Group 8 Preliminary Report

De-aerating Solutions to be Used in Vitreoretinal Surgeries

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1. <u>Background</u>

1.1 Applicable Eye Structure and Key Terminology (Simplified):

- **Cornea**: translucent membrane in line with the **pupil** and **iris**. Focuses some light to the **lens**.
- **Pupil**: hole surrounded by and maintained by the **iris**.
- **Iris**: muscle that regulates the size of the **pupil**.
- **Lens**: fibrous translucent structure that focuses light to the **retina**.
- **Retina**: optic fibers in the back of the eye, absorbs light and grants vision.
- **Lens Capsule**: membrane that contains the **lens** and is connected to the muscles that deform the **lens** to focus light.
- **Anterior Segment**: The first third of the eye, or all components from the **lens** to the **cornea**. It is Filled with **aqueous humor**.
- **Aqueous Humor**: Fluid that fills the **anterior segment** of the eye. It plays a role in maintaining eye shape and pressure as well as nutrient transport.
- **Anterior Chamber**: Chamber in the **anterior segment** composed of the space between the **iris** and the **cornea**. It is filled with **aqueous humor.**
- **Posterior Chamber**: Chamber in the **anterior chamber** composed of the space between the iris and the lens capsule.
- **Posterior Segment**: The section of the eye from the rear **lens capsule** to the **retina**. It is filled with **vitreous humor**.
- **Vitreous Humor**: Viscous, gel-like substance that fills the **posterior segment**. Plays a role in maintaining eye structure, pressure, and clarity.

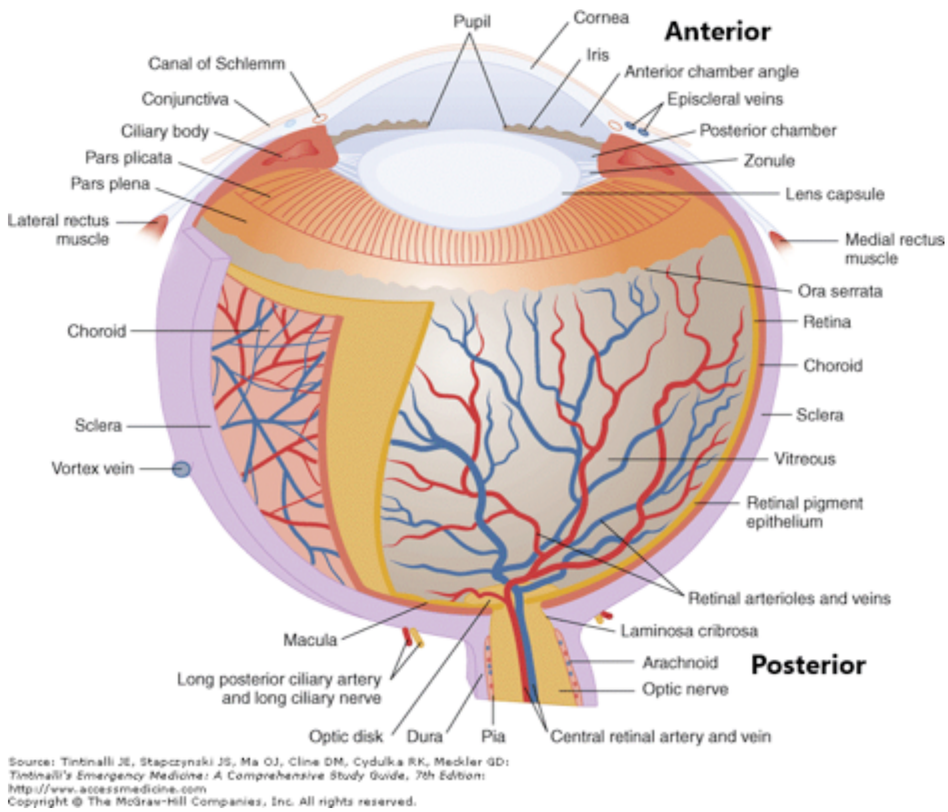

Figure 1: Diagram of the eye, showcasing its components and the Anterior and Posterior segments.

1.1 Cataracts:

Cataracts is a disease that accounts for 51% of world blindness or about 20 million people according to the World Health Organization. Cataracts occur when proteins in the lens of the eye clump together and inhibit vision. Risk factors include: genetics, smoking, UV exposure, and aging. Cataracts treatment and surgeries costs the US $6.8 billion annually in direct medical costs.

1.2 Phacoemulsification Surgery:

Phacoemulsification (phaco) surgery is a technique in which a small need vibrates ultrasonically to ablate and remove a dense cataract and then insert an Intra Ocular Lens (IOL).

1.2.1 Components:

Phaco surgery cannot be done without machines capable of the technique. The modern standard or required components are listed below.

1. Infusion line: A tube or system that takes solution and infuses it into the eye.
2. Aspiration line: A tube or system that takes fluid and materials out of the eye.
3. Handpiece: A small, needle tipped device, commonly equipped with the infusion and aspiration systems; the aspiration line connects to the needle and the infusion line connects to a plastic sleeve surrounding the needle. The needle vibrates ultrasonically.
4. Foot Pedal: A foot-controlled button, lever, or combination of buttons the surgeon uses to activate the hand piece's vibration, or change the settings of the infusion, aspiration, vibration power, etc.
5. Control System: a machine with a screen to control the settings and levels of inspiration, aspiration, handpiece power/vibration frequency and power, etc.

1.2.2 Mechanism/Effectiveness:

The ultrasonic motion of the needle breaks the dense cataract. There are many theories to explain the effectiveness of the motion, but none are conclusively proved/accepted; furthermore, different companies' systems set the motion/vibration of the needle along different axes, directions, and rotations. The two most commonly accepted theories explaining the most effective aspect of the vibration are: the speed and motion of the needle creates miniscule cavitation bubbles that collapse and create destructive shockwaves; and, the jackhammer effect or the physical motion of the needle that hammers and weakens the cataract.

1.2.3 Standard Technique:

The technique consists of the following steps:

1. Making a small incision in the cornea.
2. Inserting forceps/other specialized instrument to carefully tear open the capsule (membrane that surrounds the lens).
3. Inserting the Phaco hand piece needle tip into the eye, inside the capsule.
4. Activating the Phaco hand piece to destroy and remove (aspirate) the cataract.
5. Inserting the IOL.

1.3 Bausch & Lomb Vitreoretinal Surgical Systems:

The newest Bausch and Lomb vitreoretinal surgical systems are the Stellaris PC and Stellaris Elite. Both of these systems are capable of both anterior (cataract) and posterior (retinal) chamber surgeries. Both systems utilize uniaxial movement for vibration for phaco surgery and straight needles. The phaco needle slides along a single axis in line with the hand piece, moving directly forwards and backwards. Other companies include some amount of rotation/torsion and/or slightly bent needles.

1.3.1 Stellaris PC:

The precursor to the Stellaris Elite, it uses a variable height solution infusion system to control infusion flow. All fluid runs through a set of tubes and a disposable cassette that is filled with the aspirated material and fluid.

1.3.2 Stellaris Elite:

The successor to the Stellaris PC, this system uses the same chassis as the Stellaris PC with a few key differences and upgrades. The most applicable difference to this assignment is that the Elite is capable of the variable height fluid infusion system, but also of Adaptive Fluidics. In this system, the bottle of the solution to be infused is pressurized/de-pressurized in order to control the infusion flow faster and more accurately.

1.4 Bubbling During Phaco Surgeries

1.4.1 Formation of Bubbles

The movement of the phaco needle creates cavitation bubbles that should implode to create shockwaves. However, in solutions with high amounts of dissolved gases these vacuum bubbles instead degas the solution and create gas bubbles.

1.4.2 Significance of Bubbles

Bubbles created during phaco surgery can cause a myriad of problems. They obscure the surgeon's vision, must be cleared out leading to longer and riskier surgeries, and can damage the cornea.

2. Need Statement with Project Scope

2.1 Need Statement

Based on conversations with our client the identified ***need*** is to:

"Build a device by determining the most efficient and effective method of de-aerating the Balanced Salt Solution (BSS) for use in phacoemulsification cataract removal surgeries by eye surgeons in order to prevent gas bubbles from forming in the lens of the patient's eye during the surgery."

2.2 Project Scope:

In phacoemulsification surgeries, BSS is used to maintain the shape of the cavity in the eye where the removed cataract used to be so that an artificial lens can be inserted. During the surgery procedure, dissolved oxygen can create bubbles in the eye, causing complications such as extended durations and obstructed surgeon vision. Thus, there is a need to prevent this problematic bubbling by eliminating the dissolved oxygen from the BSS. Our device is expected to be attached between the bottle the fluid is stored in and the tool used to inject the fluid into the eye. This device is expected to be implemented in Bausch + Lomb phacoemulsification surgery machines, both already on the market and yet to be developed.

This device prototype is scheduled to be delivered to the client by April 26, 2019.

3. Specific Design Specification

General specifications:

1. For use during surgery.
2. Single use.
3. Made of material that can withstand gamma radiation which is used for post-packaging sterilization of surgical equipment.

Figure 2: Specific Design Metrics

Description	Metric	Value
Sterilize-able	Device dimensions - limited by the equipment packs in which they are stored and shipped	12” x 6” x 6”
Inexpensive	Cost of final product	$1 per unit
In- Line	Inner diameter of the openings on the device for the fluid tubes	1.25 mm
Patient Safe	Temperature of fluid flowing out of device	37℃ (body temperature)
Consistency During Surgery	Minimum flow rate	20 ml/min
Efficiency	Dissolved O_2 concentration in fluid flowing out of device	< 55%

4. Existing Solutions for Degassing Liquids

There are 7 common ways to degas a liquid: pressure reduction, thermal regulation, membrane degasification, substitution by inert gas, addition of reactant, freeze-pump-thaw cycling, and ultrasonic degasification. The methods of pressure reduction, membrane degasification, and ultrasonic degasification are of most importance as the remaining methods are incompatible with the required specifications. The lightly researched methods either would contaminate the sterile solution, heat the solution to temperatures unsafe for human infusion, take too much time to maintain the required flow, or require too large of a mechanism.

4.1 Pressure Reduction Degasification

This method involves some surface area of a fluid in contact with a vacuum of some kind. The lower partial pressure of gases in the vacuum induces gas to flow from the fluid to the vacuum. This method is used in tandem with others to greatly increase the efficiency of degassing. Devices using this method that are of note are listed as follows. Most of these devices are very similar and are used to prevent boilers from corroding.

4.1.1 Patent US1401101A: System for Removing Air and Gases form Water

This patent is for an improvement on a device for removing air from water. The previous device just employed a heater and condenser to heat the liquid and then cool it back down separate from the gas. This new design adds an evaporator that lowers the pressure of the liquid in order to separate off some of the gas particles before they enter the heater. This allows the whole process to be more efficient.

4.1.2 Patent JPH06170357A: Method for Stabilizing Dissolved Oxygen Concentration in Deaerator

This technology is used in boilers to prevent dissolved oxygen from accumulating and corroding the metal structure of the boiler. The technology uses the relationship between the water temperature and the dissolved oxygen content to control the dissolved oxygen content of the water and keep it below the threshold that causes corrosion. This method for controlling dissolved oxygen levels in water could be adapted for use in phaco surgery machines to prevent gas bubbling in the eye.

4.1.3 Patent CN203428947U: Deaerator for Removing Oxygen in Water by Utilizing Steam Waste Heat

This device combines pressure reduction with temperature modification. It utilizes steam from the water heated by the pressure changing process to recycle some of the energy wasted in the deaeration process back into the system in order to promote sustainability. This could be very important because in the phaco surgery machines the deaerator device will be implemented in may be used by hospitals in places where using excess power is not an option due to poor infrastructure. However, as stated at the beginning of section 4, any process where the fluid would be heated would not work for phacoemulsification, as it must be body temperature upon leaving the device.

4.2 Membrane Degasification

This method involves some surface area of a fluid, flowing or stagnant, in contact with a gas-permeable and liquid-impermeable membrane in contact with a vacuum. This method is presently used to degas solutions in large volumes for sterile use. Devices of particular importance are listed below. The majority of devices falling under this category are used to deaerate some type of fuel so that it is more efficiently combusted.

4.2.1 Patent US6709492B1: Planar Membrane De-oxygenator

This device is designed to remove oxygen from jet fuel to prevent insoluble byproducts of fuel combustion from forming in the engine and decreasing the efficiency of the process. While the deaerator for phaco systems will be deaerating BSS instead of fuel, the same principle of oxygen removal holds useful.

4.2.2 Patent US5584914A: Membrane Deaerator Apparatus

This device is a combination of several vacuums and membranes to efficiently pull oxygen out of a water supply. This is perfectly relevant to the phaco deaerator design, as that design requires a way to deaerate a water supply, however the size and complexity of this system would most likely prove too cumbersome for an inline deaerator.

4.2.3 Patent US7329305B2: Membrane Based De-oxygenator for Process Streams

This is a patent for a membrane de-oxygenator for process streams that does not quantifiably restrict the process but does reduce the amount of oxygen in the stream and therefore increases the efficiency. Efficiency is a key part of the deaerator and therefore this design could prove helpful.

4.3 Ultrasonic Degasification

This method involves an object in contact with a fluid vibrating ultrasonically to induce bubbles that are removed via vacuum. This process is the same one that creates the bubbles during phaco surgery. Essentially, this method would be repeating the process that causes the bubbles in the first place in order to allow them to form outside of the eye and be removed before the fluid enters the eye at all. Devices that use this method that are of particular note are listed as follows.

4.3.1 Patent CN 200620062505: Ultrasonic Degasser

This device consists of a fluid container with an ultrasonic plate affixed to the inside base of the container. The plate vibrates, degassing oil and allowing the bubbles to float up and exit the fluid container. This device could be simply miniaturized and a vacuum applied to the fluid surface to increase efficiency.

4.3.2 Patent US4428757A: Sonic Energy Fluid Degassing Unit

This device is a gas stabilization unit capable of removing unwanted gas and infusing desired gas. The degassing section of this device is a shallow tray with perpendicular ridges/walls that vibrate ultrasonically as fluid flows over them. This section is of importance as it can be miniaturized and can maintain a steady flow rate.

4.3.3 Patent JPH09187603A: Deaerator and Deaerator for Ultrasonic Washer

This device utilizes two deaerators in series, each consisting of a foam stick secured to the bottom of a fluid container. The stick vibrates ultrasonically causing the fluid to degas and bubble to the surface of the fluid container whereby it is removed via vacuum. This system can be miniaturized and implemented with a sterile protocol easily.

5. Design Schedule (Preliminary)

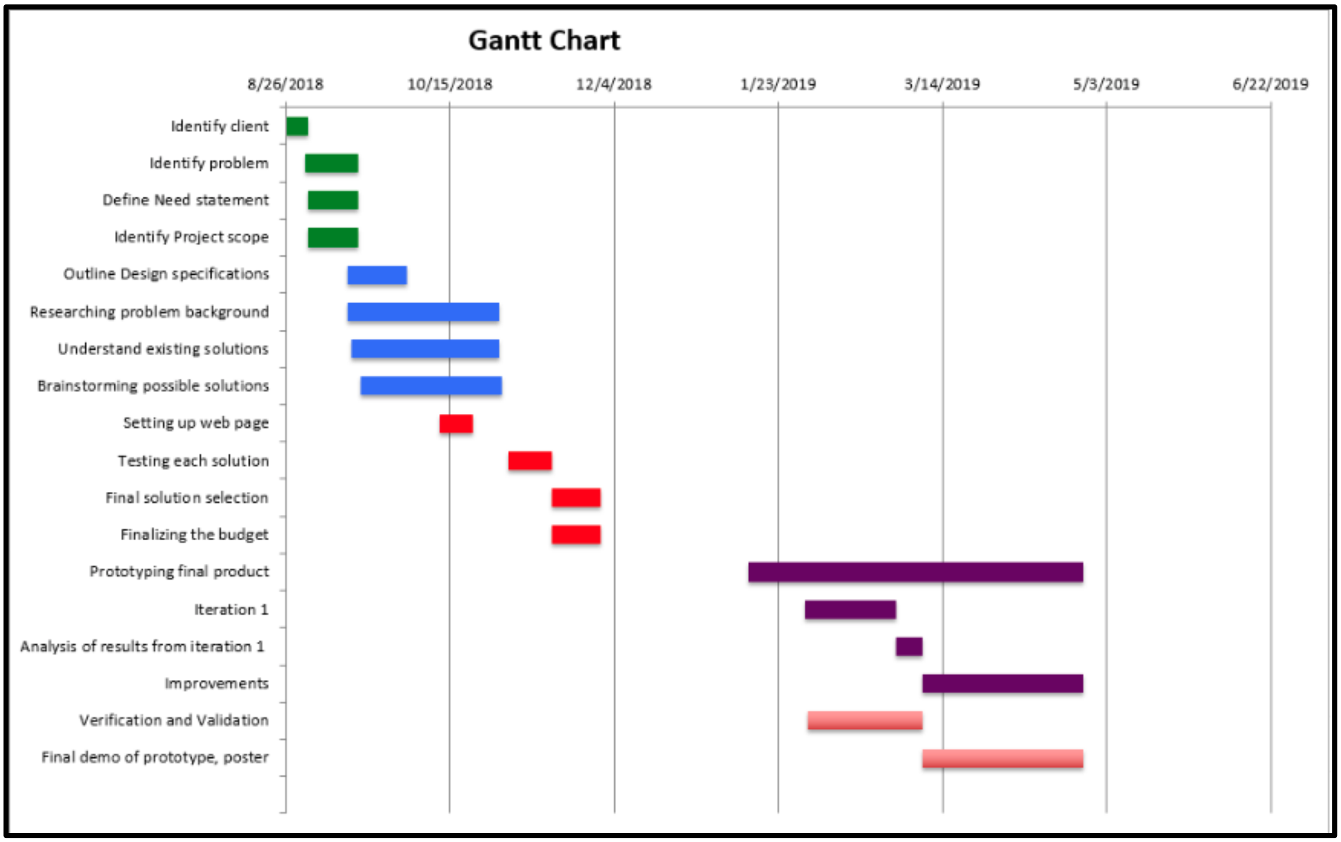

Figure 3: Gantt chart with the planned design schedule

6. Team Responsibilities

Figure 4: Table of team responsibilities.

Name	Brandon Lum	Anupama Melam	Michael Morgan
Responsibilities	- Communicating with the client, Brian McCary - Lab experimentation - Obtaining materials - Researching vacuums - Prototype testing	- Maintaining project website - Researching sterilize-able materials - Updating Gantt Chart - Keeping notes for composing weekly reports	- Researching existing solutions - Communicating with Professor Klaesner - Updating class schedule - Researching material pricing

Bibliography

Ehrhart, Raymond N. (1920). *U.S. Patent No. US1401101A*. Washington, DC: U.S. Patent and Trademark Office.

Hall, Mark N. (1981). *U.S. Patent No. US4428757A*. Washington, DC: U.S. Patent and Trademark Office.

Keiwei, Liu. (2013). *China Patent No. CN 201320573443*. Beijing, China. National Intellectual Property Administration (NIPA), PRC.

Kim, Eung K. "Corneal Endothelial Damage by Air Bubbles During Phacoemulsification." *JAMA*, American Medical Association, 1 Jan. 1997, jamanetwork.com/journals/jamaophthalmology/fullarticle/641952.

Komai, Mitsumasa, Toshio Sawa, Kenchiki Izumi. (1974). *U.S. Patent No. US05518616*. Washington, DC: U.S. Patent and Trademark Office.

"Membrane Deaeration System." *Sintrol.fi*, 2006, www.sintrol.fi/images/Esitteet/358.pdf.

Miyagawa, Yasuhiro, Kenchiro Takematsu, Kazuhiro Tateno. (1992). *Japan Patent No. JP34976592A*. Tokyo, Japan. Japan Patent Office.

Schaub, Robert F. (1954). *U.S. Patent No. US2783853A*. Washington, DC: U.S. Patent and Trademark Office.

Sebald, Joseph F. (1945). *U.S. Patent No. US2572527A*. Washington, DC: U.S. Patent and Trademark Office.

Senoo et al. (1992). *U.S. Patent No. US5584914A*. Washington, DC: U.S. Patent and Trademark Office.

Shibano, Yoshihide, Chaiye Jiaying. (1996). *Japan Patent Patent JPH09187603A*. Tokyo, Japan. Japan Patent Office.

Spadaccini, Louis J., Steven Lozyniak, He Huang. (2003). *U.S. Patent No. US10407004*. Washington, DC: U.S. Patent and Trademark Office.

Tatsuo, Okabe. (1989). *U.S. Patent No. US07562760*. Washington, DC: U.S. Patent and Trademark Office.

Sloan, Michael A. (2005). *U.S. Patent No. US7329305B2*. Washington, DC: U.S. Patent and Trademark Office.

Yehao, Cai. (2006). *China Patent No. Patent CN 200620062505*. Beijing, China. NIPA, PRC.