Device for Extraction of Non-metallic Intraocular Foreign Bodies

BME 301

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CLIENT:
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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 subjected for immediate removal by surgery. However this can be difficult when they are round, smooth, and non-metallic such as air soft pallets. Currently there is no surgical instrument designed specifically to remove these kinds of IOFBs. We hoped to create an intraocular instrument design that would successfully remove air-soft pallets of up to 8 mm in diameter with locking 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, Fish Net design was determined to be the most ideal and effective and it was chosen to be continued for fabrication and testing.

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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 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. 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 pallet 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 eared her Medical degree at Brown University Medical School and did her internships 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 (Mete, 2011). 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 are different for each. Common causes of metallic IOFBs is hammering and using machine tools. Non-metallic, usually plastic, are generally air soft pallets caused from BB guns.

Methods of IOFBs are simple enough that they can enter through any part of the outer eye, the reason why they are called open-globe injury. Usually IOFBs enter through cornea, sclera or limbus, the outermost parts of the eye. After they enter, their final location can be anywhere of the inner eye but the most common area is the vitreous cavity, the posterior segment. When IOFBs enter the eye, they can cause damage to the eye tissue, including the lens and retina (Rathod, 2011). Retina is where the optic nerves are and therefore considered sensitive (Encyclopedia, 2011). It is important that the intraocular instrument does not interfere with the retina.

IOFB injuries normally do not lead to poor prognosis and often result in fairly minor outcomes. However BB gun injury, large IOFBs and dense vitreous hemorrhage 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 (Rathod, 2011).

The design in this project targets specific types of IOFBs that are round and plastic, and those that are found in the vitreous body.

Current Devices

There are currently no instruments specifically designed for the removal of smooth, spherical, and non-metallic IOFB. Metallic IOFB can typically be removed by using a magnet, but this is not an option with non-metallic IOFB. Several surgical device companies make ophthalmological forceps with various kinds of tips that can be used to remove non-metallic IOFB. 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 1 shows the ophthalmological forceps sold by Alcon surgical with three tip variations.

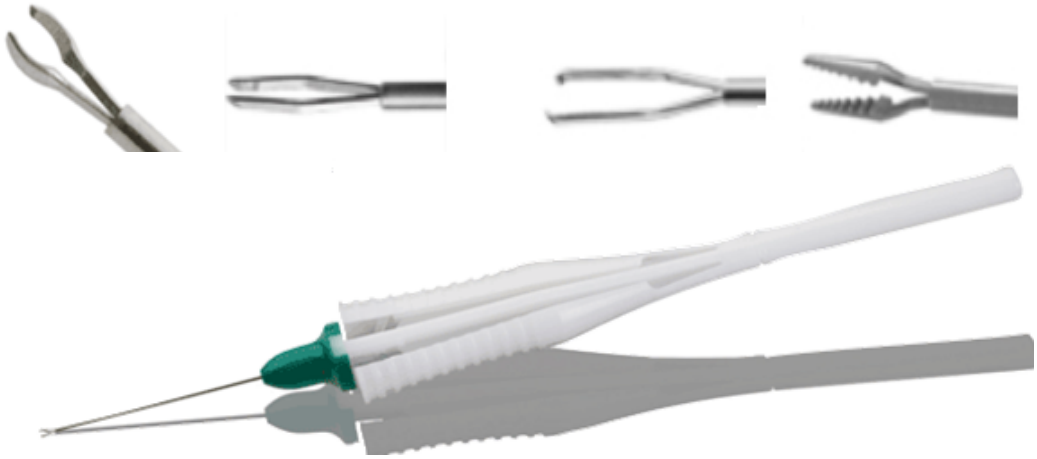

Figure 1. Alcon Surgical Ophthalmological Forceps: An image of ophthalmological forceps with various tips. From right to left, a multi-purpose tip for grasping IOFB, a multi-purpose tip for grasping fibrous membranes, a tip for retinal membrane manipulation, and a serrated tip for grasping fine membranes.

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 2. 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 (Rajiv). 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 3, 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.

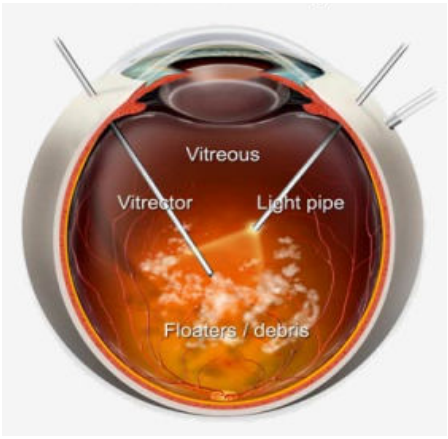

Figure 2. Diagram of Pars Plana Vitrectomy: An animated cross-section of the eye including the components used during a vitrectomy procedure (Brinton, 2012)

Figure 3. 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, figure 3, inspired design 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.

Figure 3. 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 (SolidWorks).

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.

Fish Net

The second design alternative looks very similar to a net used for fishing (Figure 4). 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 5). 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 4. Image of a Roth Net Retriever. Instrument that inspired the mechanism of the Fish Net design (Endoscopy Support Services).

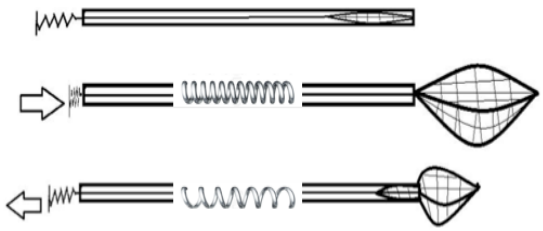

Figure 5. Image describing the mechanism of the Fish Net design. Contraction and relaxation of the spring pushes and pulls the net embedded inside the rod

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 very 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. 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 6. Image of a Claw Pick-Up Tool. Instrument that inspired the mechanism of the Claw design (Autocut, 2012)

The claw design would be both 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.

Table 1. Intraocular Device Design Matrix

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	

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 were 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 has weighted as 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 highest score of five for an outstanding design that is least invasive while still ensure the purpose of capturing 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 device in order to optimize patient's well being and overall system performance.

Although three design alternatives are different in the grab-catch mechanism, they all exhibit one-hand operation feature. The fish net received highest score for an outstanding design due to its most 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 a long run. Therefore, it received a rating of good. Meanwhile, the ice-cream scoop shows highest ability to capture and secure in place the intraocular foreign object received highest score for an outstanding mechanism in term of safety. The fishnet granted 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 a lowest score due to the higher cost associated with biocompatible polymers for the net's material.

Final Design

The final design of the extraction instrument was that of a four-pronged retractable claw. The fabricated prototype of the final design can be seen in figure 7. The four curved prongs of the claw retract into a tube, which is inserted in the eye. The prongs are connected to a spring-loaded handle, which aids in their retraction and expulsion from the tube. Upon expulsion from the tube they open to a diameter of nearly 7 mm, which allows them to capture a 6 mm diameter air soft pellet. Once the pellet is within the prongs, they are retracted to form a tight locking grasp around the pellet. The instrument can then be safely extracted from the eye with the pellet in its grasp. The handle of the instrument is designed with the intent of a one handed operation. It is modeled after a syringe with a plunger, which slides into a hollow receiving tube containing a spring. The plunger has a loop on the end for the insertion of the operator's thumb to allow for quicker retraction and secure handling.

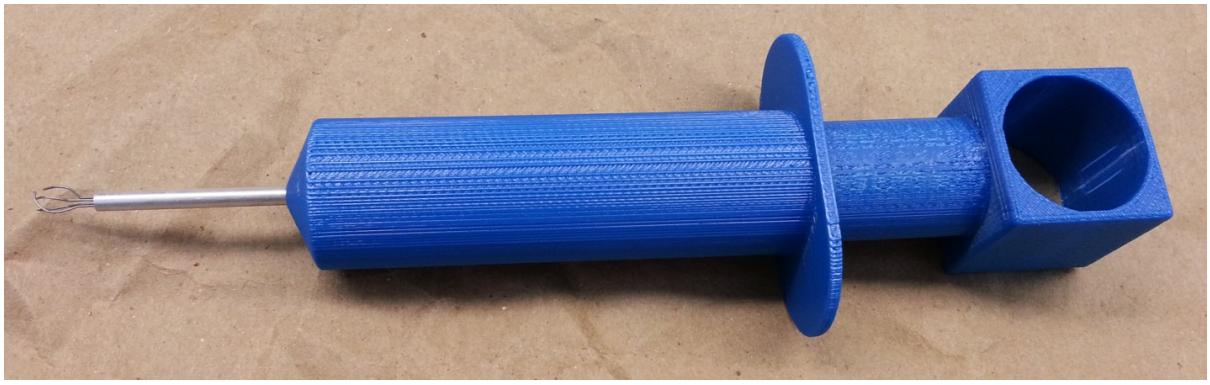

Figure 7. The Final Prototype**.** The syringe handle and four-pronged claw of the final design can be seen in the figure.

Prototype Fabrication

Handle Design

The handle was inspired by the shape of a syringe and considered because of its simple one-handed usability by the surgeon. In order to quickly create the handle in the desired dimensions, the computer-aided design program Solidworks was used. This model contained three separate components with the goal of 3-D printing each one individually and manually putting them together. The first component is the main outer shell (figure 8A). This part is the main body of the handle that will hold the compression spring and the second component, the plunger. This plunger will be placed into the outer shell and will be compressing a spring within the body (figure 8B). The plunger is also connected to the rod and claw and when compressed will release the claw from the center tube. Included on the end of the plunger is a thumb loop, which will decrease the risk of the users hand slipping. It's also included as a safety precaution in case the spring is not strong enough to retract the claw back into the tube, the user may pull on the loop to manually force the claw back. The third component is a small chip that will be placed inside the main body and in between the compressional spring and plunger (figure 8C). This chip will keep the plunger from slipping out of the main body.

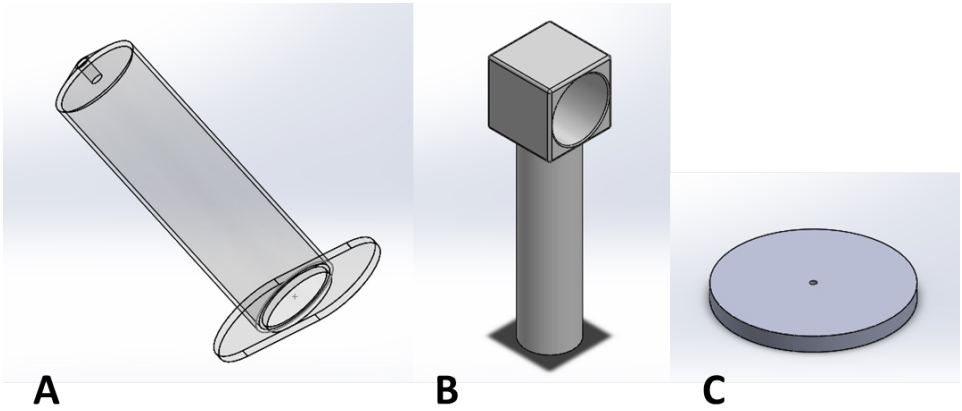

Figure 8. The Solidworks designs for the three 3-D printed components, (A) the outer body, (B) the plunger, (C) the chip.

The handle was fabricated twice, each with slight modifications in design and dimensions. The first handle prototype overall had dimensions that were over exaggerated and uncomfortable for the user. The diameter of the outer shell was too large for the user to place their hand around and the protrusions on the bottom of the shell where the user rests their fingers were too long. In addition the plunger's finger hole was large and obtrusive with the first prototype. The second time around these problems were addressed and fixed with a few other modifications. A 3.25 mm hole was added where the tube will be placed which will assist with the durability of the tube and keep it better in place.

Initial Net Design

The initial plan was to fabricate a net as the mode of retrieving the IOFB. The design would work nearly identical to the design of the claw but with a biocompatible net in place of

the claw. The net would be released from the center tube when the handle is compressed and retracted after relaxing the spring and pulling the handle back. The net was to be constructed from nylon netting and attached to a wired rim using sutures. The net design prototype was fabricated according to the initial plan (figure 9).

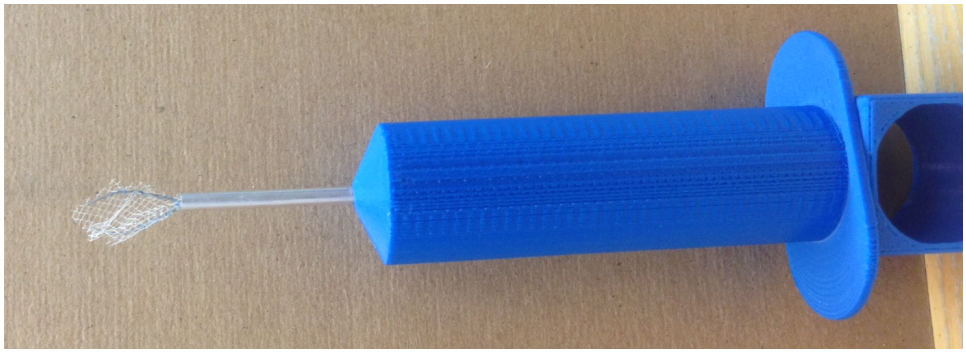

Figure 9. The prototype of the initial retractable net design. Net is released from the tube due to handle compressing the spring inside.

During the fabrication process many obstacles occurred. It was very difficult to keep the netting from slipping around the wire rim. Suturing the netting to the wire kept the net in place initially but once the net was placed into the center tube, the sutures would slip causing the net to get stuck and move around. This led to the team attempting to glue the net onto the wired rim but similar problems arose. The glue would scrape against the insides of the tube causing the net to get stuck. In addition to attachment concerns, the net itself was much more rigid than expected. The net ideally would have been smoothly released from the tube, scooped up the IOFB and retracted back into the tube with the IOFB secured inside the net. Unfortunately the net, being so small in size (8 mm in diameter) would not successfully open and leave enough room to grasp the IOFB. Even though the size of the net was small, trouble occurred in storing the net inside the 3 mm tube. The net, along with the wire rim was too large to fit inside the tubing, which prevented smooth release and retraction.

Final Claw Design

The claw was fabricated using 0.38 mm (diameter) music wire. Four prongs were created by bending two pieces of wire into a triangular shape, each piece becoming two opposing prongs. These four prongs were glued onto the center rod so that each prong was 90 degrees from another.

Because there are four prongs, the claw took up more space that the original net and therefore the claw could not be fully retracted into the tube. In the prototype's natural relaxed state the claw protrudes around 3 mm and is 4 mm in diameter. When fully released from the tube, the claw opens and becomes 8 mm in diameter. This gives enough room for the claw to easily grasp the IOFB but it's still small enough so that it does not take up any more space than what the net would have. The final prototype that was used for tested and analyzed is shown in figure 10.

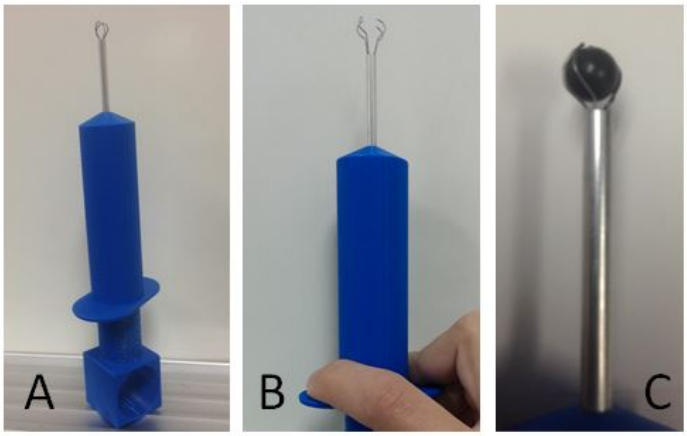

Figure 10. (A) The claw prototype retracted (closed) inside the tube, (B) The claw released and open from the tube, (C) the claw grasping an airsoft pellet.

Attaching the Claw

In order to create the tube at the front of the prototype, aluminum tubing was found with an outer diameter of 3.2 mm. This tubing was cut down to a length of 32 mm and glued into the 3.25 mm hole at the front of the 3-D printed handle. The rod that connects the claw to the plunger was made out of 0.625 mm (diameter) music wire. The wire rod was attached to the prototype by first drilling a hole through the center of both the 3-D printed chip and plunger. This allowed the rod to be sent through the chip and plunger and then all three were glued into place.

Four compression springs were evaluated to determine which would work best with our prototype. The final spring was chosen based on its ease of use in order to release the claw as well as its strength to retract the claw back into the tube. The client chose which spring she found most easy to use and compress within the handle and the stiffness constant was calculated to determine the spring's strength. By measuring the change in length when different forces were applied, the constant could be calculated from the following equation:

$$k = F/\Delta x$$

k = spring stiffness constant (N/m), F = force (N) and Δx = change in length (m)
The team used weights of 500 g and 700 g, measured the change in length and averaged the measured constants in order to determine the approximate spring constant. The spring used in the final prototype gave a stiffness constant of 500 N/m.

Testing & Analysis

With our fabricated final prototype, we performed testing to analyze its effectiveness and the ease of use. Testing was done with the client for accuracy purpose since the client was a surgeon, representing the population of the potential users of the final prototype. We obtained pig eye and human eye samples from the ophthalmology lab at the University of Wisconsin Madison Hospital. Prior to testing, appropriate vitrectomy and microscope was used when testing (figure 11).

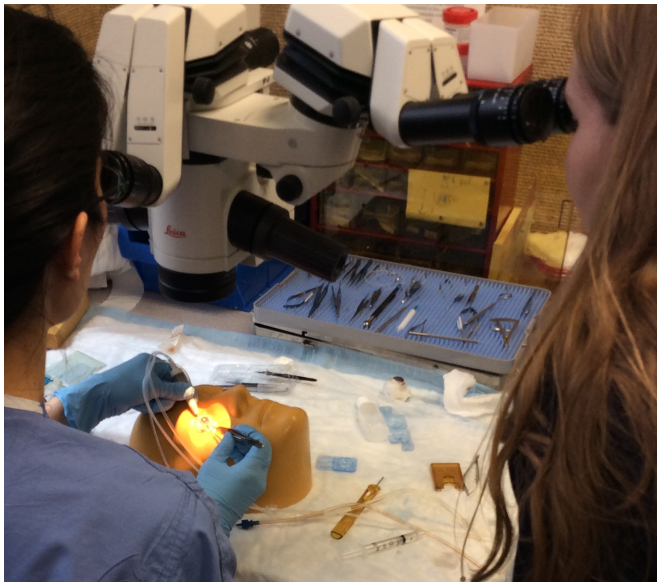

Figure 11. Figure of our client performing vitrectomy to create an appropriate testing setting inside the eye sample, while one of our team members is observing the process through the shared microscope.

In order to test the prototype's effectiveness and the ease of use, we gave the client a task, to pick up an airsoft pallet using either the current device (forceps) or the final prototype. This was done ten trials for each device. While she was performed the task, we obtained two data sets for each trial and for each device. First, we obtained how long it takes the client to complete a task, that is, until she successfully removes the pallet. This was done to evaluate the final prototype's ease of use compared to the current device's since the longer time it takes, harder it is to use and also more fatigue he or she will be. Second, we observed the number of retries, equivalent to re-picking up the pallet after a slip, until successful removal. This was done to test the final prototype's effectiveness compared to the current device.

At the beginning of the testing, we embedded the airsoft pallet into the eye sample's vitreous body directly to make our data as significant as possible. This was done to create a most similar environment that the device will actually be used (Figure 12).

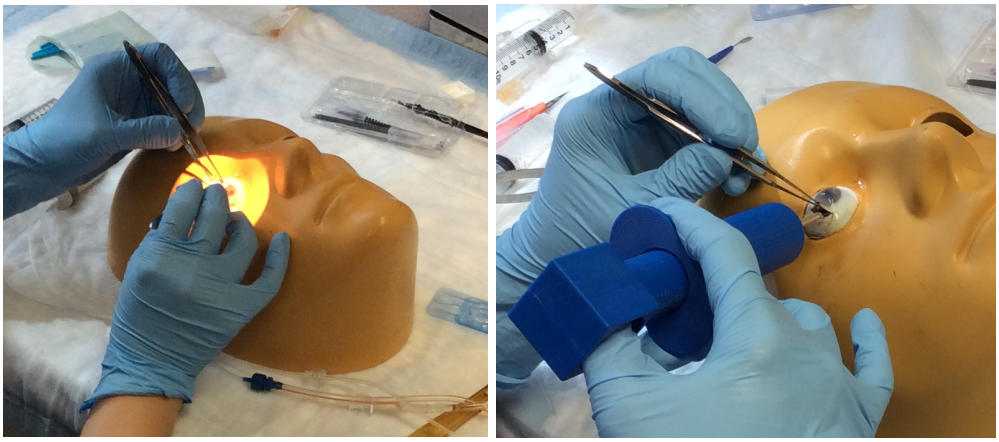

Figure 12. Figures of our client performing a given task directly inside the eye sample by using the current device (left) and using the final prototype (right).

However after multiple attempts, our client claimed that because the eyes are have been removed from the body, it was hard to get a view of the pallet through the cornea. This was also because a microscope was used to look through the cornea for the testing; in normal surgery, camera navigates inside the eye for the better view.

Therefore we decided to perform testing outside the eye. It was still important to create a similar environment of the real life uses. We extracted the vitreous from two pig eye samples and mixed with BSS, basal salt solution, in a small cup to create a vitreous cavity setting outside the eye. Then the air soft pallet was dropped into this solution to begin our testing (Figure 13). This time, testing went fairly successful.

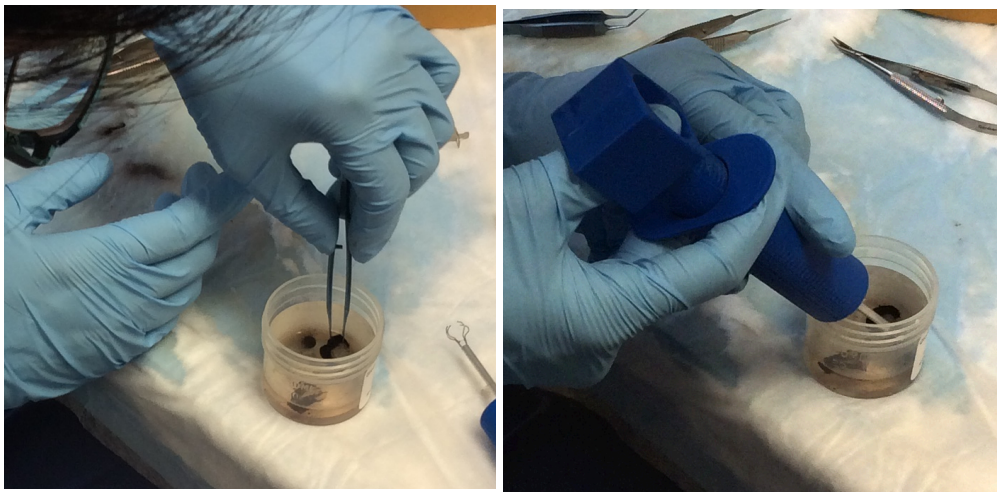

Figure 13. Figures of our client performing a given task inside a vitreous and BSS combined fluid by using the current device (left) and using the final prototype (right).

After recording all the data values, average and standard deviation were calculated for the current device and the final prototype for the time required data set (Table 2) and the number of retries data set (Table 3). Then we compared the average and standard deviation between the two devices to analyze the final prototype's effectiveness. The graphs to compare the average between the current device and the final prototype were created for two data sets (Figure 14). Standard deviations were implemented in the graphs.

Table 2. Time required to successfully remove an airsoft pallet by using the current device and the final prototype. Average and standard deviation were calculated for each device's ten trials.

	Time required	
Trial	Current device (forceps)	Final Prototype
1	9.61	10.36
2	7.03	21.6
3	7.03	5.76
4	12.13	29.05
5	7.18	17.45
6	12.53	11.7
7	5.8	16.54
8	8.1	16.08

9	8.5	6.33
10	11.43	13.21
Average	8.934	14.808
Standard Deviation	2.377	7.0420

Table 3. Number of retries required until successful removal by using the current device and the final prototype. Retries indicate the number of picking up a pallet after it has slipped from the device for each trial. Average and standard deviation were calculated for each device's ten trials.

	Number of Retries	
Trial	Current device (forceps)	Final Prototype
1	1	0
2	0	0
3	2	0
4	0	1
5	3	0
6	0	1
7	1	0
8	1	1
9	1	2
10	0	0
Average	0.9	0.5
Standard Deviation	0.994	0.707

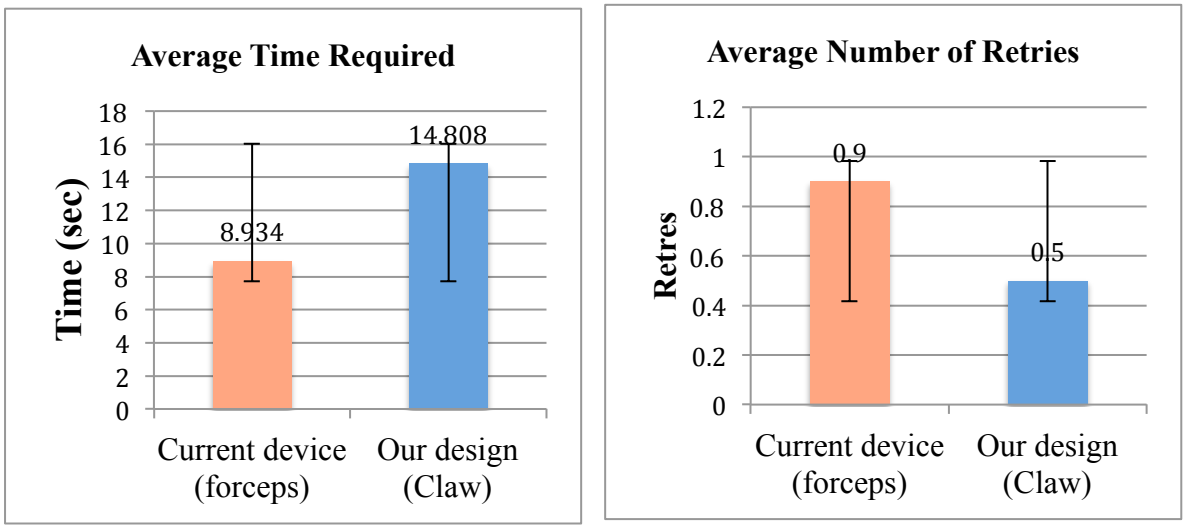

Figure 14. Left: comparison of average time required per trial for the two devices. Right: comparison of average number of retries required per trial for the two devices.

Overall, our final prototype had longer average time required but fewer average number of retries per trial. This can mean that the final prototype reduces the slips and increases the effective of its purpose but takes longer to remove the intraocular foreign body, reducing the ease of use. However, the calculations also show that the standard deviations are

relatively large for all data sets for both the current device and the final prototype. Therefore, we cannot conclude whether our final prototype is more effective than the current device.

We propose that there are multiple factors that could have affected the results. First at the time of testing, it was our client's first time using our prototype, while she already had numerous experiences with the current device. Comparison would have been more accurate if more time was given for her to get comfortable with our prototype. Also this design project was focused on improving the slips that the current device creates at the extraction surface. Therefore our prototype's main focus was to improve the grip on the round pallet that it does not slip out at the exit wound. However because we performed testing outside the eye, we do not know how this problem is compared between the two designs. Using the current device would have given much less effective results if the testing were done inside the eye itself. Overall, we think that further testing that depicts the real usage situation better is needed to analyze our final prototype to conclude its effectiveness and ease of use.

Future Work

Our team has reached many significant milestones throughout the lifecycle of the product development, but many more lay ahead prior to real world implementation of the device for extraction of non-metallic intraocular foreign bodies. Several aspects of the design could be changed or improved as outlined in the subsections below.

Scale Reduction

Size is the utmost important parameter for our project, as we want to minimize damage to the eye thus for future work, we would modify the dimension of the device, specifically the handle. Both the length and width of the handle could be shortened based on the size of the vitrector. We decided to keep the diameter of the extruding tube at 3.2 mm while the length could be trim down to approximately 1-2 cm. Our current prong design promoted high ability in tightly grasping and locking the intraocular foreign bodies thus would remain the same. However, future prototype would be expected to be more compact to increase both the surgeon's ease in use and ergonomic factor.

Material Selection

According to FDA guidelines for review of medical devices, the materials in the device should not, "(i) produce adverse local or systemic effects; (ii) be carcinogenic; or (iii) produce adverse reproductive and developmental effects" (ISO-10993). The FDA for novel materials requires extensive testing. Proven materials may have fewer requirements for device approval.

Our design was inspired based on the syringe design and retractable claw. Therefore, it would be beneficial to look into company such as Becton Dickinson & Company, the world's largest manufacturer of medical syringes and needles (Walsh, 2004) that have garnered FDA approval, extensive material compositions that have a long-term history of use in the human body to select appropriate materials for the device handle, extruding tube and four prongs. All materials come in contact with human eyes such as the tube and the metal

rod attached to four prongs could potentially be type 304 Stainless Steel. Stainless Steel is commonly used for implant device and other medical devices, as well as has a history of biocompatibility. Additionally, stainless steel is autoclavable that could satisfy one of our long-term goals for a reusable tool to reduce health care cost and potentially, become more attractive on the market.

Fabrication

As mentioned above, our future prototype needs to be scaled down to size in order to function in the proper operating environment. This fabrication step would likely require outsourced manufacturing, as we would not be capable of machining components on this order of magnitude.

Testing

Once our prototype is completed, we wish to conduct further tests in order to draw a solid conclusion about our device's function. We would like to test our device on animal eyes to ensure its successful operation in vitreous environments. If the prongs can tightly grasp the intraocular foreign body without slipping, then we know that our design will be effective in capturing and locking the foreign object.

Cost

The final cost for all the parts needed for prototype fabrication was $67.22. An itemized list of all expenses can be found in Appendix B. The projected budget for this project was $250. The prototype was significantly less expensive to fabricate because surgical grade biocompatible materials were not used. Instead, less expensive and more commercially available parts were used for the proof of concept prototype. Part of the budget also went to purchasing multiple springs and wires for testing that were not included in the final prototype. A professionally manufactured prototype of surgical scale would likely cost around $50-100.

Acknowledgement

The team would like to extend special thanks to the following individuals:

- Dr. Leslie Wei, MD (client)
- Prof. John Webster (advisor)
- Prof. John Kao (collaborator)
- College Of Engineering Student Shop Employees (technical consultants)

Timeline

The following table shows the timeline with goals completed throughout this semester. The filled boxes are the projected timeline and the check marks indicate the actual progress.

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	X	X					X		X	X	
Client	X	X	X				X			X		X		X	X
Team	X	X	X	X	X	X			X	X	X	X	X	X	X
Product Development															
Research	X	X	X	X		X	X		X	X	X				
Brainstorming		X	X	X		X	X		X	X	X				
Design Matrix			X	X											
Design Prototype			X	X		X	X	X	X						
Order Materials											X	X			
Fabricate Prototype											X		X	X	
Testing														X	
Deliverables															
Progress reports	X	X	X	X	X	X	X		X	X	X	X	X	X	X
PDS		X	X	X	X										
MidSemester PPT			X	X	X										
MidSemester Report					X										
Final Report															X
Final Poster														X	
Website Updates	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

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Appendix A

Product Design Specification

Device for extraction of non-metallic intraocular foreign bodies:

Client: Dr. Leslie A. Wei

Advisor: John Webster

Team Members: Amy Kim,
Ngoc (Ruby) Phung
Carly Hildebrandt
Adam Strebel

DATE UPDATED**:** 05/07/ 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 Intraocular 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. [1]

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. [2]

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 should provide a minimum operating distance and sight for a 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. [3]

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.

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Appendix B

Cost

Item	Price	Sales Tax	Purchase Date	Store	Category	Purchased By
Metal Wire (0.17 in)	$ 0.99	$ 0.05	4/8/2014	Hobby Lobby	Parts	Adam Strebel
Metal Wire (0.25 in)	$ 0.99	$ 0.05	4/8/2014	Hobby Lobby	Parts	Adam Strebel
Metal Wire (0.32 in)	$ 1.29	$ 0.07	4/8/2014	Hobby Lobby	Parts	Adam Strebel
Hollow Metal Tubing (1/8 in)	$ 3.49	$ 0.19	4/8/2014	Hobby Lobby	Parts	Adam Strebel
Nylon Fabric (2 yds)	$ 1.16	$ 0.06	4/8/2014	Hobby Lobby	Parts	Adam Strebel
Store Total	**$ 8.36**	$ 0.44				
Comp Spring 5/8 X 1-1/16	$ 0.79	$ 0.04	4/8/2014	Menards	Parts	Adam Strebel
Comp Spring 3/4 X 3-3/8	$ 0.85	$ 0.05	4/8/2014	Menards	Parts	Adam Strebel
Comp Spring 1/2 X 1-1/8	$ 0.89	$ 0.05	4/8/2014	Menards	Parts	Adam Strebel
Comp Spring 13/16 X 3-1/4	$ 0.89	$ 0.05	4/8/2014	Menards	Parts	Adam Strebel
Store Total	**$ 3.61**	$ 0.19				
3D Printed Part	**$ 40.19**	---	4/16/2014	COE Student Shop	Parts	BME Department
Spring Shipping	**$ 13.30**	---	4/9/2014	UPS	Shipping	Carly Hildebrandt
Sand Paper 120G	$ 0.75	$ 0.04	4/23/2014	Dorn True Value	Supplies	Adam Strebel
Sand Paper 100G	$ 0.75	$ 0.04	4/23/2014	Dorn True Value	Supplies	Adam Strebel
Store Total	**$ 1.58**	$ 0.08				
Sub Totals	$ 66.33	$ 0.89				
GRAND TOTAL	**$ 67.22**					
Remaining Budget	$ 182.78					