Device for Extraction of Non-metallic Intraocular Foreign Bodies

BME 301

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CLIENT:
Dr. Leslie Wei, MD

ADVISOR:
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Abstract

Intraocular foreign bodies (IOFBs) account for almost 40% of open-globe ocular trauma cases. When they penetrate the eye, they are subject to immediate surgical removal. However, removal is more difficult when the IOFBs are round, smooth, and non-metallic, such as air soft pellets. Currently, there is no surgical instrument designed specifically to remove these kinds of IOFBs. We hope to design an intraocular instrument that would successfully remove air-soft pellets of up to 8 mm in diameter, with a locking grasp mechanism around them. We developed three possible designs that were evaluated based on reliability, size, ergonomics, safety, feasibility and cost effectiveness. By comparing the designs over these criteria, a fish-net inspired design was determined to be the most ideal and effective. This design was chosen to be continued further into fabrication and testing.

Table of Contents

Problem Statement/ Motivation

Traumatic intraocular foreign bodies (IOFBs) are becoming increasingly common and can be visually devastating. Among various types of IOFBs, smooth, round, and non-metallic foreign bodies, such as air soft pellets are uniquely difficult to remove surgically. These pellets are approximately typically 6 mm in diameter, enter the eye with at high velocity, and cause significant damage, such as including globe rupture, retinal detachments, and cataracts. Such injuries are more prevalent in children and young adults. Currently, there is no intraocular device specifically designed to remove such type of IOFBs. A need exists for an intraocular instrument that will easily grasp and remove such an object within the eye.

The instrument ideally would be low profile enough to enter the eye and manipulate the object without damaging surrounding structures. It should also be able to easily grasp round, smooth objects that conventional forceps are unable to grasp. Moreover, it needs to enter and exit the sclera, eye wall, without enlarging the entrance wound. The primary goal of our project is to design an ergonomic intraocular device to effectively remove air soft pellet types of intraocular foreign bodies without failure, while minimizing the invasiveness of the device to the eye.

Background

Client Information

Our Client is Dr. Leslie Wei, MD. She is an ophthalmologist with subspecialty in ophthalmology facial plastic surgery. She earned her Medical degree at Brown University Medical School and did an internship at Presbyterian St. Luke's Hospital and residency at University of Colorado Anschutz Medical Campus. Currently she is working at University of Wisconsin-Madison Hospital.

Intraocular Foreign Bodies

Intraocular foreign body, IOFB, refer to any object or material that penetrates into ocular tissue [1]. IOFBs can consist of various types of materials that can be divided into metallic or non-metallic. Metallic IOFB account of 90% of IOFBs and are again subdivided into magnetic or nonmagnetic, since the management method is different for each. Common causes of metallic IOFBs are hammering and using machine tools. Non-metallic, usually plastic, are generally air soft pellets caused from air soft BB guns.

IOFBs can enter through any part of the outer eye, the reason why they are called open-globe injuries. Usually IOFBs enter through the cornea, sclera, or limbus, the outermost parts of the eye. After they enter, their final location can be anywhere in the inner eye, but the most common area is the vitreous cavity, the posterior segment (figure1). When IOFBs enter the eye, they can cause damage to the eye tissue, including the lens and retina [2]. The retina is where the optic nerves are, and therefore considered sensitive [3]. It is important that the intraocular instrument does not interfere with the retina.

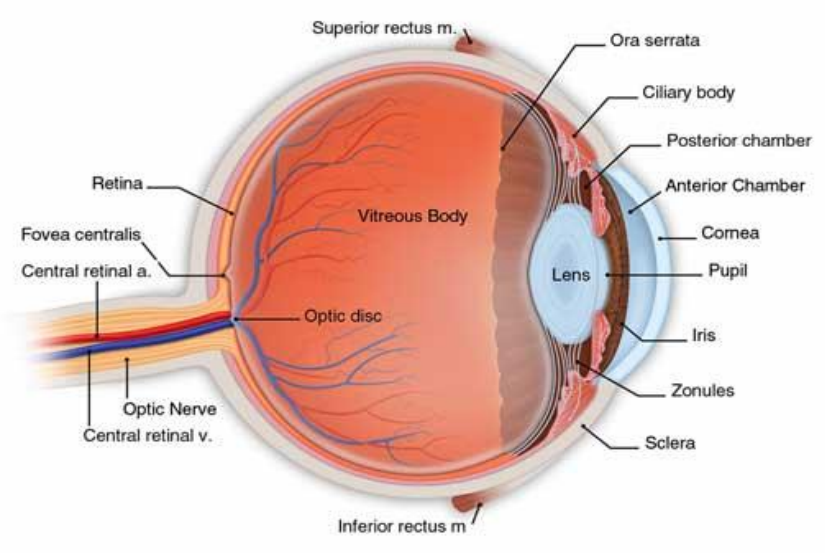

Figure 1. Anatomy of a Human Eye [4]

IOFB injuries normally do not lead to poor prognosis and often result in fairly minor outcomes. However BB gun injuries, large IOFBs, and dense vitreous hemorrhages are thought to carry worse prognosis. Removing the IOFBs as soon as possible is critical because permanent IOFBs in the eye can lead to complications such as endophthalmitis, infections, and metallosis. Normally, removing the IOFBs through their entry site is not recommended since it can lead to further damage. It is recommended that IOFBs be removed through the plane of the smallest cross section [2].

The design in this project targets a specific type of IOFB, that are round, plastic, and are found in the vitreous body.

Current Devices

There are currently no instruments specifically designed for the removal of smooth, spherical, and non-metallic IOFBs. Metallic IOFBs can typically be removed by using a magnet, but this is not an option with non-metallic IOFBs. Several surgical device companies make ophthalmological forceps with various kinds of tips that can be used to remove non-metallic IOFBs. One such company is Alcon Surgical who makes forceps specific for grasping fibrous membranes and manipulating retinal membranes, but not forceps for spherical IOFB. Figure 2 shows the ophthalmological forceps sold by Alcon Surgical with four tip variations.

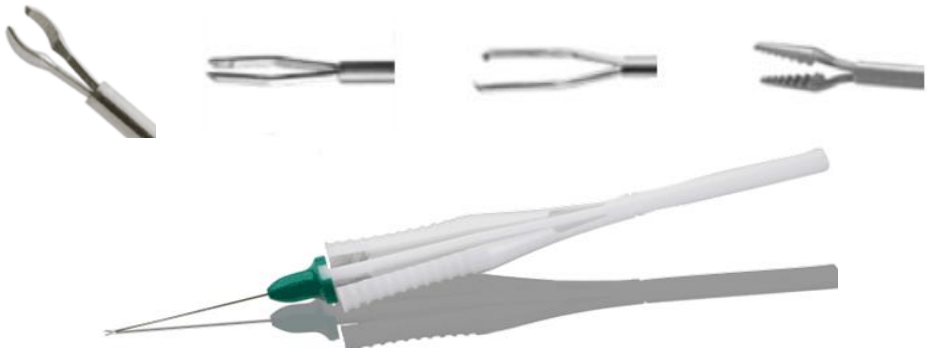

Figure 2. Alcon Surgical Ophthalmological Forceps: An image of ophthalmological forceps with various tips. From left to right, a multi-purpose tip for grasping IOFB, a multi-purpose tip for grasping fibrous membranes, a tip for retinal membrane manipulation, and a serrated tip for grasping fine membranes [5].

Methods

The instrument designed for IOFB extraction shall be used by a surgeon during a pars plana vitrectomy procedure. The pars plana vitrectomy procedure requires the insertion of three surgical instruments, via trocars, in the pars plana site on the sclera of the patient's eye. The orientation of these instruments, a light pipe, a vitrector, and an infusion line, can be seen in figure 3. The light pipe is used to illuminate the vitreous body while the vitrector is used to cut and suction out the gel-like vitreous solution, which sometimes attaches itself to IOFB [6]. The infusion line carries water and saline solution into the vitreous body to keep it pressurized throughout the procedure. Once all the vitreous solution has been removed, the surgeon will attempt to extract the IOFB by moving it to the sclera. The instrument designed by the team shall aid in this process and operate fluidly with the environment of this procedure. The vitrector instrument shown in figure 4, an instrument ophthalmology surgeons are already comfortable using, shall be the inspiration for the design of the extraction instrument's handle. The handle is fairly thick, around 3 cm in diameter, and grooved to provide a more comfortable grasp and added control.

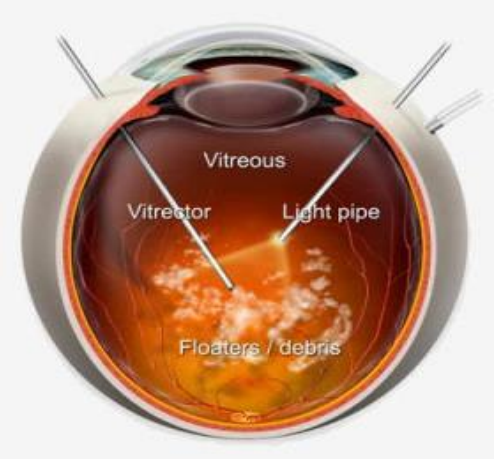

Figure 3. Diagram of Pars Plana Vitrectomy: An animated cross-section of the eye including the components used during a vitrectomy procedure [7].

Figure 4. Vitrector: An image of a 25 gauge (0.515 mm outer diameter needle) vitrector. The grooved and thick (3 cm) handle can be seen. Image courtesy of Dr. Leslie A. Wei.

Client Requirements

The client requires an instrument, which will safely and reliably extract a non-metallic, spherical, and smooth IOFB, typically a plastic air soft pellet. The instrument must not unnecessarily enlarge the entrance wound it creates. It must also not have any sharp edges or difficult to control pieces that could cause damage to the fragile inner eye. The client requires the device to be easily handled to make precise movements with a comfortable, one-handed, no-slip grip. The instrument must be autoclavable or disposable to ensure it is sterile before each use. In addition, the instrument shall require little or no assembly by the surgical team. To ensure reliability of IOFB extraction, the instrument shall have a locking grasp mechanism, which will immobilize the IOFB within the instrument.

Design Alternatives

Ice Cream Scoop

The ice cream scoop inspired design, figure 5, incorporates two coinciding 8 mm diameter half-spheres connected to a handle. The handle would measure 32 mm in length and use a spring and gear mechanism in order to rotate the innermost half-sphere about the center. This rotation will create a full hollow sphere around the top of the device. The surgeon will enter the eye initially with the half-spheres coinciding, encircle the round foreign body and compress the spring within the handle. This rotates the gear, thus rotating the half sphere and encapsulating the foreign body. Once the object has been captured by the surgeon, the sphere will lock into place allowing the foreign body to be removed without any further movement of the IOFB. This design would be made of stainless steel and would be autoclaved for sterilization between patients.

A benefit to this design is the locking mechanism. The spherical grasp of the device will fit perfectly around the IOFB and the locking ability of the spheres once the object is captured will alleviate any further effort of behalf of the surgeon. Once the object is within the hold of the scoop, the surgeon will simply need to maneuver the object out of the inner eye. This design will eliminate the slipping of IOFBs commonly encountered during removal.

Although this design would be reliable in the removal of IOFBs, a concern for the device is size. The device will enter the wounded eye with a width of 8 mm by 4 mm at the widest point. Ideally the entrance wound should not exceed its original size. This design would expand the wound diameter by approximately 1 mm depending on the size of the pellet that caused the injury. After the surgeon inserts the device into the inner eye, the bulkiness of the scoop has potential to disrupt other areas of the eye as well.

Figure 5. Image of an Ice Cream Scoop. Our design Ice Cream Scoop will replace the inner piece of the scoop with another half sphere, just large enough to fit the outer one [8].

Fish Net

The second design alternative looks very similar to a net used for fishing (Figure 6). This design consists of a wire-outlined mesh net and a middle tubular rod connected to a spring-loaded handle. The net is initially set within the tube and functions so that when the spring in the handle is compressed, it is released from the tube. The surgeon will capture the foreign body within the released net and once the pellet is within grasp, the spring will be relaxed retracting the net, back inside the tube. This will cause the mesh of the net to tighten around the foreign body essentially locking it into place (Figure 7). From there the surgeon can successfully remove the body without the possibility of losing grasp. This design would be made out of a non-toxic plastic or other polymer and disposable between patients.

Figure 6. Image of a Roth Net Retriever. Instrument that inspired the mechanism of the Fish Net design [9]

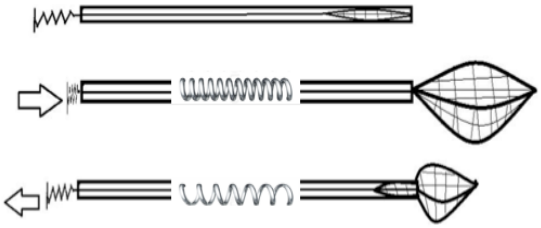

Figure 7. Drawing of the mechanism of the Fish Net design. Contraction and relaxation of the spring pushes and pulls the net embedded inside the rod

The size of this design allows it to stand out from others. The narrow tube center would not be more than 4 mm in diameter and would be the only part that initially enters the wound. The surgeon will release the net only after the rod has entered the eye and the IOFB is within reach. Because the mesh net will tighten around the body and the remainder of the net will retract into the center, removing the body should not widen the wound any further than the pellet has already done. The flexible shape also increases its versatility, giving this design the possibility to work with many different shapes and sizes of IOFBs.

Due to the mesh-net design, a thin biocompatible polymer would be ideal. This causes concern with the cost of manufacturing disposable devices that will only be used once. Finding appropriate polymers as well as manufacturing them to be sterile after opening may require outside production sources.

Claw

The claw design incorporates a similar mechanism as the net. This design has a four pronged claw at the tip and a tube center connected to a spring loaded handle (figure 8). The claw is initially packed within the center of the tube and released by the spring in the handle once the surgeon has cleared the sclera and entered the vitreous body. The surgeon can then maneuver the claw so the IOFB is within its grasp. Relaxing the spring will retract the claw back into the tube, tightening the prongs around the object. This should lock the IOFB within the claw of the device and the surgeon can then easily remove it. This design would be stainless steel and autoclavable, therefore reusable between patients.

Figure 8. Image of a Claw Pick-Up Tool. Instrument that inspired the mechanism of the Claw design [10]

The claw design would be simple to manufacture. Since the device would be made entirely out of stainless steel, materials would be easily obtained and the device, although small, could be manufactured using resources available in the COE Student Shop.

The first concern associated with the claw design is safety. The four prongs have the capability of being sharp and posing a threat to the eye. Another disadvantage is the size of this design. The tube in the middle would require a larger diameter than that of the net since

the four prongs will take up more space within. Once the prongs are released, the claw must open wide enough to grasp around the IOFB. This could be a concern of taking up much space within the vitreous body and disturbing other areas of the eye.

Design Matrix

The design matrix can be found in Table 1. The five factors that were considered with each design were: reliability, size, safety, ergonomics, feasibility of fabrication, and cost effectiveness. Each design was evaluated on a scale of one to five for each of the parameters. Score one through five corresponds to a poor, fair, good, excellent, and outstanding design, respectively. The criteria are discussed in the following sections.

Design: / **Criteria (weight)**	**Ice Cream Scoop**		**Fish-net**		**Claw**	
Reliability (30)	5	30	4	24	3	18
Size (25)	4	20	5	25	3	15
Ergonomics (15)	5	15	4	12	3	9
Safety (15)	3	9	5	15	3	9
Feasibility (10)	3	6	5	10	4	8
Cost Effective (5)	4	4	3	3	5	5
Total (100)	84		**89**		64	

Table 1. Intraocular Device Design Matrix

Design Matrix Criteria

Reliability

We defined reliability as the number of times the design should be able to successfully grasp and lock in place the foreign object. The number of times the device needs to be in service was estimated to be numerous during its shelf life. The reliability category was granted a highest weight due to its importance, as it is the purpose of our design. An outstanding design would open and close effectively 100% of the time. An excellent design would operate flawlessly 95-99% of the time. Good, fair and poor designs would be reliable 75-95%, 50-75%, and less than 50% of the time, respectively.

In terms of reliability, the ice-cream scoop scored the highest as its mechanism secures the ability to capture and lock the intraocular object and is the least prone to error in

comparison to other designs. The fish net was ranked good also based on the assumption that it would be reliable 95-99% of the time in addition to the ease in use. The retractable claw was ranked fair due to the uncertainty in performance of controlling multiple components (four prongs).

Size

Size was weighted with the second utmost importance, as it is another purpose of our design: minimize the entrance wound. The operating environment inside human eye is sensitive and considering that we will be introducing foreign materials, the less invasive device would be highly preferred. Among three possible designs, the fish net exhibits the smallest size, as it is also retractable inside a tube, which highly minimizes the diameter for entrance wound. As a result, the fish net received the highest score of five for an outstanding design that is least invasive while still ensuring the purpose of capturing the foreign object. The ice-cream scoop and claw had a score of four and three, respectively, due to their larger dimensions.

Ergonomics

Ergonomics is an important factor in our design as it is defined as the interaction between surgeons, specifically ophthalmologists and the handling of the device in order to optimize the patient's well being and overall system performance.

Although the three design alternatives are different in the grab-catch mechanism, they all exhibit a one-hand operation feature. The fish net received the highest score for an outstanding design due to its more simple user interface. Both the ice-cream scoop and claw were given a score of three for a good ranking.

Safety

Safety and ergonomics parameters were non-differentiable in relative importance thus were then each given a weight of 15.

As our device will be in direct contact with human eyes, we must make sure that the device is fully compatible with the biological system. The device will not release any toxic chemicals that will cause harm, or additional risk to the local and systemic levels.

As the retractable claw requires multiple components, there is an increased risk that one of the components will not work in accordance with other parts at the same rate; thus, may not be 100% safe to use for the long run. Therefore, it received a rating of good. Meanwhile, the ice-cream scoop shows the highest ability to capture and secure in place the intraocular foreign object. It received the highest score for an outstanding mechanism in terms of safety. The fishnet received a rating of excellent design as it has a less invasive dimension and can be constructed of FDA-approved biocompatible polymers

Feasibility

Feasibility was based on the team's ability to fabricate a prototype. To achieve an outstanding rating, the prototype must be able to be completed during this semester, within our given budget and with no outside help. For an excellent rating, the device prototype would be within 100% of the budget and outside help for fabrication under micro-scale could constitute no more than 10% of total fabrication hours.

A good rating and a fair rating were as described for excellent, with a 25% tolerance and greater than 25% tolerance, respectively. A poor rating was given a score of zero and was assigned to any designs that could not be fabricated.

The fish net received the highest rating of excellent. We determined the prototype materials to be readily available and relatively expensive compared to both the ice-cream scoop and the claw. However, the overall cost for full production will fall below the $250 budget. We predict that we may need a small amount of assistance during the fabrication process. The ice-cream scoop received the lowest score due to its novel configuration.

Cost Effective

This parameter evaluates our designs based on their cost of full production for each unit. It was given a weight of 5 out of 100. Specifically this parameter compares each design's cost per unit to our allocated budget of $250.

The retractable claw received the highest scores in this category while the ice-cream scoop received a good rating of 4. These designs were rated high due to the belief that they would both be composed of inexpensive materials, which would allow both designs to be produced under the $250 allocated budget. The fish net had the lowest score due to the higher cost associated with biocompatible polymers for the net's material.

Final Design

Although every design deserves merit, the fish net scores the highest on the design matrix, as it is a rather compact design without major benefits, and can be utilized for intraocular objects with different shapes. We have selected this option as our final design. We are comfortable with the score of 89 out of 100 because it nearly meets our definition of an excellent design. However, it is important to note that this design is preliminary and subject to change if, through fabrication and testing, it is determined to be inadequate for our requirements.

Future Work

Testing

First more research will be done on choosing the appropriate material for the fish net design, considering that it must be disposable, surgically sterile and still be cost effective. Then the fabrication of a prototype will be done. After a prototype is ready, appropriate testing will be done with a cow or pig's eye as a model for a human's eye. This testing will be done to evaluate the prototype's ease of use, controllability, its ability to successfully remove air soft pellets with a firm grasp, and its magnitude in enlarging the entrance wound.

Timeline

The following table shows a timeline with goals outlined for this semester. The filled boxes are the projected timeline and the check marks indicate the actual progress. So far the design progress has been on track.

Task	Jan	Feb				March					April				May
	26	2	9	16	23	2	9	16	23	30	6	13	20	27	4
Meetings															
Advisor	X	X	X	X											
Client	X	X	X												
Team	X	X	X	X											
Product Development															
Research	X	X	X	X											
Brainstorming		X	X	X											
Design Matrix			X	X											
Design Prototype			X	X											
Order Materials															
Fabricate Prototype															
Testing															
Deliverables															
Progress reports	X	X	X	X											
PDS		X	X	X											
MidSemester PPT			X	X											
MidSemester Report															
Final Report															
Final Poster															
Website Updates	X	X	X	X											

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Appendix

Extraction Device for Non-metallic Intraocular Foreign Bodies:
Product Design Specification (PDS)

Client: Dr. Leslie A. Wei

Advisor: John Webster

Team: Amy Kim
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DATE UPDATED: 2/16/2014

Function:

Traumatic intraocular foreign bodies are becoming increasingly common and can be visually devastating. Smooth, round, non-metallic foreign bodies such as airsoft pellets are uniquely difficult to remove surgically. These pellets are approximately 6 mm in diameter, enter the eye with at high velocity, and cause significant damage such as globe rupture, retinal detachments, and cataracts. Such injuries are more prevalent in children and young adults. A need exists for an intraocular instrument that will easily grasp and remove such an object within the eye.

Ideally, the instrument ideally would be 1) low profile enough to enter the eye and manipulate the foreign body without damaging surrounding structures, 2) able to easily grasp round, smooth objects that conventional forceps are unable to grasp, and 3) enter and exit the sclera (eye wall) without enlarging the wound.

Client Requirements:

- Instrument must be sterilizable or disposable
- Minimize the damage of the retina
- Provide flexibility in handling for surgeons without changing hand position
- Easily grasp the object in its entirety

Design Requirements:

1. **Physical and Operational Characteristics**

   a. *Performance requirements*: The instrument shall be able to reliably grasp and lock into place a smooth, non-metallic, and spherical Intraoclular Foreign Body (IOFB) of diameter 6.1 mm or less. It shall not enlarge the surgical wound site beyond the size of the IOFB. It shall be easily and independently operable by a surgeon.

b. Safety: The instrument shall be able to be effectively sterilized after each use. It shall not possess any features that could pose an increased risk to the patient or surgeon, including but not limited to loose fitting parts and sharp edges.

c. Accuracy and Reliability: The instrument shall be able to repetitively grasp an IOFB without the IOFB slipping from its grasp through the duration of the procedure. Once in use the instrument shall be one-hundred percent successful in the removal of IOFB.

d. Life in Service: The instrument shall be in service for fifteen years with proper care and usage. The client is also open to the idea of a single use disposable instrument. [11]

e. Shelf Life: The instrument shall be able to be held for ten years under sterile conditions or until its sterilization has been compromised due to environmental factors. [12]

f. Operating environment: While the device is being used, it will be in contact with the inner part of the eye. It will specifically contact the sclera, cilia body, aqueous body, retina and vitreous body. It must be operable in a high-pressurized eye state with an infusion rate of 30. A surgeon in a sterile surgical environment will handle the device.

g. Ergonomics: The device should open and close smoothly while providing flexibility for a surgeon. It should be able to deliver precise movements. It must be easily graspable by one hand. It should provide a stable handling for a surgeon. Surgeon should be able to rotate the device in his/her fingers without changing hand position.

h. Size: The device must be large enough to grasp an IOFB but small enough that it does widen the original wound. Its thickness should be close to that of the foreign body. Its length shall be 24 mm from tip to handle to provide a minimum operating distance for the surgeon. The grasping part of the handle should not be too thin to provide stable performance. The device should not exceed 7mm in diameter in order to minimize the enlargement of entrance wound.

i. Weight: The device should be minimized but not too light that the surgeon could hold it comfortably and securely during the full time of the surgery.

j. Materials: The device should be made of surgical tool materials. It should be constructed with materials that do not interfere with the internal body. The material should be lightweight in order to provide small weight. The texture should provide sufficient friction for the device to not slip from a surgeon's hand. Materials should be autoclavable if will be reused. If materials are to be disposable, they should be gamma-sterilizable. [13]

k. Aesthetics, Appearance, and Finish: These factors will be determined upon the fabrication of the device. The device should have a smooth finish with rounded corners and no sharp edges that might damage tissue.

2. Production Characteristics

a. Quantity: One unit is needed per each time of the operation. Quantity demanded for production will be defined later in the process.

b. Target Product Cost: The cost of production should be targeted around $250 per unit. Cost-effective factor will be determined upon completion of the project for future work.

3. Miscellaneous

a. Standards and Specifications: FDA approval of the device is required.

b. Patient-related concerns: Materials must be non-toxic and biocompatible. Any metals used must be hypoallergenic. Must not cause any additional damage to the eye or expand the wound.

c. Customer: Ophthalmologists, hospital personnel, and the patients who require intraocular foreign body removal.

d. Competition: There is no direct competing device specific for the removal of intraocular non-metallic foreign bodies. Similar designs and current instruments include hooked prong forceps designed to remove stones, neurological surgical forceps and tweezers.