Product Design Specifications: Eye Dropper Assistant

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BME Design 400

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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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