Developing a reversible contraceptive device

Final Report
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Abstract

In today's society, there exists a need for the improvement of maternal health including reproductive health. Many of the current methods of contraception utilize hormones or pharmaceuticals, which can cause unwanted side effects. Other methods of contraception have a susceptibility to user error, which makes them less effective. Surgical contraceptive methods are often invasive and generally cause permanent infertility. This drives the need for a device that can be implanted within a woman's reproductive system that could allow her to control her fertility.

We designed and fabricated a large-scale prototype valve which can be actuated by an electromagnetic field. An external controller controls the opening and closure of the valve which will allow or disallow passage of gametes, controlling a women's state of fertility.

We powered the valve mechanism using an AC powered solenoid. Although we were unsuccessful in powering a short-circuited coil as originally planned, we were still able to generate force on ferrous but non-magnetic material.

1. Introduction

1.1 Client Description

Our client is Dr. John Webster, PhD. He is a professor in the Department of Biomedical Engineering at the University of Wisconsin-Madison. His areas of interest include medical instrumentation, implantable intracranial pressure monitors, and bioelectrodes, among many others. He has expertise in biomedical instrumentation, implantable intracranial pressure monitors, and bioelectrodes. In addition, he has authored many publications, which are too numerous to be named here.

1.2 Motivation

A long-term, reversible contraceptive method is a global necessity. The United Nations Millennium Development Goals include the improvement of maternal health. One component of accomplishing this goal is achieving universal access to reproductive health.[1]

While the level availability of contraception is relatively high in the United States, the methods of contraception currently available have many deficiencies. Oral hormonal methods can cause side effects such as headaches, uterine bleeding, nausea, breast tenderness, abdominal pain, and mood changes. They are contraindicated for women with a history of high blood pressure, women who smoke, and women over the age of 35. Additionally, these hormonal methods increase the risk of vascular problems and liver disease.[2]

Current surgical methods of contraception are generally permanent; fertility cannot be restored after the procedure is performed. Nearly all methods and devices have some opportunity for user error. If the method is used incorrectly, it lowers contraceptive efficacy.

Lastly, it is recommended to space births at intervals greater than one year. However, most contraceptive methods cannot be used for a period of 6 weeks postpartum due to increased risks and the altered physical condition of the body.[3]

1.3 Problem Statement

Current technologies for female contraception often require the intake of pharmaceutical agents or invasive surgeries. These chemicals can cause side-effects such as: headache, uterine bleeding, nausea, breast tenderness, abdominal pain, mood changes, and increased risk of vascular problems, liver disease, or high blood pressure.[4] Mechanical surgeries can lead to scarring and usually involve ligation, which causes permanent infertility. Ultimately, a female should be able to choose when to be fertile or infertile without the use of hormones.

The primary goal of our project is to design a valve that can be controlled from outside the body. The device should provide non-permanent, or reversible contraception to allow a woman to control her fertility. The design should involve a valve consisting of biomaterials that can be integrated into the reproductive system.

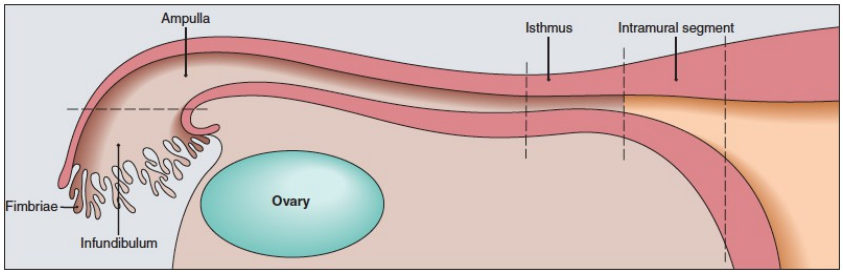
1.4 Design Requirements

The device must be safe for use in the female reproductive system. All materials used in construction of the device, especially those directly exposed to tissue must be biocompatible, pharmaceutically inert, and non-toxic. The device must be able to function at a temperature of 37°C. In addition, it must be MRI compatible, and therefore contain only non-ferrous materials. The device must also satisfy the Electromagnetic Compatibility (EMC) level in order not to cause electromagnetic interference with other devices in proximity.[5]

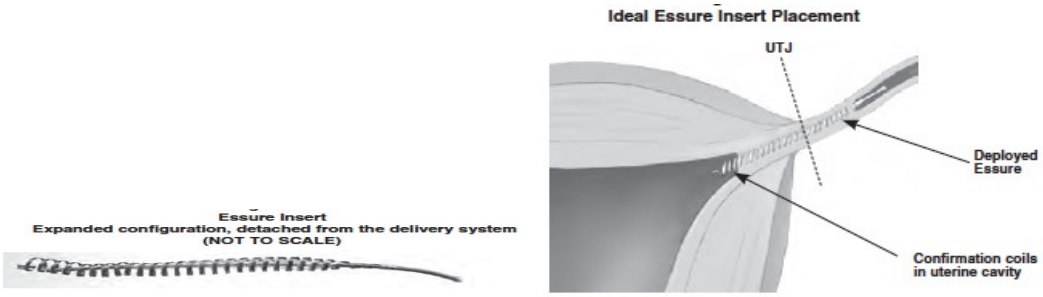
Once implanted, the device must not disrupt the environment of the oviduct or perturb its functions.[6] The device must open and close at intervals greater than one year for the duration of a woman's reproductive years, with an estimated maximum of 50 times. It must be able to endure the rigors of labor and delivery. The device should not require maintenance or replacement once implanted. The life in service is up to 50 years. The device will be in service throughout a woman's reproductive years. The complete Product Design Specifications can be found in the Appendix.

1.5 Physiology

The oviduct leads from the ovary to the uterus. It has four sections; the intramural segment lies proximal to the uterus; continuing distally lies the isthmus, ampulla and infundibulum shown in Figure 1. The lumen is lined with secretory cells, peg cells, and columnar ciliated epithelial cells, which are predominantly near the ovary. The oviduct is ten to fourteen centimeters in length with an inner diameter of 1.5 mm at the uterine opening and 3 mm at the ovarian opening. The oocyte enters the oviduct at the infundibulum. Tubal transport is facilitated by ciliary action. Fertilization occurs in the oviduct. The fertilized ovum is then transported to the uterus, where implantation occurs.[7]



The isthmus is the preferred location for implantation of a reversible contraceptive device because it has the most developed musculature. It is four centimeters long and has an inner diameter of 1.5 mm.

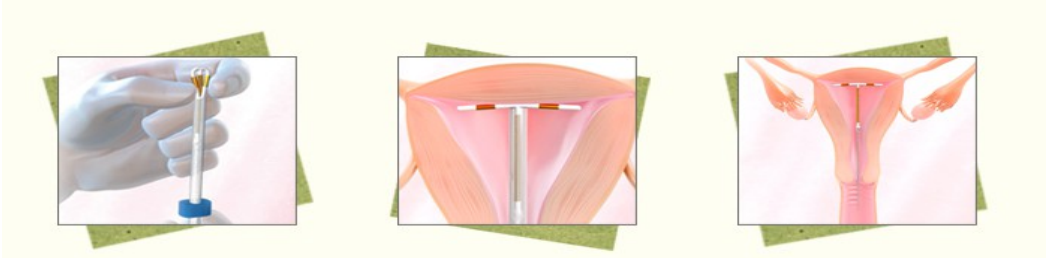


1.6

Competing Designs

There are many contraceptive devices available today. There are two products that offer some of the features we are looking for. Essure is a nonsurgical, non-hormonal, permanent sterilization method. The Essure insert consists of a super-elastic, nitinol outer coil and stainless steel inner coil.[8] It is wrapped in polyethylene terephthalate (PET) fibers. Inserts are implanted into each fallopian tube and within three months tissue grows into the implant and occludes the fallopian tube. Figure 2 shows the device and placement.

A second device is ParaGuard. It is also nonsurgical and non-hormonal. It offers a reversible, long-term contraceptive method. It is an intrauterine contraceptive device (IUC) placed in the superior region of the uterine cavity. It has a T-shaped construction with a polyethylene frame.[9] It is thought to prevent conception by preventing the sperm from reaching the egg. Additionally, it diffuses copper, which has contraceptive properties. Figure 3 illustrates the placement of ParaGuard.



Reference: 1. ParaGard® [package insert]. Sellersville, PA: Teva Women's Health, Inc; 2011.

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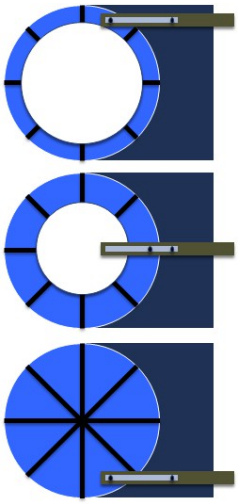
2. Materials and Methods

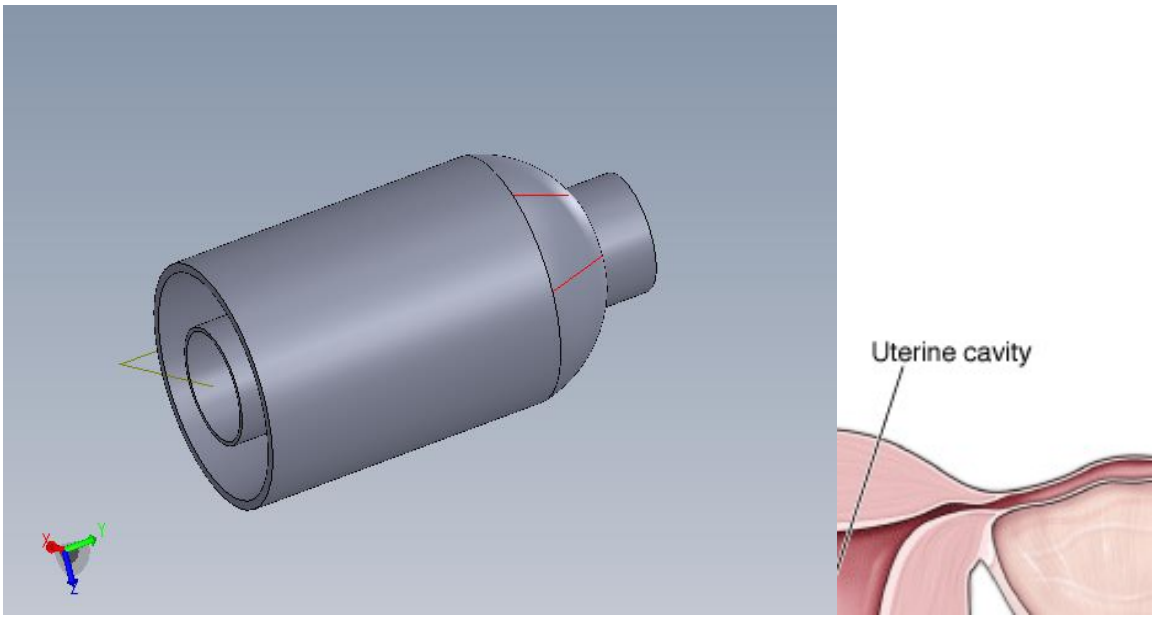


2.1 Design Alternatives and Design Matrix

Iris Valve

The Iris Valve is similar to the shutter within a camera lens. It contains multiple blades that are all attached to a diaphragm. Normally, an applied torque causes the blades to open and close. As it is difficult to apply a torsional force within the confines of the fallopian tube, we are using a free-sliding pin fixed to the diaphragm of the valve, which slides along a slot in the lever arm. This allows for a torque to be provided via a translational force applied to the lever arm. This is depicted in Figure 3. When the blades are all open, the fallopian tube is unobstructed, allowing conception to occur. In the closed position, the blades create a watertight seal blocking the passage of sperm and egg through the valve.

Both the diaphragm and the lever arm will be in a housing and attached to the fallopian tube. The lever arm will be controlled externally using an electromagnetic field, which will be expounded upon in the future.



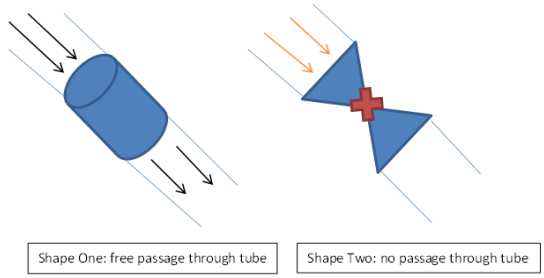
Leaflet Valve

The second design alternative is called the Leaflet Valve. It consists of 2 nested cylinders. The outer cylinder has leaflets with induced tension to form a dome. The device is implanted into the fallopian to with the dome end proximal to the uterine cavity. This inner cylinder moves along its central axis in response to a force applied by an external controller while the outer cylinder remains stationary. When the inner cylinder slides proximal to the uterus it forces the leaflets open; when it slides in the opposite direction it pulls the leaflets closed. It will be constructed from a biocompatible polymer. Refer to Figure 4 for a schematic of the design.

Sliding Valve

The sliding valve is illustrated in Figure 5. The device utilizes a double funnel design to guide the passage of gametes through the valve. Embedded in the housing are two discs, each with a circular opening in their center. To close the valve, a plate slides between the discs to seal their openings; to open the valve, the plate retracts into a recess in the housing. The plate could respond to an electromagnetic field to be applied with an external controller.

Shape Memory Polymer Valve

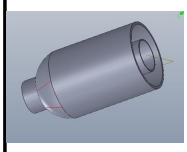
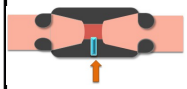
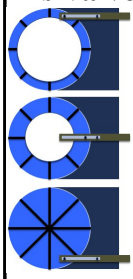
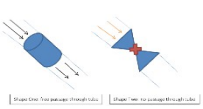


Unlike the previous designs, the shape memory polymer valve does not function based on the principles of a traditional valve where multiple moving parts are at hand. These polymers are stimuli-responsive and have the ability to change shape when an external stimulus is applied. For our operating environment we cannot drastically change the temperature as an external stimulus, but would rather use an applied magnetic field. This magnetically induced shape memory effect incorporates magnetic nanoparticles and inductive heating of these compounds in alternating magnetic fields.[10] Figure 6 shows the two different shapes of the device in relation to their contraceptive function. The open shape would be a "cylinder like" shape that would all for the free passage of egg and sperm, and would transform into the closed shape, a "bowtie like" shape that would block the passage of egg and sperm. No power is required in order for this device to remain closed. Based on these two shape configurations the woman can select whether to be fertile or infertile by the induction of a magnetic field. This device may not be MRI compatible due to the shape changing properties of the material in the presence of a magnetic field.

Design Matrix

The design matrix can be found in Table 1. The five factors that were considered with each design were: purchase cost, contraceptive effectiveness, biocompatibility/safety, reliability, and feasibility of fabrication. Each design was evaluated on a scale of one to five for each of the parameters. Scores one through five correspond to a poor, fair, good, excellent, and outstanding design, respectively. The criteria are discussed below.

Table 1. Design Matrix

Parameters (Weight)	**Leaflet Valve** 	**Sliding Valve** 	**Iris Valve** 	**Shape Memory Polymer Valve** 
Contraceptive	(4) 28	(4) 28	(4) 28	(3) 21

Efficacy (35)				
Biocompatibility/ Safety (35)	(4) 28	(3) 21	(3) 21	(4) 28
Purchase Cost (10)	(3) 6	(5) 10	(5) 10	(3) 6
Reliability (10)	(2) 4	(4) 8	(3) 6	(3) 6
Feasibility of Fabrication (10)	(2) 4	(4) 8	(3) 6	(3) 6
Totals (100)	70	**75**	71	67

Contraceptive Efficacy: This specification refers to the probability that the design will provide effective contraception. It has a weight of 35 out of 100, one of our two highest-weighted categories. It was granted a high importance because it is the purpose of our design. If the device is not contraceptive, there is no valid reason for implantation in the human body. An outstanding design utilizes two or more contraceptive methods. An excellent design has a 100% probability of providing contraception. A good, fair, and poor design have a 90-100%, 50-90%, and less than 50% probability of being contraceptive, respectively. Probability percentages are estimated to the best of our knowledge. The shape memory polymer valve received a rating of good in this category. This was decided based on the estimate that there's a 90-100% chance that the shape of the valve will collapse effectively to block sperm passage. We were uncomfortable scoring the design any higher because we are not positive that the required shape is possible, given the properties of the polymers required. The remaining designs all received a rating of excellent. For these designs, we were confident that the contraceptive mechanism for each design would effectively prevent conception. However, each design only utilized one method of contraception.

Biocompatibility and Safety: As our device will be placed within the reproductive system of a woman, we must make sure that it is fully compatible with its surroundings. Considering that we will be introducing foreign materials, we must ensure that these materials are compatible with the biological system. There are several factors we must be conscious of when choosing materials and designs. First and foremost is how long the material can withstand being placed within the body. We need our material to last the reproductive life of a woman and therefore must not degrade within the body for a 50 year time period. Next we must make sure that the device will not release any toxic chemicals that will cause harm at the local and systemic levels. We defined an outstanding biocompatibility as being able to stay in the body without damage or biodegradation for the entire period in which a woman is fertile – around 50 years. An excellent rating can stay inside the body without the need for replacement for 20-50 years. A good rating can stay within the body for 15-20, fair for 10-15, and poor is anything less than that.

As the iris valve and the sliding valve require multiple materials, there is an increased risk that one of the components will wear at a faster rate; the devices may not last as long in the body as the other two devices. Therefore, they both received a rating of good. The can be constructed of FDA-approved biocompatible polymers. Because the leaflet valve and the shape memory polymer valve can be constructed from a single FDA-approved, biocompatible polymer, they received a rating of excellent.

Purchase Cost: This parameter evaluates our competing designs based on their cost per unit. It was given a weight of 10 out of 100. This was decided based on the belief that contraceptive efficacy and biocompatibility were by far the most important design parameters for our competing designs. The remaining three parameters were non-differentiable in relative importance and were then each given a weight of 10.

Specifically this parameter compares each design's cost per unit to our allocated budget of $100. For a design to be rated outstanding the cost per unit of the device must be under the $100 budget. In order for a design to be rated an excellent design, the cost per unit must be $100. A good design would be roughly 110% of the allocated budget, while a fair design is 125% of the allocated budget, and a poor design would be anything more.

The sliding valve and iris valve received the highest scores in this category. These designs were rated outstanding due to the belief that they would both be composed of inexpensive materials. This would allow both designs to be produced under the $100 allocated budget. The leaflet valve and shape memory polymer valve both received a good rating. This is due to the higher cost associated with biocompatible polymers, estimated to be 110% of the allocated cost per unit.

Reliability: We defined reliability as the percentage of times the design should be able to open and close without failure. The maximum number of times the device needs to be opened and closed was estimated to be 50. The reliability category was weighted 10 out of 100, equal to the weights of both purchase cost and feasibility of fabrication. 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 sliding valve scored the highest, as it has the simplest mechanism that is the least prone to error in comparison to other designs. The shape memory polymer and iris valves were ranked good based on the assumption that they would be reliable 75-95% of the time. The leaflet valve was ranked fair due to the uncertainty of performance of the underlying mechanism.

Feasibility of Fabrication: 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 could be no more than 10% over budget and outside help 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 sliding valve received the highest rating of excellent. We determined the prototype materials to be readily available and inexpensive. We predict that we may need a small amount of assistance during the fabrication process. The leaflet valve received the lowest score due to its novel configuration.

Although every design deserves merit, the sliding valve scores the highest on the design matrix, as it is a rather well rounded design without major flaws. We have selected this option as our final design. We are comfortable with the score of 75 out of 100 because it nearly meets our definition of an "excellent" design. Compared to our other designs we feel that the sliding valve is the most likely to meet our client's needs and provide the function we intend our device to

serve. We believe in our ability as a team to fabricate this device at a scale larger than the operating environment, but in the future, our design could be scaled-down to the necessary size requirements for the female oviduct.

2.2 Final Design

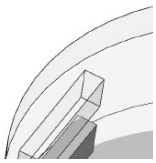
2.21 Valve Mechanism

The sliding valve mechanism is depicted in Figure 7. It consists of two circular discs with a diameter of 5.5 inches, and a sliding plate positioned in between. All three components have 1 inch diameter coaxial holes through which the egg can pass when the valve is open. To close the valve, the sliding plate is moved so the holes are no longer aligned. When the valve is closed, egg passage is not permitted and the woman is temporarily infertile. The top and bottom discs are supported by a series of rectangular pieces positioned in between the discs and around the sliding plate, which also guide the movement of the sliding plate when the valve is opened or closed. To control valve movement, the sliding plate has a push-push latch mechanism housed in the gap on the right side in the figure, and two tension bands connected to the left side (not pictured).When in the open position, the push-push latch mechanism is engaged with the strike, holding the sliding plate in position to the far right. When a force is applied toward the direction of the strike, the latch disengages, and the tension bands pull the plate into the closed position.. To open again, a force in the same direction will overcome the force of the tension bands, and push the plate towards the strike until the push-push mechanism engages. The holes will then be aligned.

The prototype was made at a scale ten times larger than the required size of the actual device. This scale is justified because the push-push mechanism we purchased to operate the device is 2 inches long, and the material used (acrylic) is brittle and cannot be machined at dimensions on the order of 1 millimeter. The to-scale device would utilize a mechanism made to appropriate dimensions (not purchased) and be composed of Teflon.

2.22 Solenoid System

In order to create movement without using ferrous materials, we utilized an induced current. According to Faraday's law, a change in magnetic flux induces a current in a closed coil of wire; this relationship is displayed in Equation 1. When the flux is varied, the amount of induced current in the closed coil changes. The change in current generates a magnetic force shown by Equation 2. By Lenz's law, the induced magnetic field, and magnetic force, will be oriented in the direction opposite of the applied magnetic field and force.[11]



(1)

(2)

To utilize the concepts described in Faraday's law, we will power an external coil using alternating (AC) current. This creates a high magnetic flux which will induce current in a smaller, short-circuited coil positioned on the sliding plate of the device. This allows us to actuate the valve from outside the body. The block diagram of the setup is shown in Figure 8.

We were unable to obtain an external coil large enough to carry the current required by our set-up. The length of copper wire required to make an adequate coil is outside of our budget. In addition, the practice of winding a coil which performs ideally is beyond our expertise. Pre-made coils are available but extremely costly. To overcome these difficulties, we borrowed Macalaster air core solenoids from Madison West High School to conduct testing. These coils are constructed using 540 turns of 16 gauge wire; they are 16.5 cm long with an inner diameter of 4 cm. They were not well-suited for our needs, however they were sufficient for experimental testing purposes.

2.3 Fabrication

A 12” x 12” x 0.472” square of cell cast acrylic was acquired from Grainger. The top and bottom discs and sliding plate were milled on an Eisen Mill in the COE student shop. The discs were finished on a Sharp lathe. The seven rectangles used to separate and support the top and bottom discs were drawn on Adobe Illustrator CC and cut on an Epilog Mini Laser Cutter.
The pieces were affixed with Loctite epoxy for plastics, clamped, and allowed to cure.

2.4 Testing

2.41 Valve Mechanism

We used the MTS Criterion to determine the forces required to engage and disengage the push-push mechanism we utilized on our sliding plate. This allows us to measure how much force we need to generate using the solenoid system in order to achieve actuation. The set-up is depicted in Figure 9.

We conducted a SolidWorks force simulation on the weakest component of our design, the 1.25”x 0.472”x 0.25” rectangle used to separate the discs. This piece is the smallest in dimension, and will come into direct contact with the sliding plate when it is pushed open. We simulated a force of 6 N being applied to this component, in the same direction that the sliding plate would apply a force during device operation.

2.42 Oviduct

The insertion of a device within the human body justifies a need to test if the body can withstand the stresses imposed by the device. The area of concern for our project was the female reproductive system, specifically the oviducts, where our device would be inserted. We calculated the tensile strength of a single wall of a bovine oviduct tissue in order to see if our device would damage the tissue when a force is applied to move the sliding plate. We obtained an entire bovine reproductive system and removed one oviduct. We cut the oviduct longitudinally in order to test a single layer of tissue shown in Figure 10. We stretched this tissue over a square frame with a cross sectional area of 7.6 cm^2 in order to perform low force and high force tests with the MTS Criterion. The low force testing was conducted by lowering the crosshead of the MTS at a constant displacement of 2 mm/s. The resultant force of the tissue onto the crosshead was recorded throughout testing. The high force test was done by manually lowering the crosshead while recording the resultant forces.

2.43 Solenoid System

Due to the need for high electrical current in the coil, an extensive testing protocol was developed to ensure efficient and safe testing. Testing was always done with one other team member present or in the presence of a supervisor. A Variac autotransformer provided by Professor Amit Nimunkar allowed us to control the amount of voltage was supplied to the coil. We varied the amount of current flowing through the coil which in turn varied the magnitude of the magnetic field generated by the coil. The configuration of the Variac and the primary coil is shown in Figure 11.

We initially tested with a main power coil and a short-circuited coil. We hung the short-circuited coil using string near the axis of the power coil and tried to observe repulsion caused by the opposing magnetic fields. We then tested with the main power coil and ferrous but non-magnetic materials instead of the short-circuited coil. Ferrous, non-magnetic materials are safe for use in the body, albeit not near MRI devices.

To test how much electromagnetic force we generated using the set up with ferrous materials, we set up a balance initially at equilibrium. Both sides of the balance contained a ferrous material. One side of the balance was set up over the coil, and when the current was turned on, the balance would be thrown off equilibrium due to the magnetic force. We then restored equilibrium by adding weights to the other side of the balance. The resulting magnetic force is equal to the gravitational force of the added weights.

3. Results

3.1 Valve Mechanism

The Using the MTS, we were able to observe a required value of about 5 N to engage the push-push latch mechanism and about 3 N to disengage the push-push latch mechanism. These results were approximate as there were small oscillations in force measurements.

Using the SolidWorks simulation we obtained a maximum stress of 0.084 MPa which can be applied to the retaining rectangle. The simulation is shown in Figure 12.

3.2 Oviduct

Following our testing of the bovine oviduct using the MTS Criterion, we were able to conclude that the oviduct tissue would be able to withstand the added stresses of our device. Using low force testing we calculated a maximum stress of 96.23 Pa resulting in a maximum displacement of 30.13 mm and a maximum force of 7.431 N. Using high force testing, we measured a maximum stress of 368.42 Pa with a maximum recorded force greater than 28 N. Due to the great oviduct tissue strength, we were unable to observe a measurement of failure stress of the bovine oviduct tissue.

3.3 Solenoid System

Following the testing procedure, we varied the amount of applied voltage supplied to the coils and measured the resultant forces. The relationship of the force and voltage are shown in Figure 13.

4. Discussion

4.1 Valve Mechanism

The values measured by the MTS to operate the push-push latch mechanism can theoretically be generated by our solenoid system. However, we were unable to observe such forces. This is discussed further in later sections.

The SolidWorks analysis generated a minimum factor of safety much larger than necessary. We are pleased to see that our device can withstand the forces imparted by operation.

4.2 Oviduct

We discovered that the oviduct is extremely flexible and strong as we were not able to observe failure even though we applied over 360 Pa of pressure. The observed forces are substantially larger than any force imparted by our device. The oviduct would not be harmed by the actuation of our device.

4.3 Solenoid System

Prior to testing the coils, we calculated the theoretical force that can be generated using Equation 3.[10] We plotted the theoretical force possible based on the different voltages we tested the solenoid system at which is shown in Figure 14.

(3)

Where u_0 is the magnetic constant, N is the number of winds (540), I is the calculated current using ohm's law, A is the area of the coil (using diameter 4 cm) and L is the length of the coil (16 cm). As shown in Figures 13 and 14, both the theoretical force and the generated force we obtained experimentally both follow a linear relationship with applied voltage. However, the theoretical force is magnitudes larger. This is caused by the poor quality of coils we have as it was not able to handle the high amount of current and got very hot due to heating. We suspect the difference in produced force and the theoretical force comes with the heat loss we observed. We also integrated the solenoid system with the valve mechanism. Figure 15 shows a free body diagram of our sliding plate and the forces imparted to determine the coil forces required to overcome frictional forces and the retaining force of the push-push mechanism. Based on our calculations the coil force must exceed 6.42 N to close the valve.

Using this data, and plugging a force of 6.42 N into Equation 3, we would theoretically, with an ideal coil, need a current of 26.25 A and a voltage of 22.55 V.

Although we both did the calculation of magnetic force needed to move the sliding plate along the disc, and observed the movement of the sliding plate, we did not perform the exact calculation as it involves complex integration over both the flux area as well as the magnetic field axis.

5. Conclusion

We discovered that the oviduct can withstand the electromagnetic force required for actuation of the device without harm or failure. Through observation of the tissue's ability to stretch, we also believe that the oviduct could be stretched over the housing of the device as a method of implantation.
We successfully observed movement of the sliding plate across one of the discs when a magnetic force was induced on the ferrous materials used. Due to the time and supply constraints, we were not able to achieve the goal of utilizing a short-circuited coil inside the device for MRI compatibility. However, the device is still safe in the presence of a stable magnetic field, as the ferrous, non-magnetic materials we used are only actuated when in the presence of alternating flux.

The experimentally determined solenoid forces were significantly lower than theoretically calculated values. We observed extensive heat loss through the solenoid during testing and believe most of the energy was dissipated as heat. Theoretically, a suitable coil should be able to operate the push-push mechanism using electromagnetic flux and a shorted coil, however, we were not able to do so due to a lack of proper equipment. With these results, we are optimistic that with better coils (both primary and shorted) and further study, successful repulsion of the shorted coil and primary coil could be observed.

5.1 Future Work

5.11 Material Selection

The FDA is currently updating its guidelines for review of medical devices. According to the guidelines, 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."[12] Extensive testing is required by the FDA for novel materials. Proven materials may have fewer requirements for device approval.

It would be beneficial to look into previously approved medical devices and their material composition to select appropriate materials. Companies such as Gore medical have several medical devices that have garnered FDA approval and have a long-term history of use in the body. Three materials used by Gore are polytetrafluoroethylene (PTFE), Polypropylene (PP), and polyester (PET).[13] Other aspects that need to be taken into consideration during our material selection process include finding a coating to ensure water-tight performance and smooth passage of an egg through our device without adhesion to the walls of the valve.

5.12 External Controller and Operating Mechanism

We used ferrous, non-magnetic materials in order to observe movement caused by an induced current from an external solenoid. In order for our device to be inserted into the human body and to be MRI compatible, a non-ferrous system is required. A possible solution involves the use of short circuited coils. We were unable to observe useful results with short circuited coil system. This concept merits future study.

5.13 Physiological Issues

After selecting an appropriate biocompatible material, we need to take into consideration the oviduct fluid viscosity and the possible effects of it on our valve. In order to better understand the movement of egg and sperm inside the oviduct, we would like to create a mathematical model that studies these kinetics.

Many physiological repercussions could be induced by the insertion of our device into the oviduct of a human. Extensive research on the interaction of our device with biological processes should be completed. Further research and testing is needed to mitigate any additional risk of ectopic pregnancy or other fertility issues due to the use of our device.

Further research regarding the possible side-effects of induced electromagnetic fields inside the body should be conducted. Specifically, the magnitude of magnetic field that can be applied safely without disrupting normal heart function should be determined. Scaling down the prototype to actual size would reduce the magnitude of force required, but these forces could still impart harm on the human body.

5.14 Fabrication

Following the partial completion of our prototype, further fabrication is required before further testing can commence. Due to the late arrival of the strike for our push-push latch mechanism, we were unable to include it on our prototype. The push-push latch mechanism should also be positioned and attached to the prototype. Another fabrication process that we wish to complete is the insertion of tension bands or springs on the part of the housing that is in direct contact with the sliding plate in order for the sliding plate to move between the open and closed positions.

Finally, the prototype needs to be scaled down to size in order to function in the proper operating environment. The hole in the discs and sliding plates needs to be 194 um to accommodate the passage of a blastocyst.[14] This fabrication step would likely require outsourced manufacturing as we would not be capable of machining components on this order of magnitude.

5.15 Testing

Once our prototype is completed, we wish to conduct further tests in order to test the function of our device. We would have liked to test our device by inserting it in a hose and connecting it to a water supply. If the valve, when in the closed position, can completely stop the flow of water, then we know that the valve will be effective in stopping the egg and sperm inside the body. Finally, we will test each component of the device to its point of failure to ensure the device will safely withstand the rigors of being within a woman's reproductive system. We wish to test this valve at many orientations in order to ensure its successful operation when the body is positioned in different ways.

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7. Appendix

7.1 Product Design Specifications (PDS)

Developing a reversible contraceptive device
Product Design Specifications

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Function:
Current technologies for female contraception often require the intake of pharmaceutical agents or invasive surgeries. These chemicals can cause side-effects such as: headache, uterine bleeding, nausea, breast tenderness, abdominal pain, mood changes, and increased risk of vascular problems, liver disease, or high blood pressure (Bayer HealthCare Pharmaceuticals, 2001). Mechanical surgeries can lead to scarring and usually involve ligation, which causes permanent infertility. Ultimately, a female should be able to choose when to be fertile or infertile without the use of hormones.

The device should provide non-permanent, or reversible contraception to allow a woman to control her fertility. Our initial design involves a valve consisting of biomaterials that can be integrated into the reproductive system. Although not a high priority, another goal is to be able to suggest suitable materials for this device. The primary goal of our project is to design a valve that can be controlled from outside the body. One possible design is to construct the valve using an electromagnetic material that would utilize two coils to induce current, creating a magnetic field that can be harnessed to open and close the valve.

Design requirements:

1. **Physical and Operational Characteristics**
a. Performance requirements: Due to the nature of the placement of this device in the female reproductive system, there are many physiological and functional constraints that we must take into consideration. The first item that we must factor in is the sensitivity of the reproductive system. Because we are looking to incorporate a mechanical system into the biological system of the body we must make sure not to damage the fallopian tubes. This calls for a material that can withstand the rigors of being in the human body, as well as work with the body without causing destruction or unnecessary stress. It must be able to withstand uterine contractions during childbirth in addition to daily biological activity. This device must be able to open and close an indefinite number of times to control the female's fertility, providing a high level of contraceptive efficacy when elected to do so.
b. Safety: Because the device will be implanted in the human body, many safety precautions must be considered to ensure proper functionality without imposing unnecessary stress on the reproductive system. There are three key concerns involving the device: implantation in the fallopian tube, the lasting effects of having the device in the body, and the moving mechanical parts within the device.

The first major hurdle comes with physically implanting the device. Currently many of our designs involve first cutting the fallopian tube, and implanting the device between the two ends of the cut fallopian tube, effectively connecting it again. The challenge of this is twofold. First the surgery itself must be performed so that permanent infertility is not caused. Second the device must be able to be implanted onto the fallopian tube snugly so that it does not move out of place.

Once in the body, the device cannot cause any long term harm to the reproductive system. Primarily, a material that is compatible with the biology of the reproductive system must be used so that the fallopian tube can grow around the device. Secondly, the device cannot involve any materials toxic to the body that could lead to sickness or permanently inhibit fertility.

The last concern is the fact that a mechanism involving a ferrous material would prevent use of an MRI because of the powerful magnetic fields in an MRI room and distortion of the MRI image.

c. Accuracy and Reliability: Once installed, the effectiveness of this device should near 100%. In other words, the women will not be able to get pregnant while the valve is closed. Also, the device will not interfere with her fertility when the valve is open.

d. Life in Service: The device should not require replacement once implanted. Therefore, the mechanism must last as long as the female is capable of reproduction. The device may be in service for up to 40 years.

e. Shelf Life: Conditions for storage prior to implantation depend on the materials the device utilizes. The shelf life of our device should be 5 years. Based on comparable devices, It's likely that hospitals will use the device within 6 months. Our device will not be composed of oxidizing metals, therefore rust will not have an impact on the duration of the shelf life.

f. Operating Environment: Our device will be operating in the fallopian tubes of a woman, both of which have a very small, irregular diameter. Each fallopian tube is roughly 10 cm in length and 1cm in diameter. The device will have to operate under body temperatures, around 37 °C. Within the fallopian tube are 3 different sections which serve different functions but overall work to unite sperm with egg for fertilization. The second segment, the ampulla, becomes more dilated in diameter due to it being the key spot for fertilization [1]. This dilation in diameter requires our device to be able to expand with the fallopian tube so it does not get dislodged. During menstruation, uterine contractions are low in pressure, around 30 mmHg. The device must be able to withstand pressures up to 200 mmHg during labor contractions.

g. Ergonomics: Due to our device being located in the fallopian tubes, it will not be involved in outside interactions. The only interaction of the device with humans will be during surgical insertion of the device into a woman's fallopian tubes. The device should be composed of materials that will be durable and not be at risk of damage during limited interaction with humans.

h. Size: The device must not greatly exceed the size of the woman's fallopian tube. Not all fallopian tubes are the same size and thus testing would need to be done in order to see the limitations of size for the device for the particular patient. The average size of the device will be roughly 4 cm in length and 1.5 cm in diameter. The only way the device may be accessed for maintenance will likely be through surgical procedures.

i. Weight: Each valve should have minimal weight, less than 30 g, due to the sensitive environment it would be placed in, inside of the Fallopian tube of female human body. Excessive weight may result in the sagging of the fallopian tube and dysfunctions of the device itself as well as other unwanted effects.

The device would achieve optimal weight when the subject doesn't feel or detect the presence of it inside the body, as well as not affecting (or altering) any regular function of the female reproductive system, especially the fallopian tubes.
j. Materials: The device must be composed of non-ferrous metal materials in order to be compatible for both MRI machine and CT scan. The use of copper exposed to tissue should be avoided due to its non-reversible contraceptive properties [3]. The materials exposed to tissue, such as the case and lumen, must be biocompatible, pharmaceutically inert, nontoxic, sterile and most importantly, must be able to function in the environmental condition of Fallopian tubes.
k. Aesthetics, Appearance, and Finish: Finish should be effective for sliding to open and close the egg passage and have no harm or any long term effect on the women's reproductive system. The device should have a smooth finish with rounded corners and no sharp edges that might damage tissue.

2. **Production Characteristic**s
a. Quantity: Two units are needed per individual
*b. Target Product Co*st: The cost of production should be targeted around $50 per unit, with two units required per individual.

3. **Miscellaneou**s
*a. Standards and Specificatio*ns: FDA approval of the device is required to test on human.
b. Patient-related concerns: Materials must be non-toxic and biocompatible. Any metals used must be hypoallergenic.
c. Competition: There are several contraception methods available. Many strategies such as oral contraception, contraceptive vaginal ring, and transdermal patch rely on hormones to prevent conception [2]. There are fewer nonhormonal contraception options available. ParaGard is an intrauterine device that is thought to prevent sperm from reaching the egg. It diffuses copper as an additional contraception source. Finally, Essure is a non- surgical, non-hormonal, permanent contraception method that is implanted in the fallopian tubes.

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7.2 Timeline Evaluation

A timeline of the design process over the course of the semester is shown in Table 2 below. The highlighted boxes are the projected schedule that was created at the beginning of the semester. The "X's" represent events that occurred during each week.

Table 2. Semester Timeline

	September	October	November	December										
	9	16	23	30	7	14	21	28	4	11	18	25	2	9
Project Development														
Research	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Brainstorming		X	X	X		X	X		X		X			
Design Matrix			X	X	X									
Final Design					X									
Order Materials											X	X		
Fabrication								X	X	X		X	X	
Testing											X		X	

There were some deviations from the proposed schedule throughout the course of the semester. Fabrication took longer than expected and this is highly due to complexity of machining device components.

7.3 Cost Analysis

Table 3. Itemized Expense Report

Product	**Quantity**	**Supplier**	**Total Cost**
Grab Catch, Push-to-open spring	1	Grainger Industrial Supply	$9.30
Clear Cell Cast Acrylic Sheet	1	Grainger Industrial Supply	$21.07
Grab Catch, Pull-to-open spring	1	Grainger Industrial Supply	$3.30
Strike for Wood	1	Grainger Industrial Supply	$14.05
Totals	4		$47.72

Our project budget was one hundred dollars. Our total expenses were significantly lower than our allotted budget, totaling $47.72 as seen in Table 3. Our budget influenced our prototype material selection. We opted for acrylic as PTFE was cost prohibitive. Frugal management of our finances leaves funds for design modifications in the future.