Eye Drop Assistant

BME 400

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Abstract

Eye drops are the leading route 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 essential for treatment progression, 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, prototype-based tests will be conducted. The team plans to perform an ergonomics test in which frequent eye drop users will use the device and respond to a survey regarding their opinion on how the device's ease of use compares to the traditional eye drop bottle. A second test will be conducted to test the device's effectiveness in consistently administering only one drop. Subsequent data analysis will determine whether the device successfully meets these specifications.

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Introduction

Motivation

Eye drops are the leading route 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 the administration of too many drops into the eye or missing the eye completely. It is found that 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 for those with reduced dexterity, therefore we propose 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.

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].

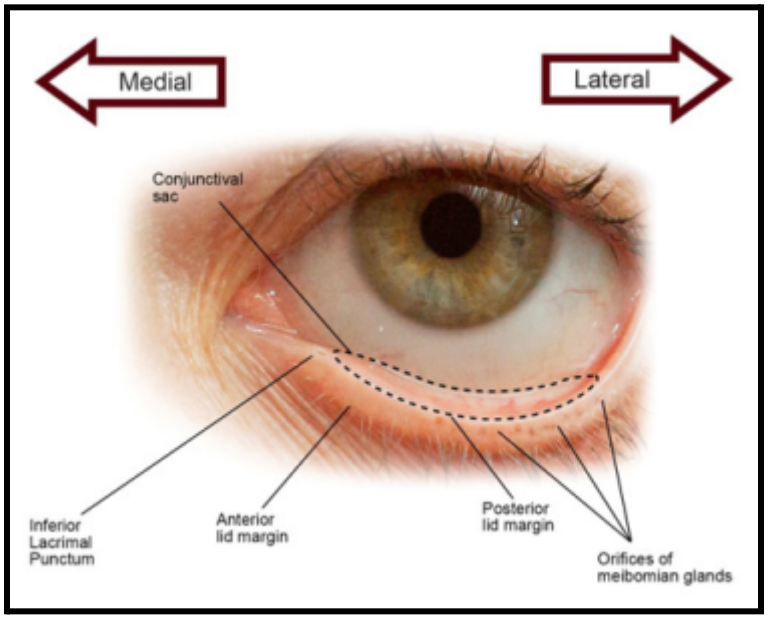

Figure 1: Anatomy of the eye, outlining the conjunctival sac where eye drops should be placed [8].

Improper eye drop administration technique, age-related physical difficulties, variable duration of use, and missing the eye during instillation 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

Figure 2: Droppy Eye Drop Dispenser [11].

Figure 3: GentleDrop Eye Drop Guide [12].

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 in all of 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.

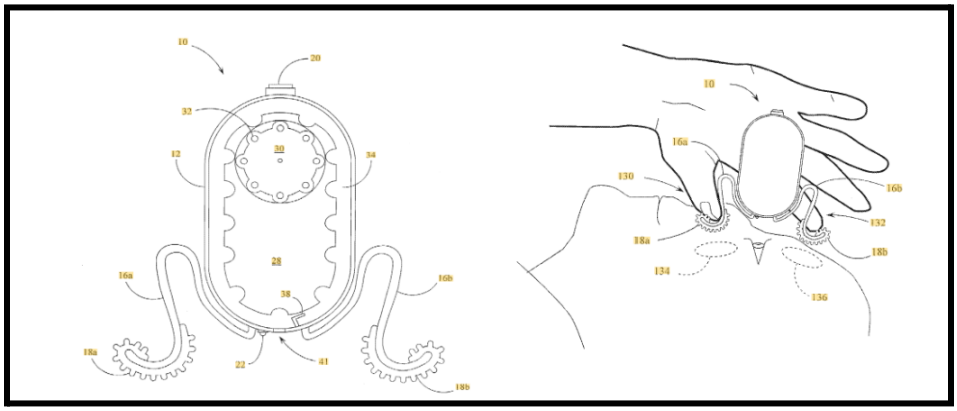

Figure 4: Bandolier Cartridge Sterile Eye Drop Delivery System With Eyelid Retracting Legs [13].

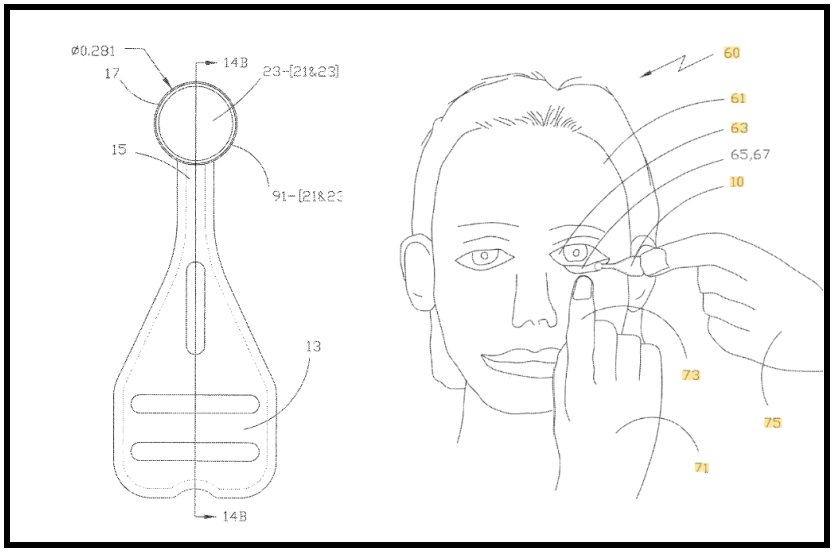

Figure 5: Eye Drop Applicator [14].

Patents surrounding 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 solution administration, but it does not directly address the proper eye drop technique or typical eye drop bottle compatibility. 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.

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

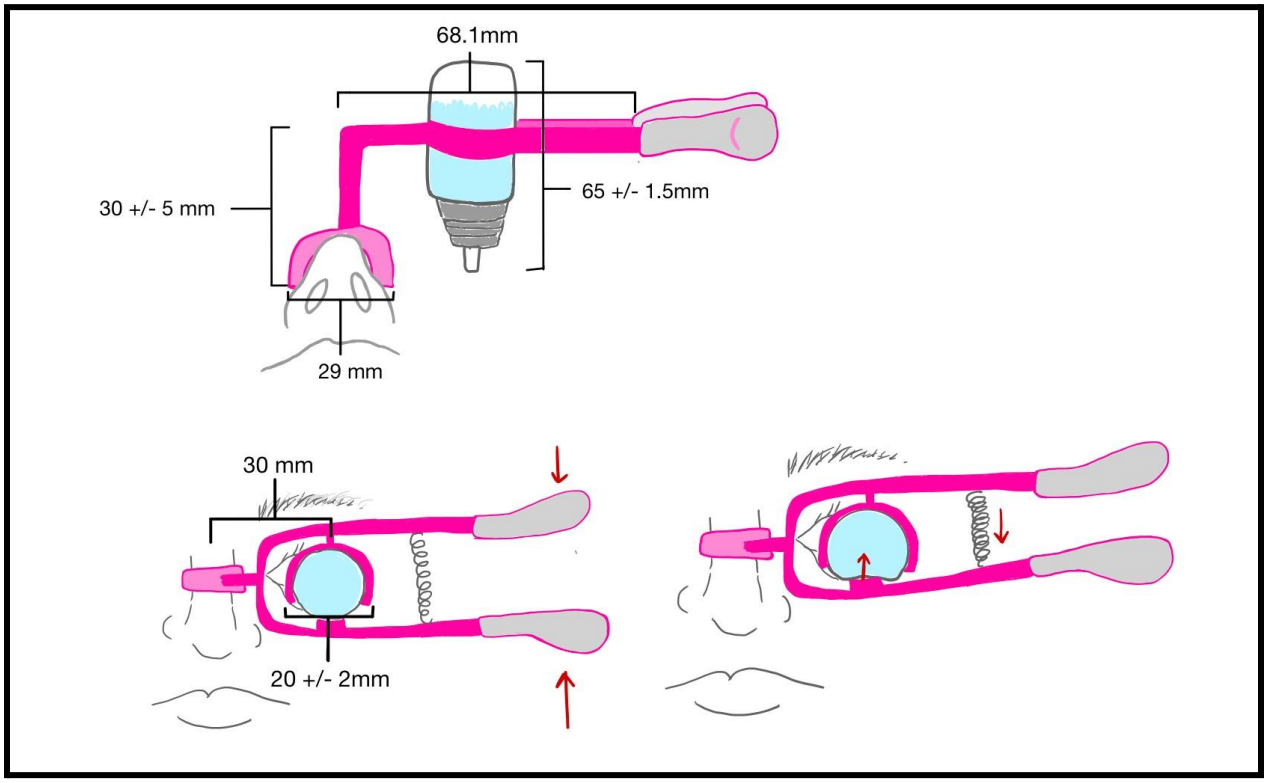

Figure 6: The Eye Lash Dropper Sketch

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.

Design 2: The Slider

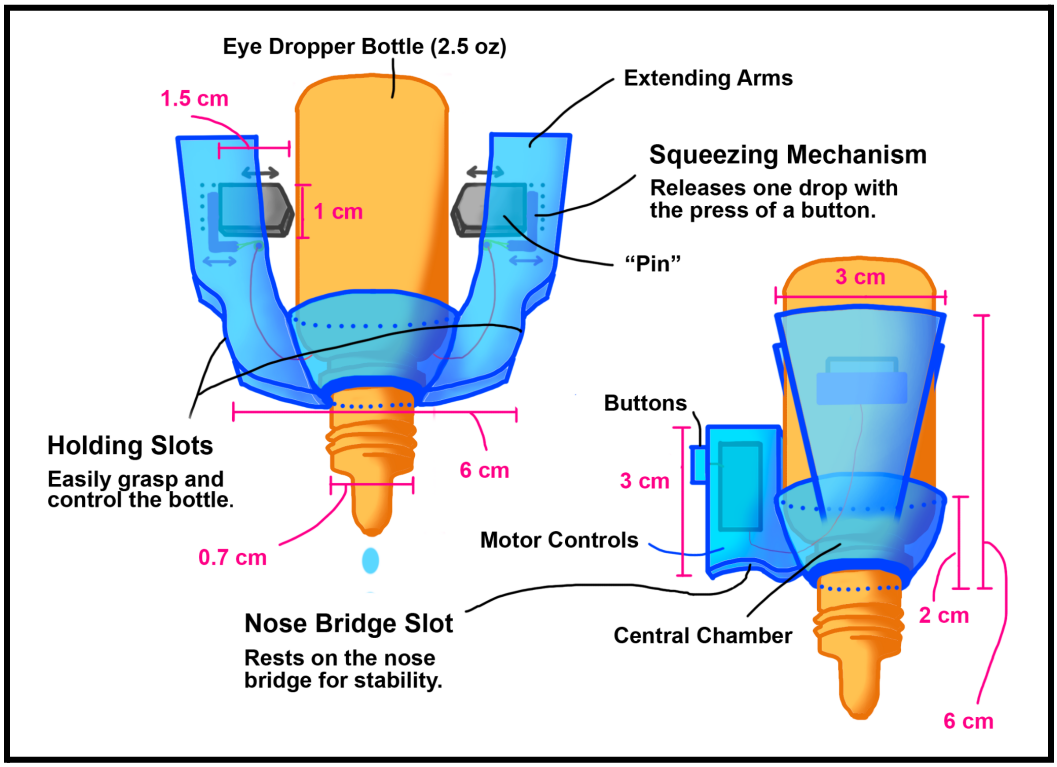

Figure 7: The Slider Design Sketch

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.

Design 3: Stopper Buddy

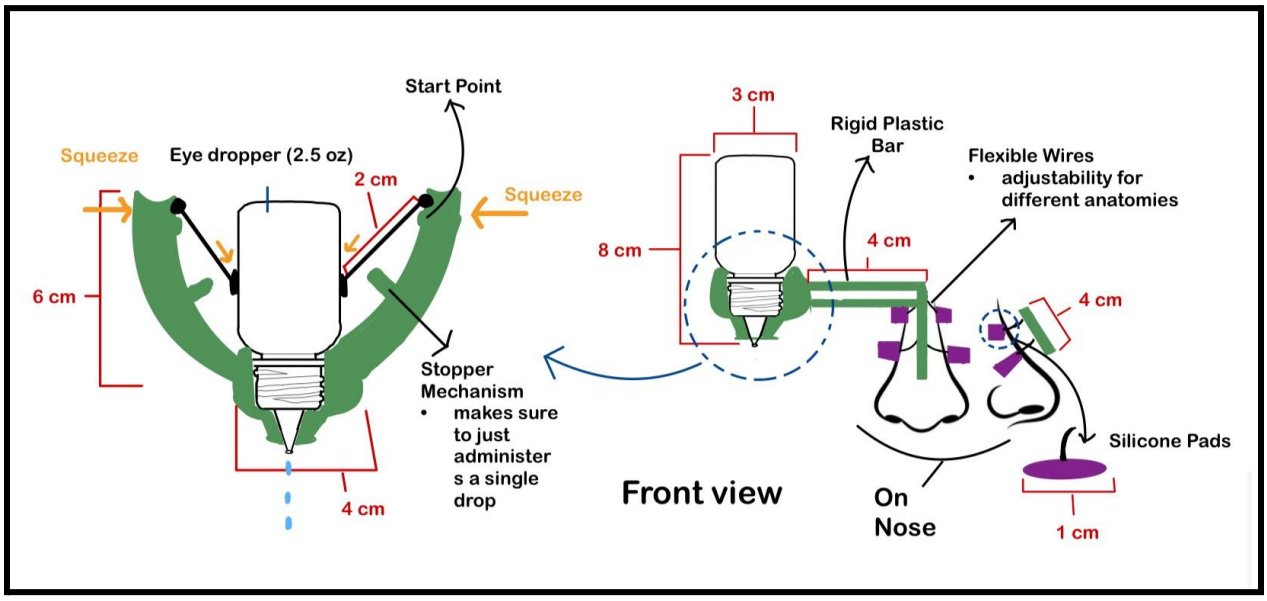

Figure 8: The Stopper Buddy Sketch

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.

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 nosepiece and handle portion of the prototype will either consist of an outsourced molded silicone or a formlabs printed elastic resin. This decision will depend on the quotes received and the budget available. This material will provide a comfortable grip and fit for the portions of the design that directly interface with the user. The main body of the final prototype will need to consist of a rigid and durable material in order to maintain the expected life in use while allowing for an adequate translation of force. Certain plastics, such as Acrylonitrile Butadiene Styrene (ABS), feature these rigid and durable qualities, allow for easy coloration, can be manufactured using injection molding, and can withstand common medical sterilization techniques [17]. Based on testing and calculations, the team will characterize the spring properties needed to output the correct forces and solution dispensing control. McMaster-Carr has many steel compression springs with a range of compression strengths and lengths that can be purchased to achieve the team's design outputs.

The team decided to move forward with using PLA plastic as the material of the initial prototype. A SolidWorks model of the final proposed design will be created and then 3D printed in the MakerSpace. The 3D model of the device can be easily altered if a problem arises at any stage of the prototyping process. These initial plastic prototypes will help the team understand if this design will be functional without using expensive materials right away. Once an adequate prototype is created, the team will move forward in building the final prototype with the aforementioned materials. Currently the only purchases related to the project that have been made are the Droppy Eye Drop Dispenser and the GentleDrop Eye Drop Guide, and the expense specifics can be seen in Appendix D. The team made these purchases to gain valuable comparison experience of in market devices.

Testing

Before any testing begins, the team must prioritize obtaining Institutional Review Board (IRB) approval to ensure that the research involving human subjects complies with ethical guidelines and safeguards the participants' rights, safety, and well-being [18]. This approval is essential in demonstrating the team's commitment to conducting responsible and ethical research, emphasizing the importance of human welfare in the project.

The client intends to present initial prototypes at Oakland Village University Woods Retirement Community to gather feedback from patients. This feedback collection is a pivotal step in the design process, allowing real users to interact with and evaluate the prototypes. The opinions and experiences shared by the patients will provide invaluable insights into the usability, comfort, and effectiveness of the device in a real-world setting.

As the volume of the eye drop solution decreases, the squeezing force required to administer drops may increase due to changes in viscosity and surface tension. Viscosity, the resistance to flow, can elevate as the volume diminishes, demanding more force to expel a drop. Additionally, alterations in surface tension, the cohesive forces within the liquid, can affect drop formation at the tip. The design of the tip and the bottle's shape also play crucial roles [3]. A smaller or narrower tip might require more force to overcome surface tension and dispense the drop. Testing to evaluate these aspects and meet the Product Design Specification (PDS) criteria is essential. Future tests could involve measuring the squeezing force required at various volumes, considering different tip designs and bottle shapes to optimize ease of use and minimize the force needed for administering eye drops. Conducting these tests under controlled conditions will provide valuable insights into how design modifications can enhance the user experience and meet the specified criteria.

Results

There are no testing results available at this time, as the group is still in the process of creating a prototype of the updated design. The team predicts that the change in force required as the eye drop bottle empties will be negligible.

Discussion

Following the testing of the device, the team will share the results with the client and discuss future enhancements to the design. The team intends to conduct tests on the device within a retirement community to ensure the absence of any design issues.

Ergonomics testing will pinpoint areas of improvement regarding patient needs. In this proposed test, subjects should give feedback voluntarily and shouldn't feel compelled to join the survey in any capacity. To minimize cross-contamination between patients during testing, the team should use multiple devices or establish sterilization protocols. A single drop accuracy test will guarantee that patients can reduce medication waste. The team also considers that the device must accommodate various bottle sizes and different face shapes of patients to ensure its universal suitability for every prospective patient.

The primary concerns regarding potential errors center around the safety and stability of the device. The team must ensure that the device can elicit at least one drop but no more after conducting the accuracy testing. This design must guarantee that the final device consistently delivers the correct number of eye drops, regardless of the bottle's shape or fill level, thereby reducing the likelihood of waste and other potential sources of error. The choice of materials, particularly the durability of the plastic components, can introduce additional potential sources of error. Inadequate strength of materials could also lead to difficulty in aligning the device with the eye, leading to further issues with stability. Additionally, errors stemming from user misuse, such as inadequate device positioning, could lead to ineffective or inconsistent dosage delivery. Any forthcoming modifications to the design following error assessments should be created and tested similarly to the initial design to assess potential improvements in the design process.

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. It can also lead to eye drop waste and potential contamination. Eye drop waste can result in financial difficulties for many patients because prescription eye drops are very expensive. 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 so it is covered by insurance, or pay the out-of-pocket cost to have their eye drops refilled early. Missing doses of their daily prescription eye drops is unhealthy for patients and out-of-pocket costs for refilling early are sometimes hundreds of dollars, which is not economically feasible for many patients. In order for patients to maximize the effectiveness of their ophthalmic medications and avoid complications, eye drop administration needs to 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 Eye Lash Dropper will provide a widened grip and account for the force that many users are not able to apply. The device will also contribute increased stability compared to normal eye drop bottles. The device will be tested on its ability to successfully dispense a proper, consistent dose of solution while also maintaining the correct eye drop technique. Overall, the team aims to create a device that greatly decreases the difficulty of treating ophthalmic diseases for all patients.

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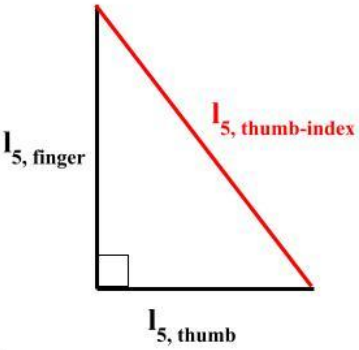
Appendix A - Maximum Width Calculations

$l_{5,\ thumb}$ = 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. 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 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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Appendix C - Anthropometric Data Used for Measurements of the Eye Lash Dropper Design

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

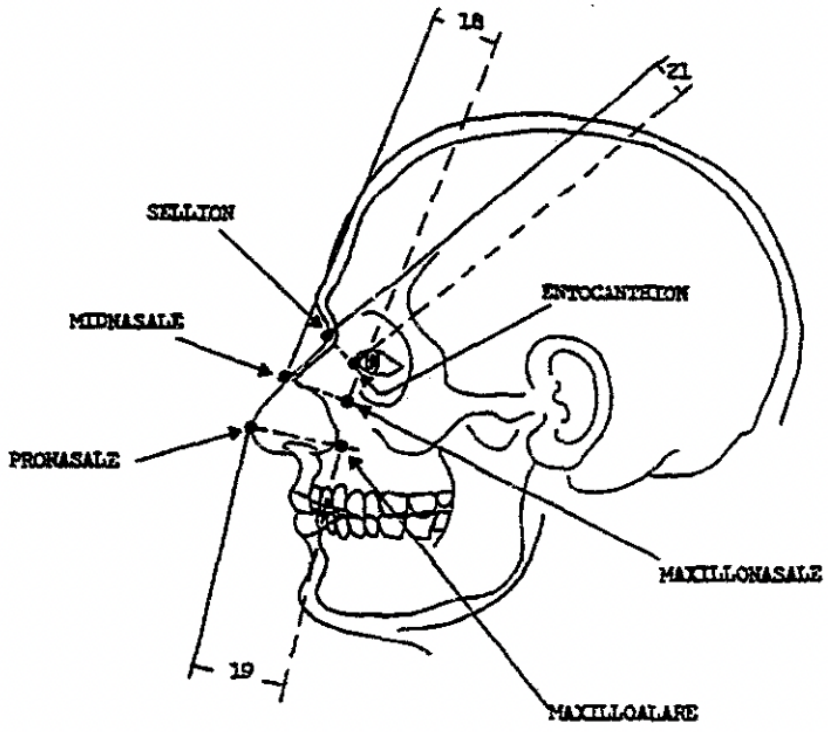

TABLE 22. SELLION HEIGHT FROM MEDIAL CANTHUS PLANE LINE

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.

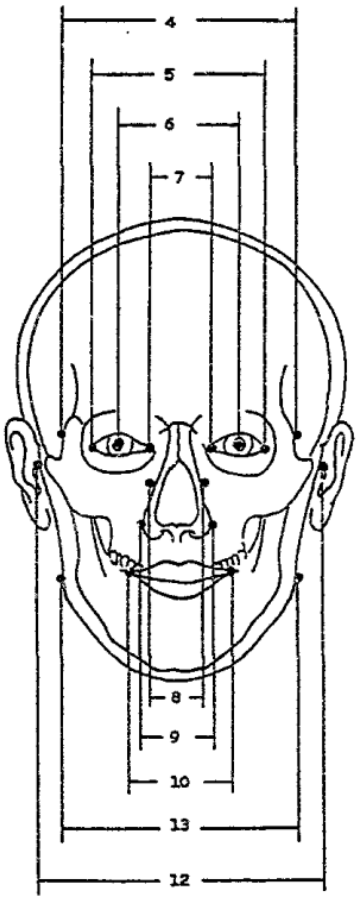

FIGURE 10. FACE BREADTH MEASUREMENTS.

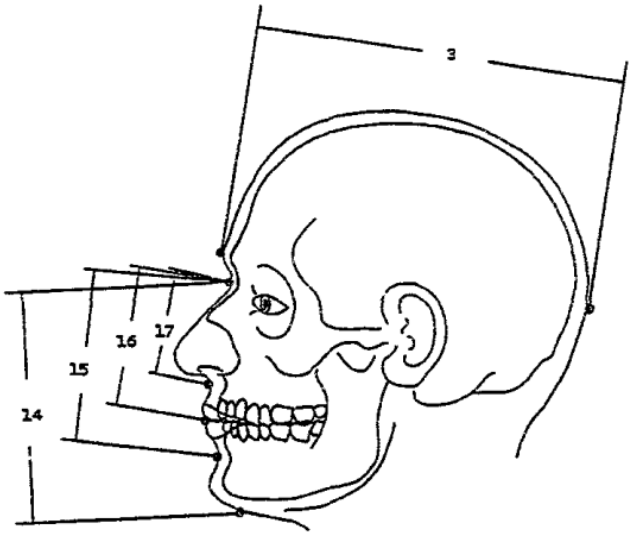

TABLE 7. BIPUPIL BREADTH

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	TBD	1	9.99	9.99	Link
GentleDrop Eye Drop Guide	Competing Design	GentleDrop, Amazon	ASIN: B0BQBHRKV1	TBD	1	17.99	17.99	Link