Ocular Lavage System

**Problem #2**

**Team 11**

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**Problem/Solution/Rationale**

The problem we were presented with encompasses the challenges encountered by patients afflicted with dry eye syndrome (DES), a condition characterized by either insufficient production of a particular component within the tear film or an accelerated drainage of tears. This necessitates the frequent application of lubricating eye drops, typically 5 to 6 times daily, the use of prescription medications often accompanied by adverse side effects, or the implantation of devices like punctal plugs. The pivotal role of the tear film in ocular moistening and patient comfort is compromised in those afflicted by this condition and when examining the multifaceted etiology of DES, our investigation pinpointed the deficiency in the production of both the aqueous and mucin tear film components as a primary source of patient discomfort so this is what we decided to direct our efforts toward ameliorating. Our solution involves the development of a wearable system for the distribution of tear film components at the lateral canthus of the eye-somewhat similar to a subpalpebral lavage system. By doing so, we endeavor to elevate the comfort of patients by mitigating the heightened evaporation rate of the tear film associated with dry eyes, thereby aspiring to enhance the daily quality of life for those afflicted with this condition.

**Design Components and Principles of Operation**

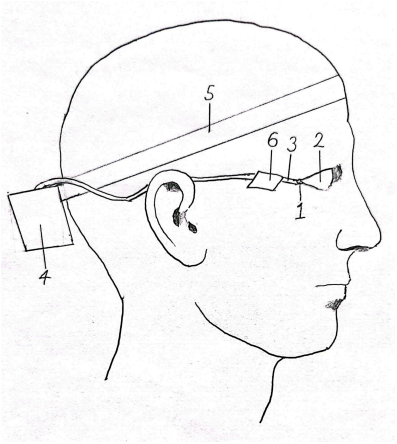
The device we have designed to address this issue comprises a user-operated lavage system. By simply depressing a button, users can regulate the dispensation of artificial tears at one of three quantities, depending on what the user needs, at a rate set to 0.15 ± 0.10 µL/min mirroring the natural tear production rate of individuals free from dry eye symptoms [1]. The delivery of these artificial tears is directed to the lateral canthus of the eye, effectively supplementing the tear formation in individuals affected by DES.

Our initial objective was to determine the optimal quantities of artificial tears that users could dispense into their eyes. Firstly, we established that the average volume of total tears in individuals unaffected by DES is approximately 6.5 µL [2]. Subsequently, we found at 2:30 pm, individuals with DES typically have an average lower tear meniscus volume of approximately 0.36 µL, while those without DES tend to have a lower tear meniscus volume of about 0.51 µL at the same time of day [3]. As there was no available data regarding the average total tear fluid volume in patients with dry eye, possibly due to the multifaceted nature of dry eye causes, we assumed a proportional relationship between the lower tear meniscus volume and total tear volume.

$$\frac{0.51\ \mu L\ (\text{Lower tear miniscus volume})}{6.5\ \mu L\ (\text{Total tear volume})} = \frac{0.36\ \mu L\ (\text{Lower tear miniscus volume})}{x\ \mu L\ (\text{Total tear volume})}$$

Based on this proportion, we calculated the average total tear volume in patients with DES to be 4.6 µL. Consequently, considering a variance of ± 0.3 µL in the tear volume of healthy individuals [2], we determined that the three quantities of artificial tears a user can administer should be 1.5 µL, 2.0 µL, and 2.5 µL. This range effectively covers the volume of tears that a patient with DES may require and aligns with potential market sensitivities for the components of the lavage system.

The lavage system is depicted below in Figure 1. Upon the user pressing one of the three buttons on the control box, the appropriate volume of artificial tears are pumped from the reservoir in the control box, which is secured to the patient's head via a headband, at a rate of




0.15 µL/min. Once the appropriate volume of artificial tears leaves the reservoir, the pump will shut off, stopping the flow of fluid. The tubing that the artificial tears pass through will be made of platinum cured silicone with an inner diameter of 0.313 in (Rubber Fab, Sparta, New Jersey, 05RFSC2) [4] and at the end of the tubing will be a 20 gauge 8.00 mm catheter positioned to deliver artificial tears at the lateral canthus of the affected eye. This specific catheter was chosen because it is similar to catheters used in other lavage systems. A view of the system being used bilaterally can be seen in Figure 2.

**Figure 1:** In the lavage system, a catheter (1) is positioned at the lateral canthus of the affected eye (2), and it is connected to tubing (3) through which artificial tears flow from the control box (4). The control box is fastened in place using a headband (5), and the tubing is affixed with adhesive (6).

The control box is made of a few key components. It can be most clearly seen in Figure 3. Within the pump are two 12-volt batteries, a 100 mL reservoir of artificial tears, a small peristaltic pump, microcontroller, and a potentiometer. The batteries power the pump, microcontroller, and potentiometer allowing for the control of flow of artificial tears throughout the device. The outside of the box has three buttons indicating each of the aforementioned volumes of artificial tears to be delivered.

**Design Requirements**

→ The device has to be wearable or implantable.
→ The device must administer artificial tears or tear components.
→ The device must be unobtrusive enough to wear during normal daily activities.
→ The device should not introduce significant risk to the health of the eye or body.
→ The device should be acceptable enough that it would show promise of a meaningful improvement in patient comfort.

**Design Justifications**

Our problem was to find a solution for patients with DES. While trying to find a solution, we came up with a few design goals. We thought it was important to have a controlled tear flow rate close to that of a healthy patient in order to avoid flushing the eye with excessive artificial tears. One of the important components of the design are the platinum cured silicone tubes which ensure that the device is sterile as possible to let the patient be worry free from getting exposed to potential bacteria build up. We made sure that the tubes were detachable from the control box to ensure ease of cleaning. Also, we made sure that our design could hold up to 100 mL of artificial tears in order to maximize the time between reservoir refillings while also keeping the whole control box under 2 kg for patient comfort. All of these goals help to ensure that the patient's experience is comfortable and safe.

**Design Goals**

→ Artificial tear flow rate of 0.15 μL/min
→ Ability to deliver all kinds of tear components
→ Under 2 kg in total weight
→ The tubes are detachable from the control box for ease of cleaning, and use in all patients regardless of whether they have DES unilaterally or bilaterally
→ The tubes are made of platinum cured silicone for maximum safety and biocompatibility
→ The design holds up to 100 mL of artificial tears
→ Can deliver artificial tears at quantities of 1.5 μL, 2.0 μL, and 2.5 μL to compensate for different severities of DES symptoms

**Safety and Efficacy**

In our development process, we have placed a strong emphasis on user safety, and ensuring that the efficacy for the device aligns with both standard requirements and project objectives. This approach addresses the challenge of creating a wearable device to help supplement lacking tear production in DES patients, all the while safeguarding the health and safety of the users. One of the ways we protect our users is through the material used in the tubing connected to the eye, platinum cured silicone from Rubber Fab. We choose this material for its compatibility with biological tissue, crucial in preventing irritation, inflammation, or adverse reactions. Another safety and efficacy measure taken can be seen in that the tubes are detachable from the control box to provide easy access to the interior, facilitating a thorough cleaning process. This ensures that the tubing can be cleaned properly throughout use. This helps maintain the sterility of the device, contributing to optimal results and user safety. Furthermore, our device enhances efficiency through various flow rates. Given that individuals with DES have an average total tear volume of 4.6 μL, compared to healthy individuals' average of 6.5 ± 0.3 μL, we offer users three artificial tear quantities: 1.5 μL, 2.0 μL, and 2.5 μL. This diverse range allows users to select a setting that best suits their individual needs, tailoring the solution for maximum effectiveness.

**Wearability and Feasibility**

Our ocular lavage system offers an innovative and feasible solution to address health concerns with dry eye syndrome, while ensuring effective tear production supplementation. The reservoir containing artificial tears, with a connection to the eye through silicone tubing, provides a convenient and non-obstructive way to deliver artificial tears to prevent dry-eye. The device is non-obstructive because the reservoir is secured at the back of the head to prevent inconvenience or discomfort that might come from placing it elsewhere.

Our device integrates bioengineering, technical, and biological innovations, yet comes with notable challenges. In terms of bioengineering, the design of the reservoir and the delivery of artificial tears are all subject to causing unforeseen issues. In terms of technical limitations, we may encounter problems with secure tubing connectivity, as well as addressing maintenance issues with the control box. In terms of biological components, sensitivity of the skin may be problematic as the adhesive securing the tubing may cause adverse dermal reactions and congruence with the tear film of the eye may be difficult to ensure, all while supplementing tear production. Despite these challenges, a successfully developed device can offer many benefits especially in terms of addressing issues with dry eye and personal comfort in DES patients.

## Bibliography

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**Figures**

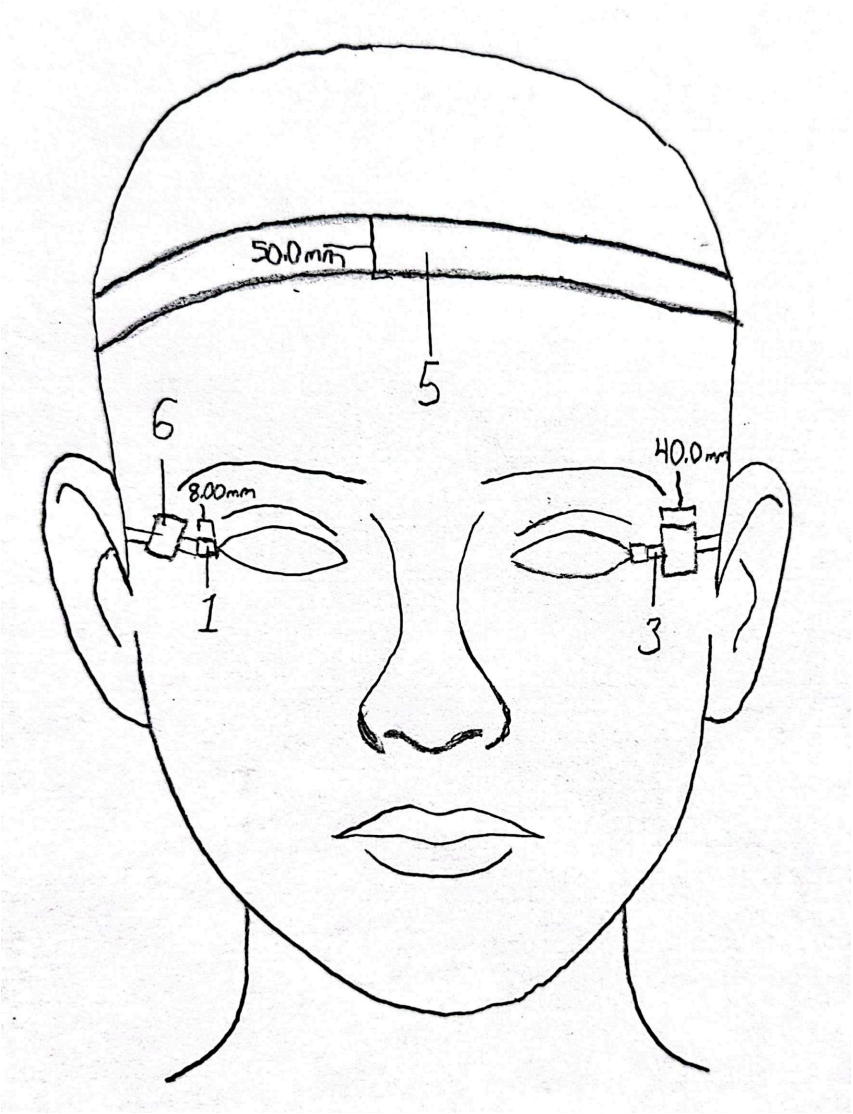


**Figure 2:** Front view of the ocular lavage system being used bilaterally. 20 gauge 8.00 mm catheters (1) are placed at the lateral canthus of either eye. The catheters are connected to tubing (3) through which artificial tears flow from the control box on the back of the patient's head. The control box is fastened in place using a 50.0 mm wide headband (5), and the silicon tubing is secured with a piece of adhesive (6).

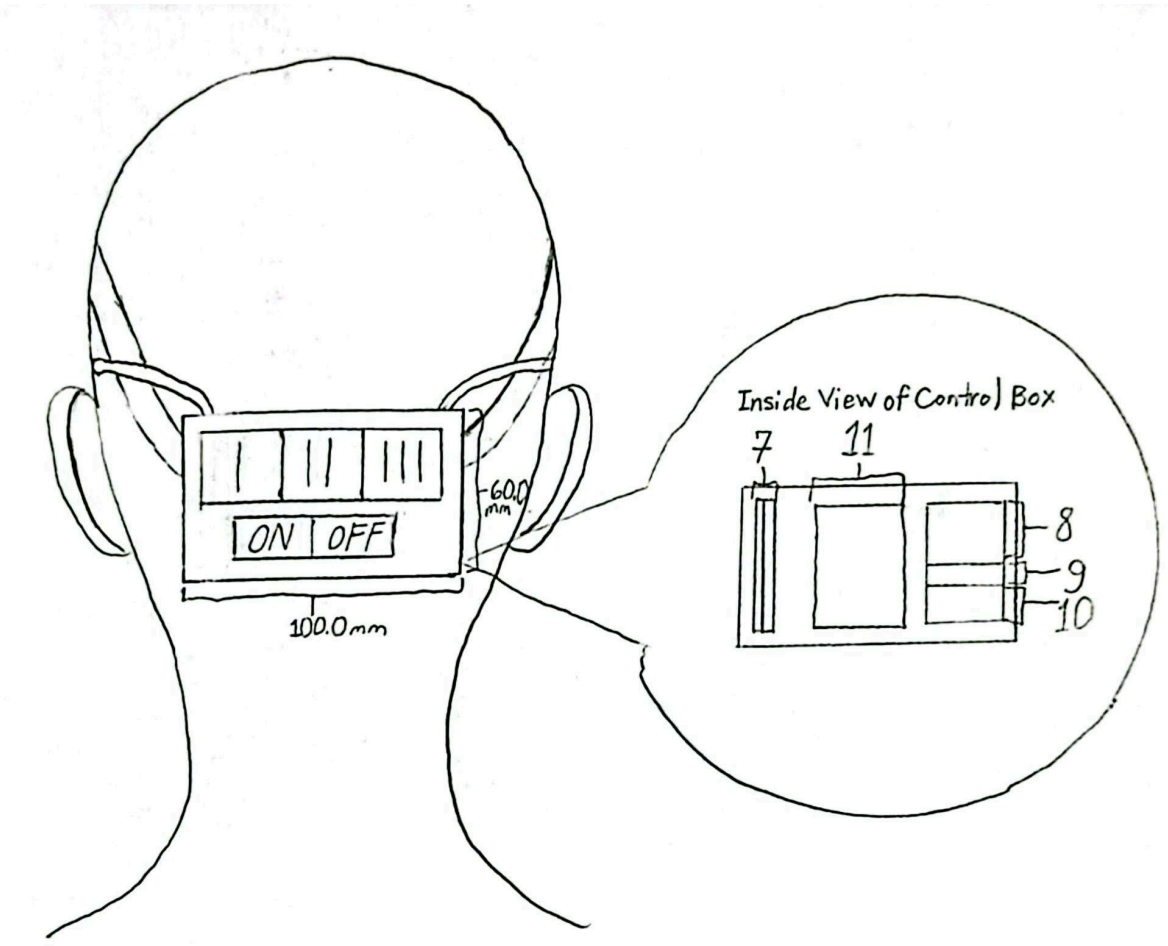


**Figure 3:** Back view of the ocular lavage system. Within the control box of the system two 12-volt batteries (7) are used to power a small peristaltic pump (8), small microcontroller (9), and potentiometer (10) which allow for the control of artificial tears from the 100 mL reservoir of artificial tears (11) throughout the device. The outside of the box has three buttons indicating each of the three possible volumes of artificial tears to be delivered to the eyes.