Developing a reversible contraceptive method

Mid-Semester Report
October 9, 203

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Abstract

In today's society, there exists a need for the improvement of maternal health. One component of accomplishing this goal is the achievement of universal access to 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 and allow her to control her fertility via an external controller.

This external controller will allow the woman to open and close a valve within the device, which will allow or disallow passage of gametes. Four designs were explored during the research phase of our project: an iris valve, a shape memory polymer valve, a leaflet valve, and a sliding valve. These four designs were evaluated based on the following: contraceptive efficacy, biocompatibility/safety, purchase cost, reliability, and feasibility of fabrication. Since our device needs to have a service life of the woman's reproductive years, biocompatibility is one of the two most important factors to consider; the other is contraceptive efficacy as this is the primary function of the device.

After scoring each design in a design matrix, the sliding valve design received the highest overall rating. The sliding valve utilizes a funnel to guide the egg up to a disc. The disc has a hole in it with a sliding plate behind it, which is controlled externally. When the plate covers the hole, the woman is infertile, and once the plate is slid to uncover the hole, her fertility returns.

The current plan is to control the sliding plate by inducing an electromagnetic field. However, further research into possible materials as well as mechanisms must be completed before proceeding with this idea. In addition to researching materials and external controllers, we must complete fabrication of a prototype, which will undergo testing to ensure that the components function correctly and that the device will serve its purpose.

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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.[1] 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.

Background

Client Description

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

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]

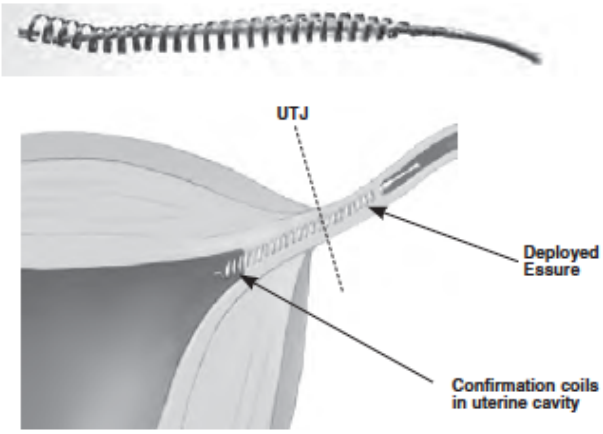


Figure 1: Essure insert and placement.

Current Devices

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.[4] 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 1 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.[5] It is thought to prevent conception by preventing the sperm from reaching the egg. Additionally, it diffuses copper, which has contraceptive properties. Figure 2 illustrates the placement of ParaGuard.

Figure 2: ParaGuard contraceptive device placement.

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 nonferrous materials.

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.

Design Alternatives

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.

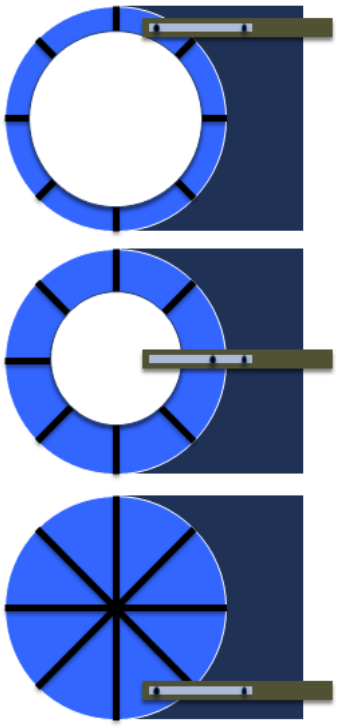
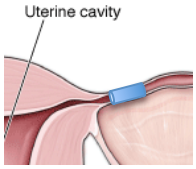


Figure 3: Iris valve in open, partially closed, and closed positions. Created in Microsoft Office.



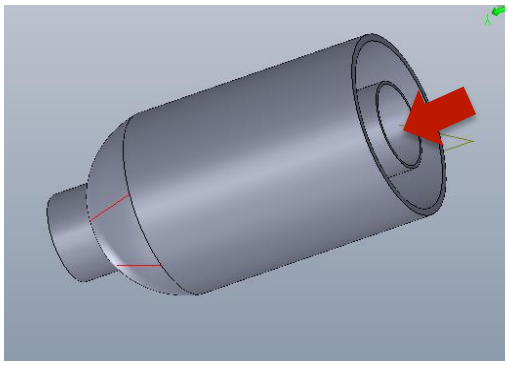


Figure 4: Leaflet valve cutaway view and placement.[6] Created in Solidworks.

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.

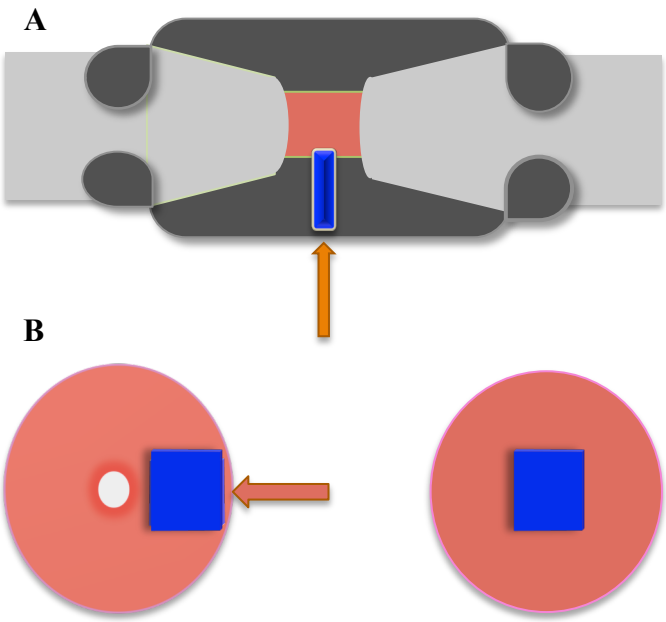


Figure 5: A) Side view of sliding valve. B) Transverse cross-sectional view of sliding valve. Open position (left) and closed position (right).

Sliding Valve

The sliding valve is illustrated in Figures 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. This design instead functions based on the properties of shape memory polymers. The properties in particular include the ability of these polymers to change shape due to an induced magnetic field. This magnetically induced shape memory effect incorporates magnetic nanoparticles and inductive heating of these compounds in alternating magnetic fields.[7] The design would work by incorporating two different shapes of the shape memory polymer and then inducing a change in shape with an externally applied magnetic field.

Figure 6 shows the two different shapes of the device in relation to their contraceptive function. 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 whenever a magnetic field is induced. This device may not be MRI compatible due to the shape changing properties of the material in the presence of a magnetic field.

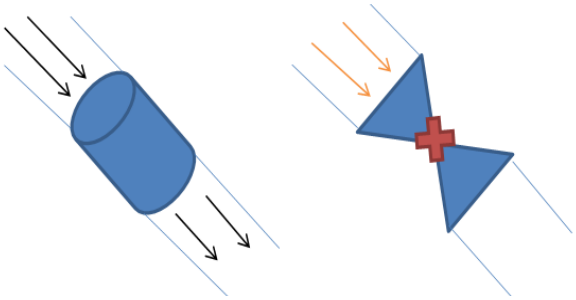


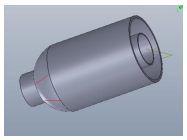
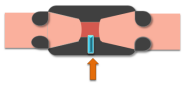
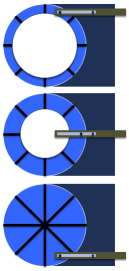
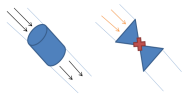
Figure 6: The open (left) and closed (right) states of the shape memory polymer valve. The shape on the left allows free passage of egg and sperm through the valve, and the woman is fertile. The shape on the right is similar to an hourglass shape. The passage of egg and sperm is blocked and the woman is infertile. Created in Microsoft Office.

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 in the following sections.

Table 1. Reversible Contraceptive Design Matrix

Parameters (Weight)	**Leaflet Valve** 	**Sliding Valve** 	**Iris Valve** 	**Shape Memory Polymer Valve** 
Contraceptive Efficacy (35)	(4) 28	(4) 28	(4) 28	(3) 21
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

Design Matrix Criteria

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 fast the material will degrade, and how long it can stay within the body. 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 degrade 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.

Summary

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.

Future Work

Material Selection

The FDA is currently updating its guidelines for its 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".[8] 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 to previously approved medical devices and their material composition to select our 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).[9]

External Controller

We must create an external controller that can induce an electromagnetic field, which will act as a switch for the valve while it is implanted in the body. We currently do not have a final design for this external controller; however, we are actively researching possible ways to utilize electromagnetic fields to move a non-ferrous sliding plate.

Testing

Due to the complexity of the design, which involves the coordination of many factors, extensive testing is needed prior to the completion of our device. Of the components we must test, the mechanism controlling the sliding plate is a priority. First, we must verify that the plate will move when is triggered by an external controller. Second, the plate must be held firmly in place by the detents once in the desired state. Third, the plate must be able to create a watertight seal when closed. The third test will be the most difficult to pass, however it is the key to contraceptive effectiveness. We plan to build a prototype valve and test it by placing it in a hose that we will send water through. 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.

Projected Cost

Our projected prototype fabrication cost is expected to be under the $100 allocated budget. Before any purchases are made, we need to determine the scale to which our prototype should be fabricated. Optimally, the final device is to be placed inside a fallopian tube with a diameter of approximately 1 cm. However, it may not be feasible for us to fabricate our prototype on this small scale. Once we have established a feasible scale, we will have a better understanding of what our projected cost will be. Many materials are available from McMaster-Carr. In the future, we will come up with a method of cost analysis for materials under consideration for the fabrication of the sliding valve.

Timeline

The design we will be pursuing needs to be finalized this week. Promptly after finalization, we will order materials. Prototype fabrication will begin the third week of October. Testing needs to be completed a week prior to the final presentation date, December 6th. This is summarized in Table 2. Filled boxes correspond to the projected timeline. X's indicate the task was worked on or completed.

Table 2. Projected Timeline

Tasks	Sept				Oct				Nov				Dec	
	9	16	23	30	7	14	21	28	4	11	18	25	2	9
Meetings														
Client	X													
Advisor	X	X	X	X										
Team	X	X	X	X										
Project														
Research	X	X	X	X										
Brainstorming		X	X	X										
Design Matrix			X	X										
Final Design														
Order														
Fabrication														
Testing														
Deliverables														
Progress Reports	X	X	X	X										
PDS			X											
Mid-Semester				X										
Mid-Semester														
Final Report														
Final Poster														
Website Updates	X	X	X	X										

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Appendix

A. Product Design Specifications (PDS)

Revised: 9/29/13

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.

Client requirements:

- Utilize a valve to implant in the fallopian tubes
- Valve should open to enable fertility and close to prevent conception
- Valve should be controlled remotely from outside the body
- Withstand contractions during childbirth
- Prevent sperm from passing through 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 1 cm 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 (Schnatz, R. H. 2012). 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 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. 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 (Trussell, 2007; WHO, 2007).

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*

Two units are needed per individual. Quantity demanded for production will be defined later in the process.

b. *Target Product Cost*

The cost of production should be targeted around $50 per unit, with two units required per individual.

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.

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 (Sitruk-Ware, 2013). 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, nonhormonal, permanent contraception method that is implanted in the fallopian tubes.

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