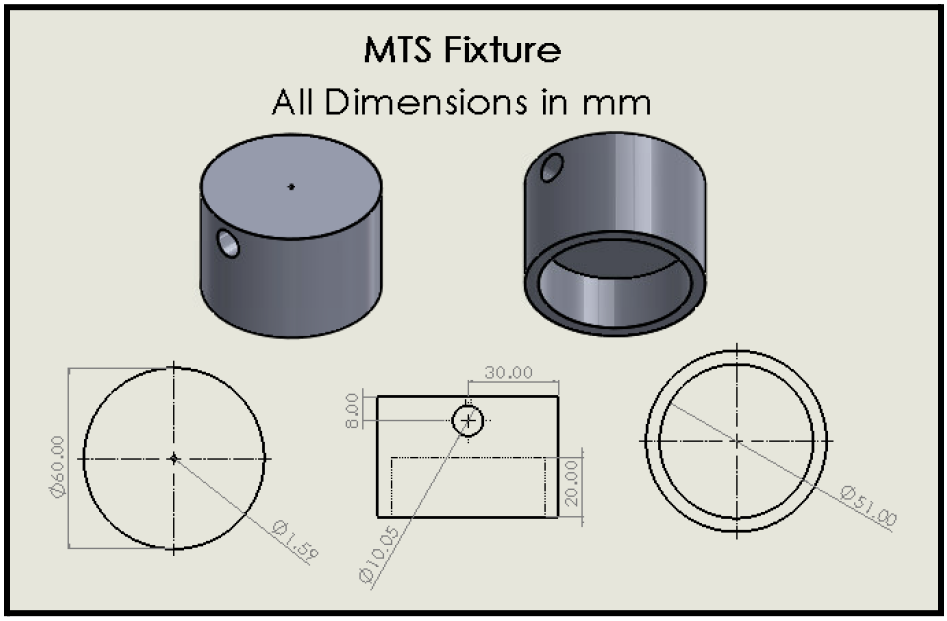

Figure 16 : Isometric View and Dimensioned Sketch of the Testing Fixture.

Simulation

The team used the displacement distance of the small and large device handles calculated in the force test protocol for the MTS machine above. The small device was opened in SolidWorks. The simulation was completed using PLA material, this was done by right-clicking the part, then selecting *Material → Edit Material*, and finally right-clicking *Custom Materials → New Material*. All the sections were left blank except the following values: *Elastic Modulus*: 324e+6, *Poisson's Ratio*: 0.33, *Mass*

Density: 500, *Tensile Strength:* 12.6e+6, and *Yield Strength*: 11.1e+6, as given by the researched literature [17], [18], [20]. The analysis was created by clicking *Simulation* → *Study* and the check mark at the top left of the screen to load a static simulation. The portion of the device that connects to the nosepiece was fixed. Right-click *Fixtures* → *Fixed Geometry,* selecting the faces of the bottom portion and then the check mark. After this, the displacement condition was applied by right-clicking *External Loads* → *Prescribed Displacement*. From this, the ovular face of the handle was selected to apply the displacement, and the handle midplane was selected as the direction reference geometry plane. For each device size, the displacement on each handle edge was applied *Normal to Plane* with a magnitude of the experimental displacement distance divided by two. These steps were repeated for the ovular face of the other handle. Then the simulation was run. A probe was 20 mm from the edge of the handles to determine the stress at this point of the device. These steps were repeated for the large bottle size and then analyzed and used to calculate the force at this point.

Figure 17: Experimental set up of stimulated force test.

Results

The team measured the distance between handles to be ~63.619 mm apart. When a single drop was released from the small bottle, this distance changed to ~51.646 mm. In the large bottle, this distance was recorded as ~43.435 mm after a drop was elicited. This means that the handles of the device were displaced 11.973 mm for the small device size and 20.184 mm for the large device size. These values were entered into the MTS machine as the *displacement* values for their respective tests.

The force, displacement, and time data from the MTS machine were exported for both the 2.5 mL and 15 mL bottle size tests. This data was then loaded into MATLAB and analyzed to determine the force required to reach each displacement value. For the complete MATLAB code, please reference Appendix

H. The Force vs. Displacement plots for the three trials of the force testing conducted on the small device and the large device are shown in **Figures 18** and **19** below. The force calculated for every force test trial is summarized in **Table 5**, and the mean force calculated for both the small and large eye drop assistant devices is shown in **Table 6**.

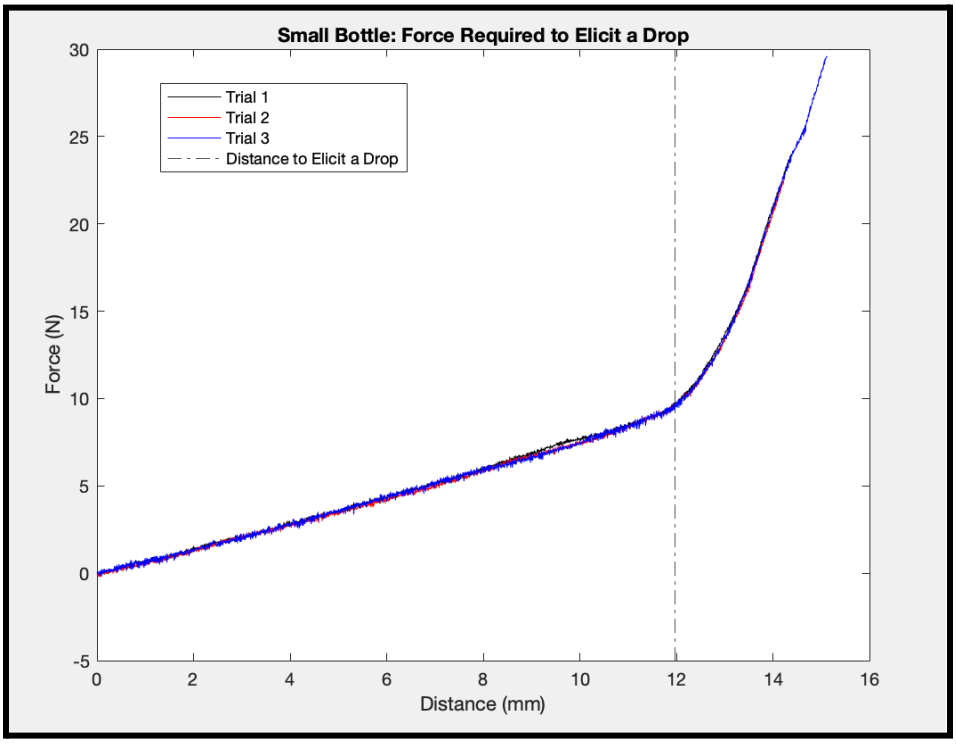

Figure 18: Force v. Displacement plot for the three compressive force trials conducted for the *small* eye drop assistant device and the associated 2.5 mL bottle.

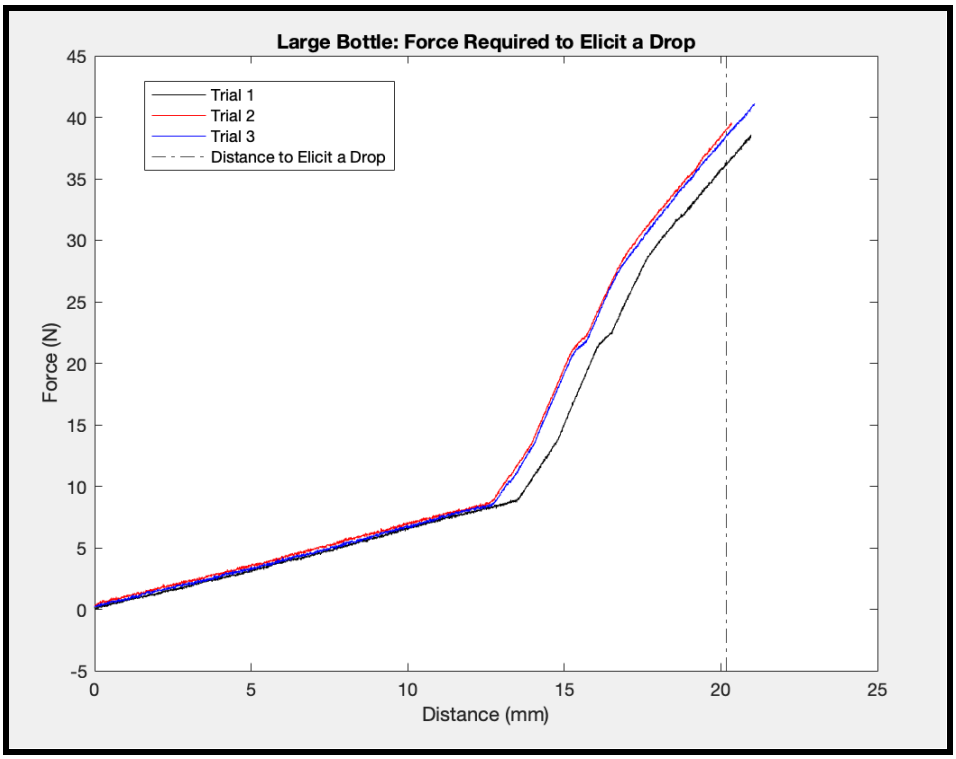

Figure 19: Force v. Displacement plot for the three compressive force testing trials conducted for the *large* eye drop assistant device and the associated 15 mL bottle.

Table 5: Raw force data calculated at the displacement distance for each respective device size.

Device Type	Trial #	Displacement to Elicit a Drop (mm)	Force (N)
Small Device	1	11.973	9.6707
Small Device	2	11.973	9.7707
Small Device	3	11.973	9.5082
Large Device	1	20.184	36.2396
Large Device	2	20.184	39.0055
Large Device	3	20.184	38.4667

Table 6: Interpretation of raw data from Table 5 into one quantifiable result for each device size.

Small Bottle Average Force	9.6499 ± 0.1325 N
Large Bottle Average Force	37.9039 ± 1.4663 N

The Von Mises stress at 20 mm from the edge of the handles in the SolidWorks model were found after completing the simulation and are highlighted in **Figure 20** and **Table 7**. At this point, the area perpendicular to the applied displacement was calculated to be *53.738 mm*^{2}. This was found using the equation of an elliptical cross-section which states that $A = d_1 * d_2 * \pi/4$. d_1 is a constant 10 mm while d_2 varies from 6 to 10 mm throughout the handle length. At this analysis point, d_2 was found to be 6.8421 mm given the linear loft geometry spanning the length of the handles. The force can be calculated using the stress and calculated area using the equation: $F = \sigma * A$. The forces for the small and large device sizes are shown in **Table 7**.

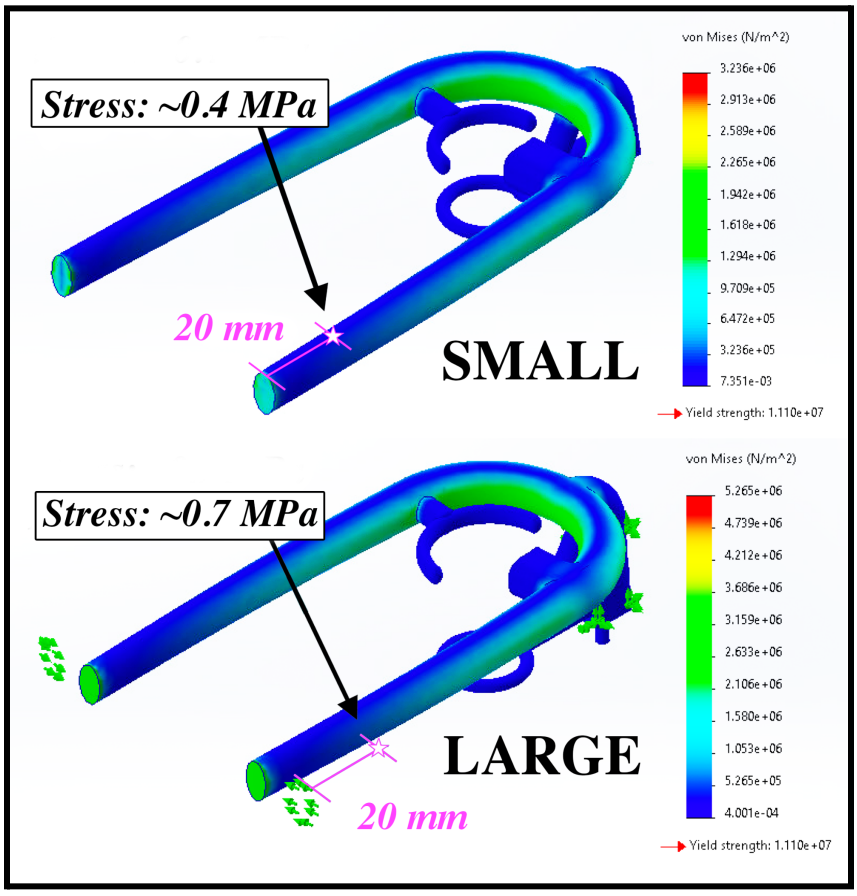

Figure 20: Stress distribution of the small and large eye drop assistant devices given each displacement condition outlined in the procedure. The stress at the analysis point is also shown.

Table 7: Simulated Von Mises stresses and calculated forces for the small and large device sizes.

Device Type	VM Stress (MPa) at 20 mm	Force (N) at 20 mm
Small Device	0.4 MPa	***21.5 N***
Large Device	0.7 MPa	***37.62 N***

Discussion

Implications

Rigorous testing of drop control, drop location precision and user applied force reveal that the final prototype accomplishes its goal as a device to assist in the administration of eyedrops. 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. Location testing showed that the device significantly increased drop precision by 35% for a 2.5 mL bottle and 43% for a 15 mL bottle. Without the device, users are more likely to miss the conjunctival sac while administering eye drops and either waste the medicated solution or put themselves at risk. Force testing through the MTS machine revealed that the force required to dispense a single drop is around 10 N for the small bottle and 38 N for the large bottle. Simulation testing in SolidWorks showed that it takes around 22 N of force to dispense one drop with the 2.5 mL bottle and around 38 N of force for the 15 mL bottle. The grip strength force minimum for extreme cases of arthritis is 35 N, and the results imply that the 2.5 mL bottle device, the bottle size commonly used by those with limited dexterity, can be comfortably used by even those with extremely limiting conditions [21]. Although the large bottle device doesn't meet the 35 N minimum, the limiting grip strength of 95% of rheumatoid arthritis patients is around 83 N, and the larger eye drop bottle size is more likely to be used by patients who don't exhibit limitations in grip [21]. Since the current test method used doesn't exactly simulate the same distributed force of a real world squeeze, future adjustments to the test fixture and device loading are needed to further verify these force test results.

Ethical Considerations

Throughout the design of the device, many anthropometric data points were used to set anatomy based dimensions. In the case of the overall width of the device, data from a study only including male anatomy was used. The team decided to assume values less than calculated based on inclusivity to all sexes. Similar assumptions were made in design aspects that surround distances between the eye and the

nose bridge. Ultimately this device is aimed to accommodate any human person who applies eyedrops in any capacity.

Sources of Error

Testing setup and method contributed to the error in final result values. The force test loading block distributed an irregular force profile on the device which does not simulate the devices' use. The location test setup included a tinfoil modeled nose bridge and a 2-D rendered eye based on anthropometric data. The nose bridge and lack of dimension in the eyeball did not accurately simulate the stability factor of the device on a nose bridge and the drop height. Potential errors based on the testing population might have arisen as well. The team members were the only subjects to perform the device testing, so the testing lacked representation of variation in user ability.

Future Work

The team is planning on conducting a Consumer Preference Test at a local retirement community to evaluate whether the eye drop device makes the eye drop bottle easier to use. However, eye drops will be dispensed onto a surface rather than directly into the user's eye, and the team is currently awaiting an IRB exemption for this procedure. Moreover, the team is in the process of developing a more accurate precision test, necessitating a new IRB application. This test involves subjects attempting to dispense eye drops into the lower eyelid pocket, offering valuable insights into the device's compatibility with a variety of anatomies. The anticipated results from this test will play a crucial role in assessing the device's effectiveness and adaptability across diverse user demographics. The team is also working on a Squeeze Force Test, aiming to establish a consistent and longer grip force location during MTS testing by modifying the fixture setup to align with the slanted design, creating a flat platform for MTS lowering.

Moving beyond the testing phase, the team plans to initiate contact with WARF to explore potential patent opportunities for the eye drop assistant device. Simultaneously, the team will look into comprehensive research on existing patents in the market. In order to proceed with this, the team will complete the WARF questionnaire, providing essential information about their device. Collaborating with a pharmacy student, the team will conduct a cost analysis and develop a marketing plan, comparing their eye drop assistant device with other devices on the market. Further research is planned into packaging options, considering the changes in the device's configuration, which now includes an attached nose piece with no assembly required, leading to potential packaging challenges. Looking ahead, the team has an exciting opportunity to participate in the Pharmacy School's "Shark Tank" competition next semester, presenting their eye drop assistant device against other pharmacy faculty and students' projects. As stated before, the team plans to explore more efficient and cost-effective manufacturing methods and materials while preserving the properties of a PLA part made with an Ultimaker at 40% infill. Additionally, the team will investigate enhancing ergonomics and usability for different nose shapes and sizes by either modifying the nose piece material or incorporating additional materials.

Conclusion

Current eye drop bottles are difficult to use, especially for those with reduced dexterity. Because of this, many patients improperly administer their eye drops, which can be dangerous and limit the therapeutic effects of their medication. Improper eye drop administration can also lead to eye drop waste and potential contamination. Eye drop waste can result in financial difficulties for many patients due to the high cost of medicated eye drops. When patients run out of their prescription eye drops early, they have to choose to either miss doses and wait until their medication is refilled and covered by insurance, or pay the out-of-pocket cost to have their prescription refilled early. Missing doses of daily prescription eye drops is detrimental to treatment of disease and out-of-pocket costs for refilling early is not economically feasible. In order for patients to maximize the effectiveness of their ophthalmic medications and avoid complications, eye drop administration must be simplified.

An eye drop assistive device can be used to improve the process of dispensing eye drops for reasons varying from dry eyes to treatment for ophthalmic diseases like glaucoma. The final eye drop assistant device provides a widened grip and accounts for the force that many users are not able to apply. The nose piece contributes stability during administration unlike normal eye drop bottles. The device has shown to consistently decrease the average drop size as well as the variability in location of the drops. Previous methods used to test the device were conclusive for drop size and precision, however the force testing was not an accurate representation of a distributed force. Future testing will assess the device's accuracy on different anatomies as well as quantify a more accurate force required for use of the device. In conclusion, this device successfully decreases the amount of force required to elicit an eye drop, while also minimizing eye drop waste.

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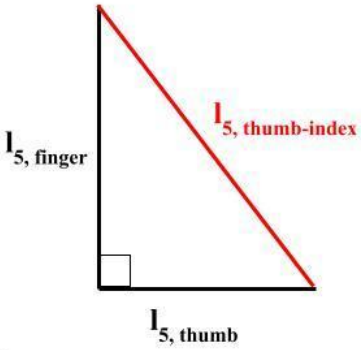
Appendix A - Maximum Width Calculations

$l_{5,\ thumb}$ = length of the 5th percentile of the thumb

$l_{5,\ index}$ = length of the 5th percentile of the index finger

$l_{5,\ thumb\text{-}index}$ = 5th percentile tip of thumb to index finger distance



The thumb makes a 90° angle with the index fingers at maximum stretch

From [14]: $l_{5,\ thumb}$ = 47.57 mm & $l_{5,\ index}$ = 63.01 mm

$$l_{5,\ thumb\text{-}index} = \sqrt{l_{5,\ thumb}^{\ 2} + l_{5,\ index}^{\ 2}} = \sqrt{6223.17\ mm^2} = 78.95\ mm\ \underline{or}\ 7.895\ cm$$

Since [14] only studies male fingers, we should assume a shorter distance to be *inclusive of all sexes.*

$l_{5,\ thumb\text{-}index}$ represents the maximum width the device can be so that patients can reach both grips.

$$l_{5,\ thumb\text{-}index\ (all)} = \sim 7\ cm$$

Appendix B - 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. <u>Product Characteristics:</u>

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. <u>Miscellaneous:</u>

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 we hope to cover in our 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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[10] C. for D. and R. Health, “Overview of Device Regulation,” FDA, Sep. 04, 2020. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation (accessed Sep. 19, 2023).

[11] Center for Devices and Radiological Health, “Classify your medical device,” U.S. Food and Drug Administration, https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device (accessed Sep. 20, 2023).

[12] Medical devices — Application of risk management to medical devices, ISO Standard 14971, 2019. https://www.iso.org/standard/72704.html

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Appendix C - Anthropometric Data Used for Measurements of the Eye Lash Dropper Design

FIGURE 12. NASAL BRIDGE HEIGHT MEASUREMENTS FROM REFERENCE PLANE LINES.

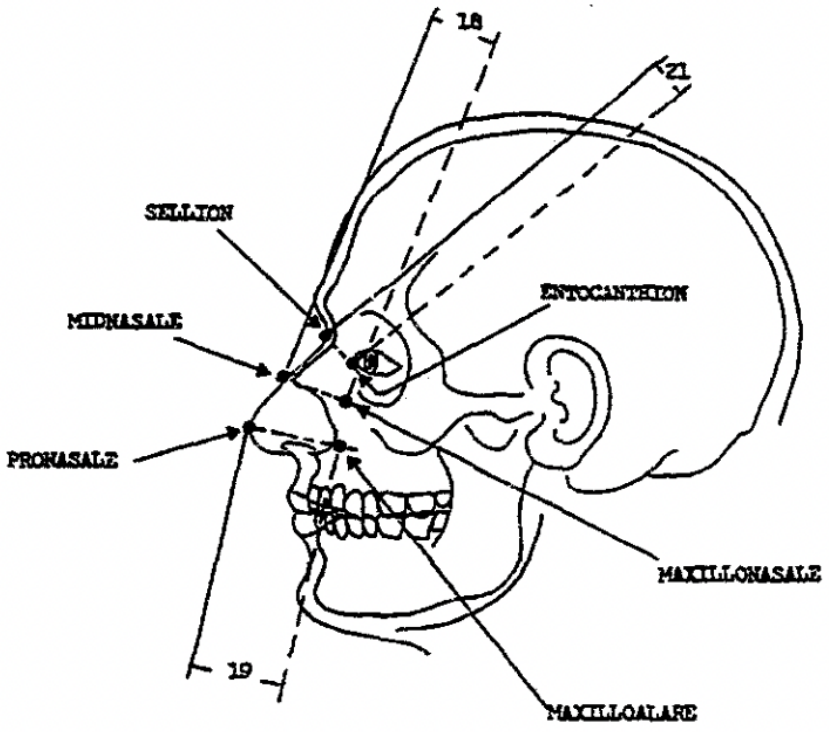

TABLE 22. SELLION HEIGHT FROM MEDIAL CANTHUS PLANE LINE

FEMALE			MALE		
SUMMARY STATISTICS			SUMMARY STATISTICS		
MILLIMETERS		INCHES	MILLIMETERS		INCHES
11.42	MEAN	Ø.45	12.87	MEAN	Ø.51
Ø.28	STD ERROR(MEAN)	Ø.Ø2	Ø.31	STD ERROR(MEAN)	Ø.31
3.13	STD DEVIATION	Ø.12	3.21	STD DEVIATION	Ø.13
6.1Ø	MINIMUM	Ø.24	7.ØØ	MINIMUM	Ø.28
22.1Ø	MAXIMUM	Ø.87	26.ØØ	MAXIMUM	1.Ø2
COEFF. OF VARIATION(%)		27.11	COEFF. OF VARIATION(%)		24.85
SYMMETRY		Ø.48	SYMMETRY		Ø.88
KURTOSIS		3.37	KURTOSIS		4.93
NUMBER OF SUBJECTS		121	NUMBER OF SUBJECTS		111
PERCENTILES			PERCENTILES		
MILLIMETERS		INCHES	MILLIMETERS		INCHES
6.1Ø	1 ST	Ø.24	7.Ø1	1 ST	Ø.28
7.11	5 TH	Ø.28	8.ØØ	5 TH	Ø.31
7.87	1Ø TH	Ø.31	8.99	1Ø TH	Ø.35
8.89	25 TH	Ø.35	11.ØØ	25 TH	Ø.43
1Ø.92	5Ø TH	Ø.43	13.ØØ	5Ø TH	Ø.51
13.97	75 TH	Ø.55	14.ØØ	75 TH	O.55
14.99	9Ø TH	Ø.59	16.99	9Ø TH	Ø.67
16.ØØ	95 TH	Ø.63	18.Ø1	95 TH	Ø.71
2Ø.Ø7	99 TH	Ø.79	23.Ø1	99 TH	Ø.91

SELLION HEIGHT FROM MEDIAL CANTHUS PLANE LINE: A perpendicular projection distance of the SELLION landmark away from a line coincident with both bilateral areas just medial of the ENTOCANTHION landmarks.

FIGURE 9. FACE & HEAD MEASUREMENTS.

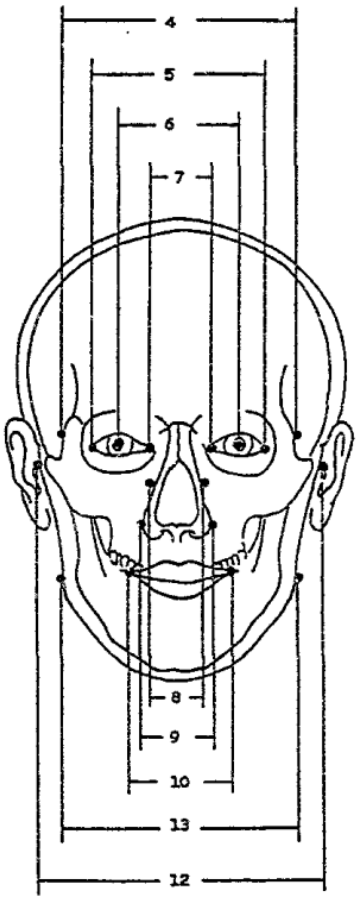

FIGURE 10. FACE BREADTH MEASUREMENTS.

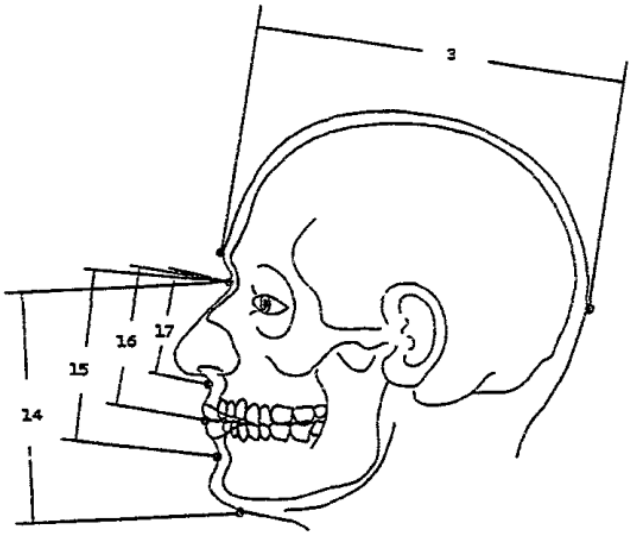

TABLE 7. BIPUPIL BREADTH

FEMALE			MALE		
SUMMARY STATISTICS			SUMMARY STATISTICS		
MILLIMETERS		INCHES	MILLIMETERS		INCHES
58.44	MEAN	2.30	61.39	MEAN	2.42
Ø.28	STD ERROR(MEAN)	Ø.Ø1	Ø.36	STD ERROR(MEAN)	Ø.Ø1
3.32	STD DEVIATION	Ø.13	3.63	STD DEVIATION	Ø.14
52.Ø7	MINIMUM	2.Ø5	54.99	MINIMUM	2.17
68.Ø7	MAXIMUM	2.68	7Ø.99	MAXIMUM	2.8Ø
COEFF. OF VARIATION(%)		5.66	COEFF. OF VARIATION(%)		5.88
SYMMETRY		Ø.5Ø	SYMMETRY		Ø.55
KURTOSIS		2.85	KURTOSIS		2.99
NUMBER OF SUBJECTS		136	NUMBER OF SUBJECTS		1Ø2
PERCENTILES			PERCENTILES		
MILLIMETERS		INCHES	MILLIMETERS		INCHES
52.Ø7	1 ST	2.Ø5	54.99	1 ST	2.17
54.1Ø	5 TH	2.13	56.Ø1	5 TH	2.2Ø
54.61	1Ø TH	2.15	57.ØØ	1Ø TH	2.24
55.88	25 TH	2.2Ø	59.ØØ	25 TH	2.32
57.91	5Ø TH	2.28	61.Ø1	5Ø TH	2.4Ø
59.94	75 TH	2.36	62.99	75 TH	2.48
62.99	9Ø TH	2.48	65.99	9Ø TH	2.6Ø
64.Ø1	95 TH	2.52	68.ØØ	95 TH	2.68
68.Ø7	99 TH	2.68	7Ø.99	99 TH	2.8Ø

BIPUPIL BREADTH: The bilateral distance between the right and left pupil centers of the eyes when looking straight ahead.

TABLE 13. BIZYGOMATIC BREADTH

FEMALE			MALE		
SUMMARY STATISTICS			**SUMMARY STATISTICS**		
MILLIMETERS		INCHES	MILLIMETERS		INCHES
131.81	MEAN	5.18	140.67	MEAN	5.54
0.36	STD ERROR(MEAN)	0.01	0.46	STD ERROR(MEAN)	0.02
5.09	STD DEVIATION	0.20	6.02	STD DEVIATION	0.24
119.12	MINIMUM	4.68	125.98	MINIMUM	4.96
148.08	MAXIMUM	5.83	152.91	MAXIMUM	6.02
COEFF. OF VARIATION(%)		3.85	COEFF. OF VARIATION(%)		4.26
SYMMETRY		0.12	SYMMETRY		-0.08
KURTOSIS		3.11	KURTOSIS		2.53
NUMBER OF SUBJECTS		195	NUMBER OF SUBJECTS		171
PERCENTILES			**PERCENTILES**		
MILLIMETERS		INCHES	MILLIMETERS		INCHES
119.89	1 ST	4.72	127.00	1 ST	5.00
122.94	5 TH	4.84	130.05	5 TH	5.12
124.97	10 TH	4.92	133.10	10 TH	5.24
128.02	25 TH	5.04	135.89	25 TH	5.35
132.08	50 TH	5.20	139.95	50 TH	5.51
134.87	75 TH	5.31	145.03	75 TH	5.71
137.92	90 TH	5.43	149.10	90 TH	5.87
139.95	95 TH	5.51	150.11	95 TH	5.91
145.03	99 TH	5.71	151.89	99 TH	5.98

BIZYGOMATIC BREADTH: The greatest bilateral distance between the lateral cheek surfaces of the zygomatic arch (ZYGION landmarks).

Appendix D - Expenses Master Sheet

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Existing Devices								
Droppy Eye Drop Dispenser	Competing Design	Droppy, Amazon	DR001	9/25	1	9.99	9.99	Link
GentleDrop Eye Drop Guide	Competing Design	GentleDrop, Amazon	ASIN: B0BQBHRKV1	9/25	1	17.99	17.99	Link
Prototyping								
Silicone Eyelash Curler	Prototype Materials (Handle Grips)	PETUNIA SKINCARE, Amazon	ASIN: B00UVLNDVQ	10/25	1	7.49	7.49	Link
MakerSpace Print	Prototype v1	UW Makerspace Ultimaker 3D Print	N/A	10/31	1	4.96	4.96	N/A
MakerSpace Print	Prototype v2	UW Makerspace Ultimaker 3D Print	N/A	11/10	1	5.07	5.07	N/A
MakerSpace Print	Prototype v3	UW Makerspace Bambu Labs 3D Print	N/A	11/13	1	4.5	4.5	N/A
MakerSpace Print	Prototype v3	UW Makerspace Bambu Labs 3D Print	N/A	11/14	1	4.96	4.96	N/A
MakerSpace Print	Prototype v3	UW Makerspace Ultimaker 3D Print	N/A	11/15	1	8.16	8.16	N/A

MakerSpace Print	Prototype v4	UW Makerspace Ultimaker 3D Print	N/A	11/17	1	10.08	10.08	N/A
MakerSpace Print	Test Fixture	UW Makerspace Ultimaker 3D Print	N/A	11/29	1	13.78	13.76	N/A
MakerSpace Print	Final Prototype	UW Makerspace Ultimaker 3D Print	N/A	12/1	1	7.36	7.36	N/A
MakerSpace Print	Multiple Final Prototypes	UW Makerspace Ultimaker 3D Print	N/A	12/8	1	11.6	11.6	N/A

Total Expenses: $105.94

Appendix E - Single Drop Test Protocol

Single Drop Testing Protocol

Date of testing: 11/17/23

- 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 assistant device in minimizing eye drop waste per use and delivering a consistent dosage of medication.
- Test Samples
  - Multiple teammates will perform trials, so that our 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
- Methods
  - 6 total subjects will participate in the testing
  - Each subject will perform four tests with 10 trials each:
    i. 15mL without the device
    ii. 15mL with the device
    iii. 2.5mL without the device
    iv. 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 device and hold it above the weight boat. Next the user 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 four tests. 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.
    i. 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 our 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.
    i. 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 our device delivers a more consistent dose of eye drop medication compared to regular eye drop bottles.

Appendix F - Precision Test Protocol

Drop Precision Testing Protocol

Date of testing: 12/04/23

- Scope
  - To perform testing to evaluate the precision of the eye drop dispensing
- Purpose
  - To understand the effectiveness of the eye drop assistant device in consistently delivering a drop into the same location every time dispensed.
- Test Samples
  - To ensure consistency in technique during data collection, one team member will conduct trials using both small and large eye drop bottles, facilitating a direct 1-to-1 comparison between the different trial conditions.
- Materials and Equipment
  - Eye Drop Assistant Device
  - 2.5 mL Eye Drop Bottle
  - 15 mL Eye Drop Bottle
  - Tin Foil and Paper
  - Sharpie
  - Light
- Methods
  - A testing setup will be created on a flat surface with a rolled up tin foil acting as a nose anatomy next to the piece of paper with a round circle on it.
    - Circle dimensions should be 24.2 mm (transverse) × 23.7 mm (sagittal) [1].
  - The subject will perform four tests with 10 drop trials each on the following conditions:
    - 15mL without the device
    - 15mL with the device
    - 2.5mL without the device
    - 2.5mL with the device
  - The experiment involves dispensing a single drop onto a piece of paper, marking it with a sharpie, and then replacing the paper. This sequence is repeated until ten drops are marked on ten different pieces of paper. Subsequently, using a light, the ten marked papers are transferred onto a single master page, capturing all drops from that trial.
  - This process will be the same for all the conditions listed.
    - In the scenario involving the device, the tin foil will serve as its stabilizing point, analogous to how it would utilize the nose in a typical human anatomy setup.
- Data Analysis and Documentation Requirements

    - The team will conduct a thorough analysis of the data using ImageJ on the master pages. Each piece of paper, featuring a calibrated line of 10.54 mm, will be used for ImageJ calibration. Initially, the team will measure the entire area of the circle, representing the eye, followed by measuring the areas covered by the 10 drops. To determine the total area covered by the drops, the team will divide the area of 10 drops by the total circle area. This process will be iterated for each condition, allowing the team to assess the precision difference between the device and no device. The precision differential will be calculated by dividing the total area covered by drops for the device by the total area covered by drops for no device, multiplied by 100, providing the percentage difference in precision.
- References

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Appendix G - Squeezing Force Protocol

Squeeze Force Testing Protocol
Date of testing: 11/21/23 & 12/1/23

- Scope
  - To perform testing to evaluate the force required to compress the handles of the eye drop assistant device together.
- Purpose
  - To understand the squeezing force required by the user to dispense one eye drop using the eye drop assistant device.
- Reference Documents
- Test Samples
  - Eye drop assistant devices (include all prototypes)
- Materials and Equipment
  - Eye drop assistant device
  - MTS machine
  - Device holder
    - used to stabilize the device on its side while using the MTS machine
- Methods
  - The team will design a device holder using SolidWorks and 3D print it with PLA plastic. The holder will conform to the shape of the device, leaving the handles free of any constraint. This fixture will support the device to ensure it cannot rotate, slip, or move during the test. Before using the MTS machine, the team will measure and record the distance between the two handle edges, which is consistent between the two sizes of the device. The team will then insert the 2.5 mL and 15 mL bottles into the small and large devices and squeeze the handles of each device until a single drop is released. The distance between the handles will be recorded, and then subsequently used to calculate the net displacement used for the MTS machine. The 3D-printed test fixture will be placed on the bottom portion of the MTS machine, and the eye drop assistant device will be secured into the test fixture on the MTS machine. 2.5 mL and 15 mL bottles will be inserted into the squeezing mechanism of small and large devices and placed into the testing fixture so that the plane between the device handles points vertically and the nozzle of the bottle faces the observer. A testing setup with a strain rate of 0.002 mm/sec will be loaded into the MTS software. The MTS machine will then be lowered manually

to the first point of contact with the device handles. The compression test on the MTS machine will be performed and the handles of the device will get closer together until the displacement reaches the previously calculated value of displacement. The MTS test will record a graph of Force vs displacement. The graph generated on the MTS software will be saved and exported to MATLAB. The MTS test will be conducted six times, three trials for each bottle size.

- Data Analysis and Documentation Requirements
    - The team will analyze the data using the graphs created by the MTS software. The maximum squeezing force required to use the eye drop assistant device will be determined by the peak of force on the graph. The precalculated displacement value will be located on the graph, and the corresponding force value will represent the amount of force required to squeeze and administer one eye drop with the device. The study aims to show that the eye drop assistant device requires less force to release an eye drop than the traditional device. The endpoint of this study will be the required force to drop an eye drop with the device is smaller than with the bottle.

Appendix H - Squeezing Force Test Analysis Code

```
%% MTS Force Code
% Eye Drop Assistant - Tommy Kriewaldt

%% Importing the Small Bottle Data:
[file, path] = uigetfile('*','Select the file to open');
SB_1 = importdata([path,filesep,file]);
[file, path] = uigetfile('*','Select the file to open');
SB_2 = importdata([path,filesep,file]);
[file, path] = uigetfile('*','Select the file to open');
SB_3 = importdata([path,filesep,file]);
% Importing the Large Bottle Data:
[file, path] = uigetfile('*','Select the file to open');
LB_1 = importdata([path,filesep,file]);
[file, path] = uigetfile('*','Select the file to open');
LB_2 = importdata([path,filesep,file]);
[file, path] = uigetfile('*','Select the file to open');
LB_3 = importdata([path,filesep,file]);

%% Setting Variables
SB_distance = 11.973; % distance to elicit a drop in mm
LB_distance = 20.184; % distance to elicit a drop in mm

%% Calculating Force and SD of trials!
% Finding the index
SB_idx = find(round(SB_1.data(:, 1), 3) == SB_distance); % rounding
to meet the distance we measured in 3 decimal places
LB_idx = find(round(LB_1.data(:, 1), 3) == LB_distance);
% Given the strain rate is consistent between trials for the small
and large
% bottle, this index will be the same for Trials 1-3 for both
scenarios.

% Force to reach this displacement for each trial:
% Small Bottle
SB_1_F = SB_1.data(SB_idx, 2);
SB_2_F = SB_2.data(SB_idx, 2);
SB_3_F = SB_3.data(SB_idx, 2);
% Large Bottle
LB_1_F = LB_1.data(LB_idx, 2);
LB_2_F = LB_2.data(LB_idx, 2);
LB_3_F = LB_3.data(LB_idx, 2);
```

```
% Averages and Standard Deviation:
% Small Bottle
SB_F = [SB_1_F(:), SB_2_F(:), SB_3_F(:)];
SB_F_avg = mean(SB_F);
SB_F_sd = std(SB_F);
% Large Bottle
LB_F = [LB_1_F(:), LB_2_F(:), LB_3_F(:)];
LB_F_avg = mean(LB_F);
LB_F_sd = std(LB_F);

%% Plotting the Data - Small Bottle
figure(1);
plot(SB_1.data(:, 1), SB_1.data(:, 2), "k");
title("Small Bottle: Force Required to Elicit a Drop")
xlabel("Distance (mm)")
ylabel("Force (N)")
hold on
plot(SB_2.data(:, 1), SB_2.data(:, 2), "r");
plot(SB_3.data(:, 1), SB_3.data(:, 2), "b");
xline(SB_distance, "k-."); % distance to elict a drop in mm.
legend("Trial 1", "Trial 2", "Trial 3", "Distance to Elicit a Drop");
hold off

%% Plotting the Data - Large Bottle
figure(2);
plot(LB_1.data(:, 1), LB_1.data(:, 2), "k");
title("Large Bottle: Force Required to Elicit a Drop")
xlabel("Distance (mm)")
ylabel("Force (N)")
hold on
plot(LB_2.data(:, 1), LB_2.data(:, 2), "r");
plot(LB_3.data(:, 1), LB_3.data(:, 2), "b");
xline(LB_distance, "k-."); % distance to elict a drop in mm.
legend("Trial 1", "Trial 2", "Trial 3", "Distance to Elicit a Drop");
hold off
```