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Abstract

Tubal Sterilization is a relatively inexpensive and effective form of birth control. By physically altering the fallopian tubes, the pathway of the egg from the ovary to the uterus is interrupted, thus insuring against fertilization. This project deals specifically with a laparoscopic device, which makes the procedure minimally invasive.

The device currently used by our client, Dr. Thomas Julian, secures a band around the fallopian tubes, closing the tube to block the egg's pathway. Dr. Julian is unhappy with this device because it often tears the tube and misfires the bands. He asked us to address these issues when we redesign the device.

We developed three preliminary design alternatives and have evaluated them based on the needs of our client. Once consulting with our client, we selected one design alternative to pursue, made an enlarged prototype to test the fundamental concepts of this design, altered the design and prototype, and presented it to our client at the end of the semester.

Introduction

Tubal Ligation is a surgery, and although it is minimally invasive there are risks and chances for complications. With the current product complications occur up to 20% of the time, which is far too high in a surgical procedure. The fallopian tube where the procedure occurs can be torn and damaged. This causes excess bleeding, and scar tissue to form inside the patient. It also reduces the chance that the surgery could be successfully reversed, since more of the fallopian tube was damaged. Other problems with the current product include misfiring of the device itself. The procedure involves placing a rubber band over the fallopian tube to create a mechanical blockage, but sometimes the rubber band does not come off or two are placed on the same fallopian tube. If the latter occurs, the doctor has to take out the device and load a new rubber band on it. This makes the procedure last longer and requires more work of the surgeon. These errors need to occur less frequently in order to decrease time spent in the operating room and reduce risks for the patient.

I. Current Products

Tubal ligation is a fairly common procedure, done approximately one million times each year. All procedures are reversible to some extent, though, if the fallopian tube is severed or otherwise damaged, the reversal becomes much more difficult. There are many different procedures that all produce the same desired result. All are laparoscopic surgeries, which use a small incision to insert a camera into the abdominal cavity in order for the surgeon to watch what he is doing with a second device that alters the fallopian tube (4). This device is inserted through a second hole. The procedure is usually done on the fallopian tube, which connects the ovary to the uterus in females. All of the procedures create a physical or mechanical blockage to the fallopian tube, which makes it so the eggs cannot reach the uterus for fertilization. Some versions are the Pomeroy technique, coagulation, clipping, or banding (1).



Figure 1: The Pomeroy technique (1).

The Pomeroy technique (as seen in Figure 1) is a common version where the surgeon ties off a section of the fallopian tube and removes it. The ligature that binds the two sides of the fallopian tube together eventually dissolves and tissue covers the two sections. There is no longer a connection between the uterus and the ovaries (1).



Figure 2: The coagulation technique (1).

The coagulation technique, as shown in Figure 2, is arguably the most common version of tubal ligation in the United States. A forceps grasps the fallopian tube for this procedure and passes an electrical current through the tube between the two ends, cauterizing the tissue. The fallopian tube can then be snipped in two (1).



Figure 3: The clipping technique (1).

Clipping, as shown in Figure 3, is yet another form of female sterilization. It is easier to reverse than the previously mentioned techniques and involves placing a spring clip on the fallopian tube, creating a mechanical obstruction (1).

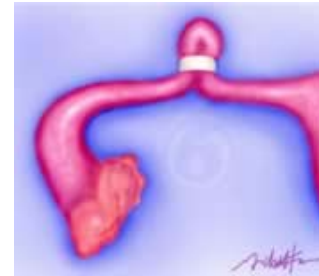


Figure 4: The banding technique (1).

The last technique, which is the one the client would like us to improve, is the banding technique (shown in Figure 4). For this procedure the fallopian tube is mechanically obstructed with a band. The fallopian tube must be brought through the band to be closed off (1).

The current (and only known) banding product is produced by the ACMI Corporation. The device is called the Falope-Ring band (shown in Figure 5). It is usually a one time use device that costs roughly \$400 for the device and band combination. The forceps (pointed out with the arrow) grab the fallopian tube and pull it inside the cylindrical column of the device. The bands are pushed off with a spring mechanism (one at a time) and slide onto the fallopian tube, sealing it off, and preventing eggs from transverseing the tube to the uterus. The pinchers then release the fallopian tube and the procedure is completed. It is designed to allow loading of two rubber bands simultaneously, one for each tube, so only one insertion in the abdominal cavity is required (2).



Figure 5: The Falope-Ring band, produced by ACMI Corporation (2).

II. Client Design Requirements

The device we are designing should perform easily reversible laparoscopic tubal sterilization in women. The device should be sterile because it will be inserted into the human body. Additionally, any portion left inside the patient, such as a band or a clip, must be as inert as possible, to minimize side effects of the procedure. The device should be less traumatic than the current device. Ideally, it will not tear the fallopian tubes during the

procedure. The device must work with the existing trocan; therefore, it cannot exceed 8mm in diameter. The device will also have a better success rate than the current device, which fails 20% of the time (3).

III. Design Alternatives

Scrunchie Design

This device, shown in Figure 6, consists of a handle, a long column that will extend into the body, the securing mechanism, and the band-releasing mechanism. The handle will be similar to the current device produced by ACMI. This includes a push function to secure the band and a sliding function responsible for releasing the band, made of silicone elastomer, onto the fallopian tube. The column section that extends into the body is approximately 40cm long, 8 mm in diameter, hollow, and composed of stainless steel.

The securing mechanism operates using a small vacuum that will grab the fallopian tube. The band-releasing mechanism uses four “fingers” that initially protrude from the device straight. When extended halfway, the fingers bend, holding the band securely. When the fingers are extended completely, they straighten, releasing the band. At this time, the surgeon should release the vacuum by releasing the push function.

There are several advantages to this design. The handle is similar to the current device used, meaning that surgeons will not have to learn a new skill set to perform the surgery and will thus be more likely to use the device. The vacuum mechanism of securing the fallopian tube will be less traumatic on the tube. The method of releasing the band onto the tube will also be more reliable than the current device.

There are several disadvantages to this design as well. Although the vacuum mechanism will be less traumatic than the pinchers used in the current device, this mechanism still involves securing the fallopian tube within a small area, so there is still some risk of the tube tearing. The design of the fingers is also more complex, which may lead to difficult construction and thus, higher production costs. Another disadvantage is that we are as of yet unsure how to simultaneously load two bands.

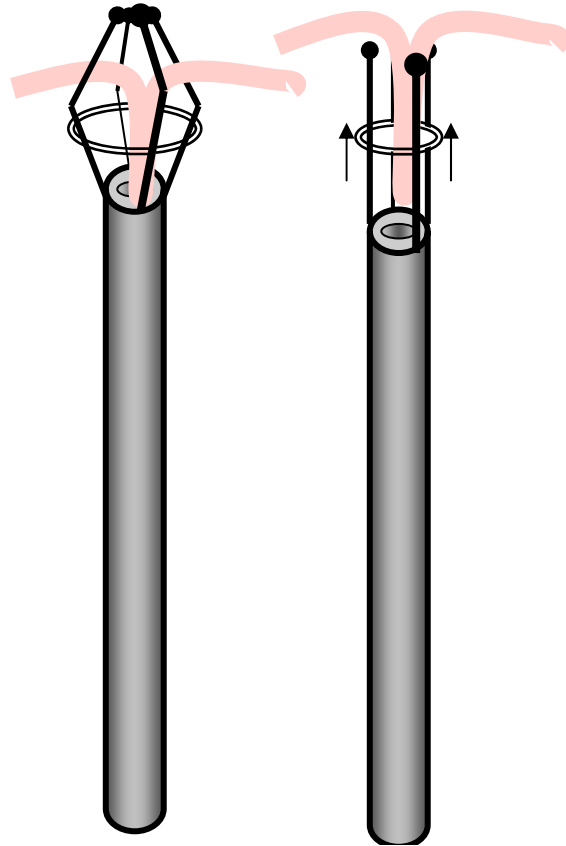


Figure 6: The Scrunchie design. When fingers are bent, band is secured. When fingers straighten, the band is released.

Pressure Cuff Design

This design uses the idea of a pressure cuff that will effectively pinch together two sides of the fallopian tube and allow the rubber band to slide onto it. The pressure cuff will enclose the fallopian tube when it is flacid. Air will then be injected into the cuff, causing the inside and outside to expand and pinch together the two sections of the fallopian tube. The pressure cuff will be manufactured into a cone shape by putting more material on the top than on the bottom. This will push off the rubber band from on the cuff to the fallopian tube, sealing it off. The part that grabs the fallopian tube is a single hook. A straight piece of metal will then be used to enclose it into the hook, trapping it in place. This part will be brought into the lax pressure cuff. When the band is on the tube, the cuff will be deflated and the hook will extend past the straight piece of metal, releasing the fallopian tube. A simplified drawing is shown in Figure 7. The hook and cylindrical column inserted into the abdominal cavity will be stainless steel. The material used in the pressure cuff will be inert plastic or rubber, and the band will be made out of silicone elastomer.

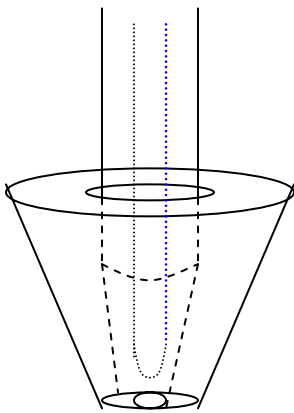


Figure 7: The Pressure Cuff design. Pressure at the top of the cuff forces the band onto the tube.

One of the benefits of this design is the gentler method of pinching off the fallopian tube. By not having to pull it into the small radius of the cylindrical portion of the device, it does not put as much strain on the tube. The grasping mechanism for the fallopian tube is also easier on the tube and will be less likely to cause a tear. This is due to the fact that it is not as easy to pinch it between the two pieces of metal, like in the current device. The band is also easier to disengage by having it slide off the end of the pressure cuff. There are also fewer mechanical parts to this design than in the ACMI version and a spring mechanism will not be required to use, hopefully allowing a smooth transition between the current surgical procedure and this one.

There are also quite a few drawbacks to this design. One difficulty will be to devise a way to allow the inner pressure cuff radius to be bigger than the cylindrical radius to allow less strain on the fallopian tube. Another issue is the mechanism used to inflate the pressure cuff. One idea is to inflate the pressure cuff using air drawn from inside the abdominal cavity. This would also allow a small vacuum to be created and potentially help draw it into the cuff. The pressure cuff could also have to be at a high pressure to push off the rubber band, which could be dangerous if it explodes. A problem could also result from having to load the rubber bands separately causing the device to be taken out of the body. The handle will also be different and the surgeons would be forced to learn a new method.

Metal Coil Design

Our third design alternative is a device that releases memory metal coils around the fallopian tubes. It consists of a stainless steel column containing two memory metal (or alternative memory material) coil strips held in a straightened position by two clamps (shown in Figure 8). The column will have a diameter of 8mm and be 40cm long. The

metal coil will be made of stainless steel memory metal and coated in plastic or Teflon so that there will be less risk of ripping or reacting with the fallopian tubes. When held straight, the metal strips will be approximately 15mm x 2 mm. Each set of clamps will be on a long rod attached to a spring mechanism to push them out of the device. Because the device will already have the metal coils straightened and clamped inside, it will not be necessary for the surgeon to load anything onto the device, as is the case in the current ACMI Falope-Ring bander. The surgeon will insert this device into the woman's abdomen after an insertion hole is created with the trocan. A trigger mechanism will push the first metal coil and clamp out of the device and the surgeon will guide it underneath one of the fallopian tubes. Another trigger will release the coil into its curled position around the tube, pinching it off to prevent eggs from reaching the uterus. The first clamp will be retracted into the device, and the same procedure will be followed to place the second coil onto the other fallopian tube. After both coils are securely curled around the tubes, the surgeon will remove the device from the patient and discard it. It is important that the device is only used once because there is a possibility of contamination due to its hollow form. This procedure may be reversed by clipping both ends of the tube, and stitching the remaining ends together.

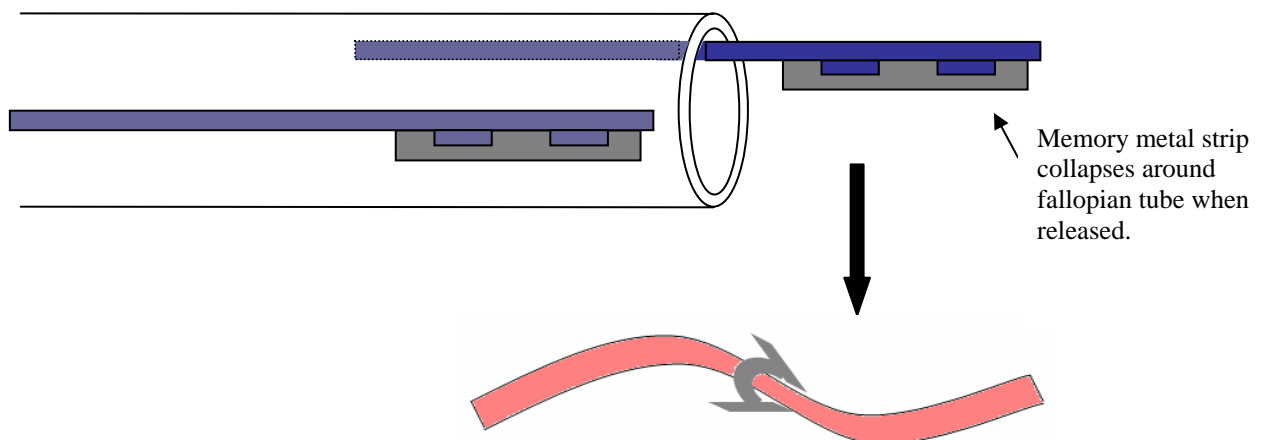


Figure 8: Metal Coil design releases memory metal strip to curl around fallopian tube.

The Metal Coil design has a couple of advantages over the ACMI product. First, it poses less of a risk to the fallopian tubes because it does not bend the tube or pull it into the device. This is an important quality because the device currently being used by our client often rips the fallopian tube as it pulls a folded section into the narrow device. The second advantage is that the design is rather simple. This means that there will most likely be fewer complications in the construction of the device.

The disadvantages of this device are that it is unclear whether the coil will securely block the fallopian tube or that it will injure the tube.

IV. Decision Matrix

To evaluate our designs, we created a decision matrix, as shown in Table 1, to compare several qualities of the designs. It is important that anything left in the body be inert, so we rated this quality out of 10, with 10 being the best and 1 being the worst. Both the Scrunchie and Pressure Cuff designs release inert plastic bands onto the fallopian tube, but the Coil design's memory metal coil may have adverse affects in the body. Another essential aspect of the design is that it must not rip or injure the fallopian tube during the procedure. Because safety is such a large concern, we rated this quality out of 10, with 10 being the best and 1 being the worst. The Metal Coil design presents the least risk to the tube, as it does not fold or move the tube far from its original position. The last quality that was evaluated was the simplicity of use of the device. This was not considered quite as important as the previous two categories, so it was rated on a scale of 5, with 5 being the best and 1 being the worst. Because of its physical design structure, the Pressure Cuff is more complicated than the other design alternatives. Finally, we evaluated the reversibility of each design. Because the procedure is reversed so infrequently, this quality was rated out of 5, with 5 being the best and 1 being the worst. The Scrunchie, Pressure Cuff, and ACMI all use a gentle silicone elastomer band that is relatively easy to remove, thus reversing the procedure. The reversal of the metal coil procedure would be difficult, and require reassembly of the two ends of the tube. We totaled the ratings in the decision matrix, and chose to pursue the Scrunchie design because it scored the highest.

Table 1: Decision matrix

	Scrunchie	Pressure Cuff	Metal Coil	ACMI
Low Risk to Tube (1-10)	8	8	9	7
Material Inertness (1-10)	9	9	7	9
Simplicity of Use (1-5)	4	2	5	4
Reversibility (1-5)	4	3	2	3
Total (4-30)	25	22	23	23

V. Design and Prototype

Initial Design and Prototype

Our initial final design was a modification of the Scrunchie design. We constructed an enlarged prototype, approximately 10x larger than the final device will be. It was supposed to create a small suction to gently secure the fallopian tube by pulling it inside the inner column. It would then extend three "fingers" (see Figure 9) with the rubber bands stretched tight them, near the end. The fingers would then collapse to release the

band around the fallopian tube. In the enlarged prototype the collapsing was accomplished by pulling on three strings on the inside of the wire fingers. The suction would then be reversed so the fallopian tube would be released.

Several factors contributed to the change of this initial design. The fingers could collapse around the tube and causing injury to the sensitive tissue. Another problem that was discovered after testing of the initial prototype was that the bands failed to release properly after the fingers collapsed. These two issues were similar to problems with the current product. Additionally, this design did not provide feedback for the surgeon once the bands had been released, aside from visual cues that are currently used now. Finally, the device would be difficult to scale to size because the fingers failed to collapse reliably.

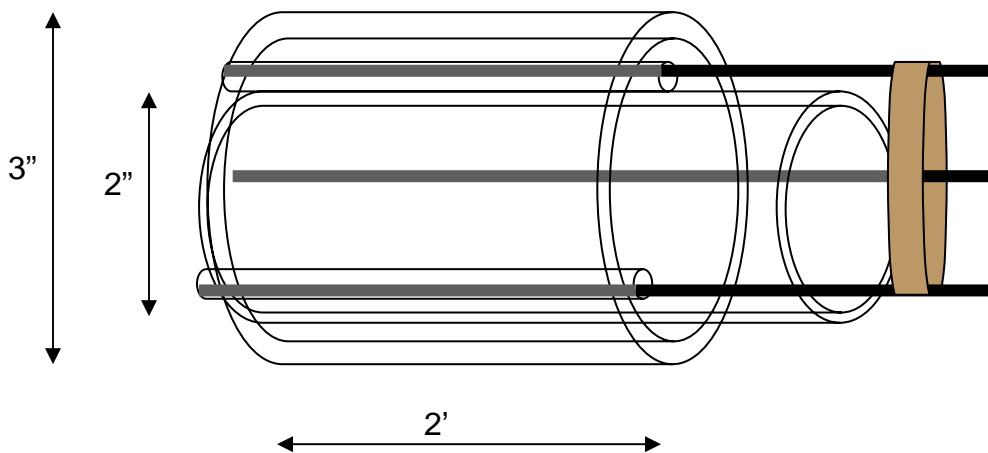


Figure 9: Schematic of the initial prototype with the fingers extended.

Final Design and Prototype

In order to resolve the problems that were encountered in the initial design, certain aspects were changed. The fingers remain an integral part of the mechanism to release the band, but in a different capacity. Instead of their initial purpose, they will slide along the inner tube within grooves and push the bands until they slide off, one at a time. Notches within the grooves provide tactile feedback to the user when each band is released, to prevent double-release or failed-release of bands.

Because the suction mechanism did not cause problems with the initial design, it remains the way the device will secure the fallopian tube. The final prototype did not include a handle because it would have been too large for practical purposes of initial testing. The next, smaller prototype will include a handle similar to the one used by ACMI, as depicted in the figures in Appendix A. Refer to Appendix A for all dimensions and figures of the final prototype.

VI. Ethics and Safety

As with most medical devices, it is necessary to consider their safety and the ethical issues that might arise. It is important that there is a low probability of internal injuries caused by the device. Equally important is the inertness of the material that is left in the body. Before this device is used on humans, much testing will need to be done to ensure safety. The surgeons who perform the procedure must be thoroughly trained so that the device is inserted correctly and no harm is done to the fallopian tubes, uterus, or other organs and tissues. Some religions prohibit all methods of birth control with the reasoning that birth control ends potential lives. It may be against a surgeon's morals to advise a patient to have a sterilization procedure. Another ethical issue to consider is that this procedure is meant to be reversible. If a woman's fallopian tubes are injured or torn, it will be more difficult to completely reverse the procedure. Surgery will be necessary to repair the fallopian tubes. A third issue is that because these procedures are reversible, there is the chance that a pregnancy could occur if the tube is not completely pinched off. If a sperm reaches and fertilizes an egg, the fetus may not grow in the correct position, which could cause serious complications. It is essential that the patient know the risks and possible consequences of the procedure beforehand.

VII. Future Work

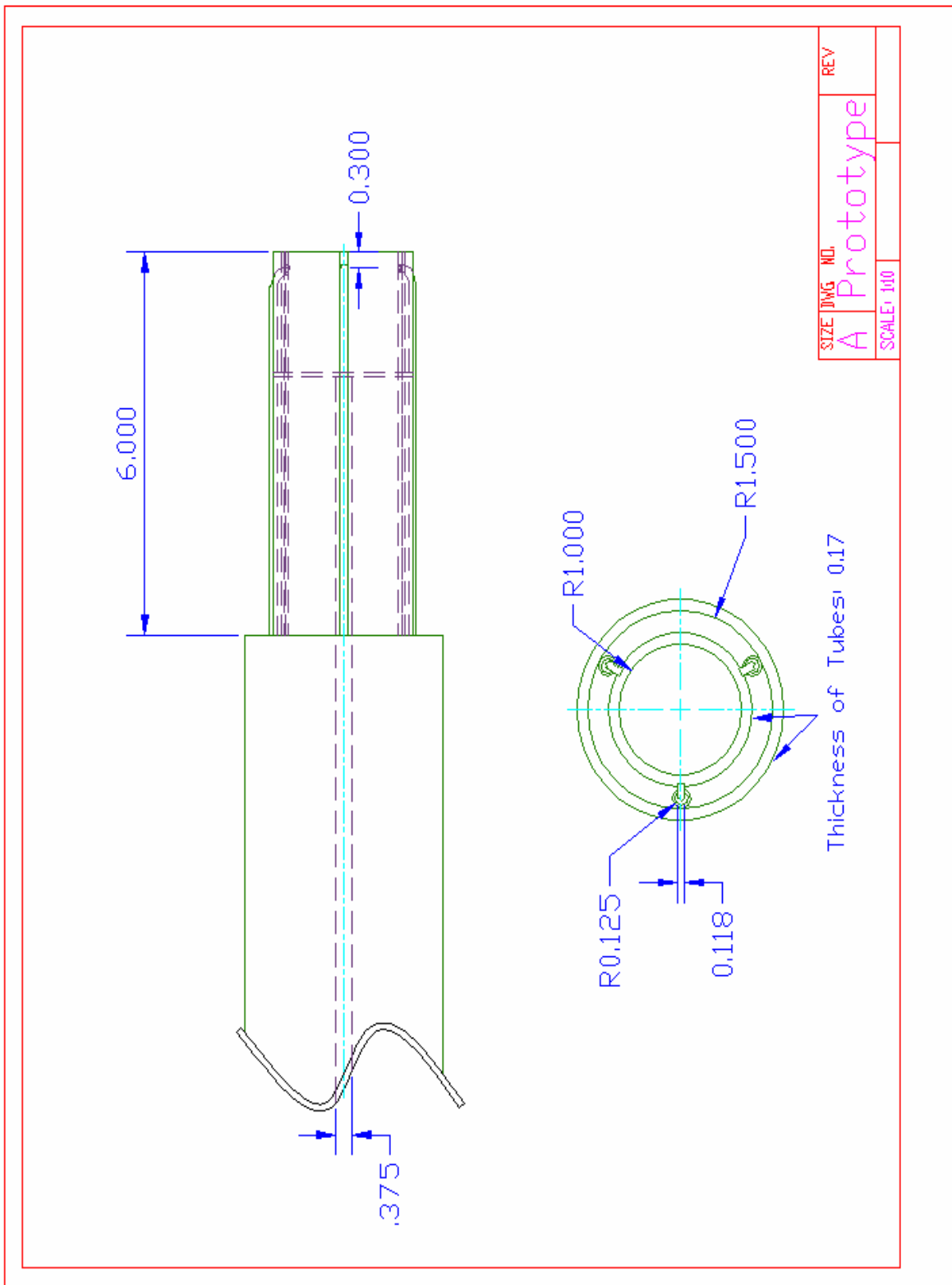
Now that we have completed our first, large-scale prototype, our next step is to begin researching and purchasing the materials that we will use for the 8mm diameter device. These materials will likely include stainless steel tubes, silicone elastomer bands, metal probes to slide the bands onto the fallopian tubes, a syringe mechanism to create a vacuum that secures the fallopian tube, and plastic parts for the handle. We will assemble the smaller device, and do preliminary testing on non-human materials. Throughout the process we will stay in touch with our client for feedback. For additional funds and time, Kailey is applying for a research and development grant for the summer of 2007.

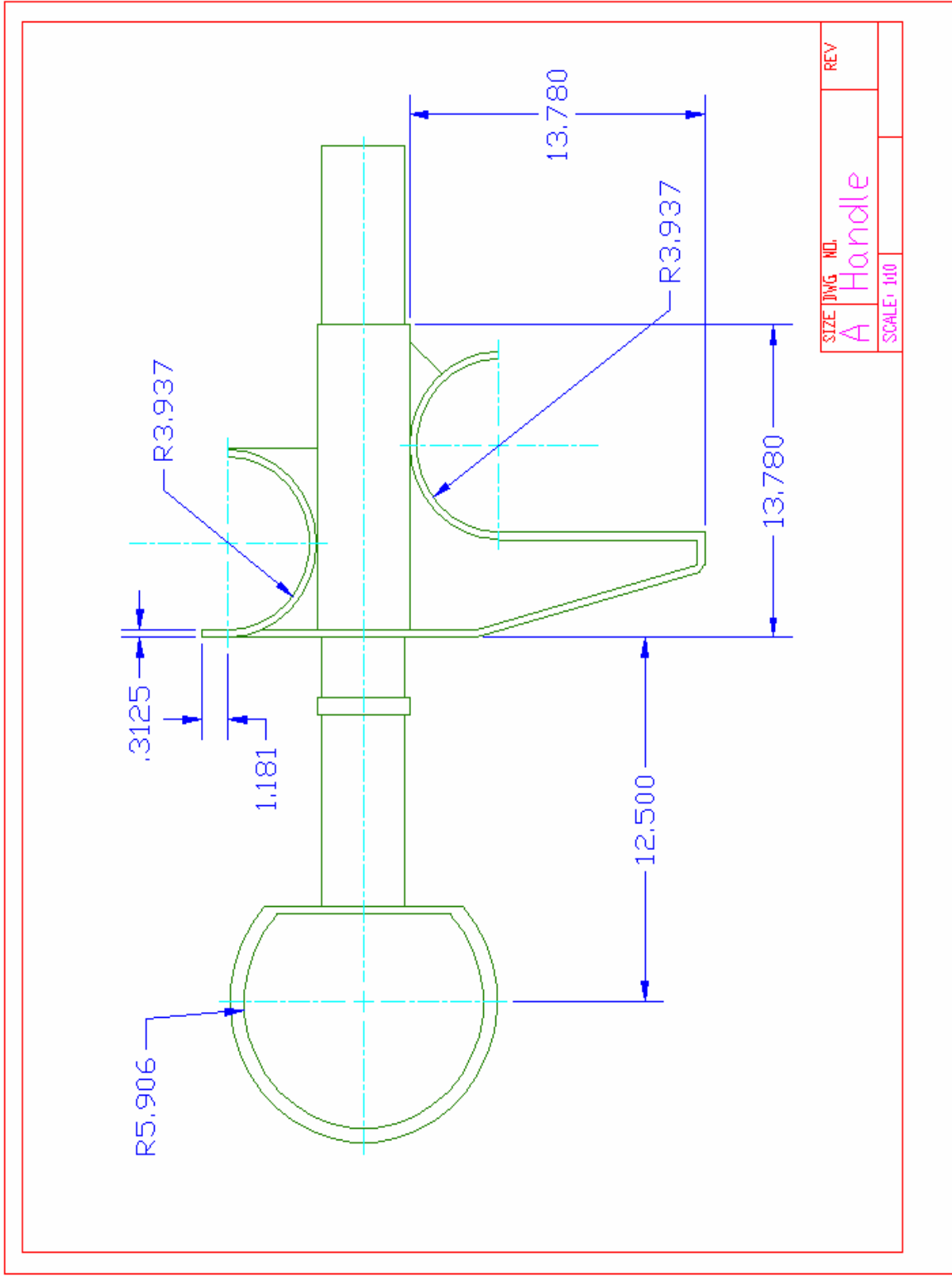
VIII. Conclusion

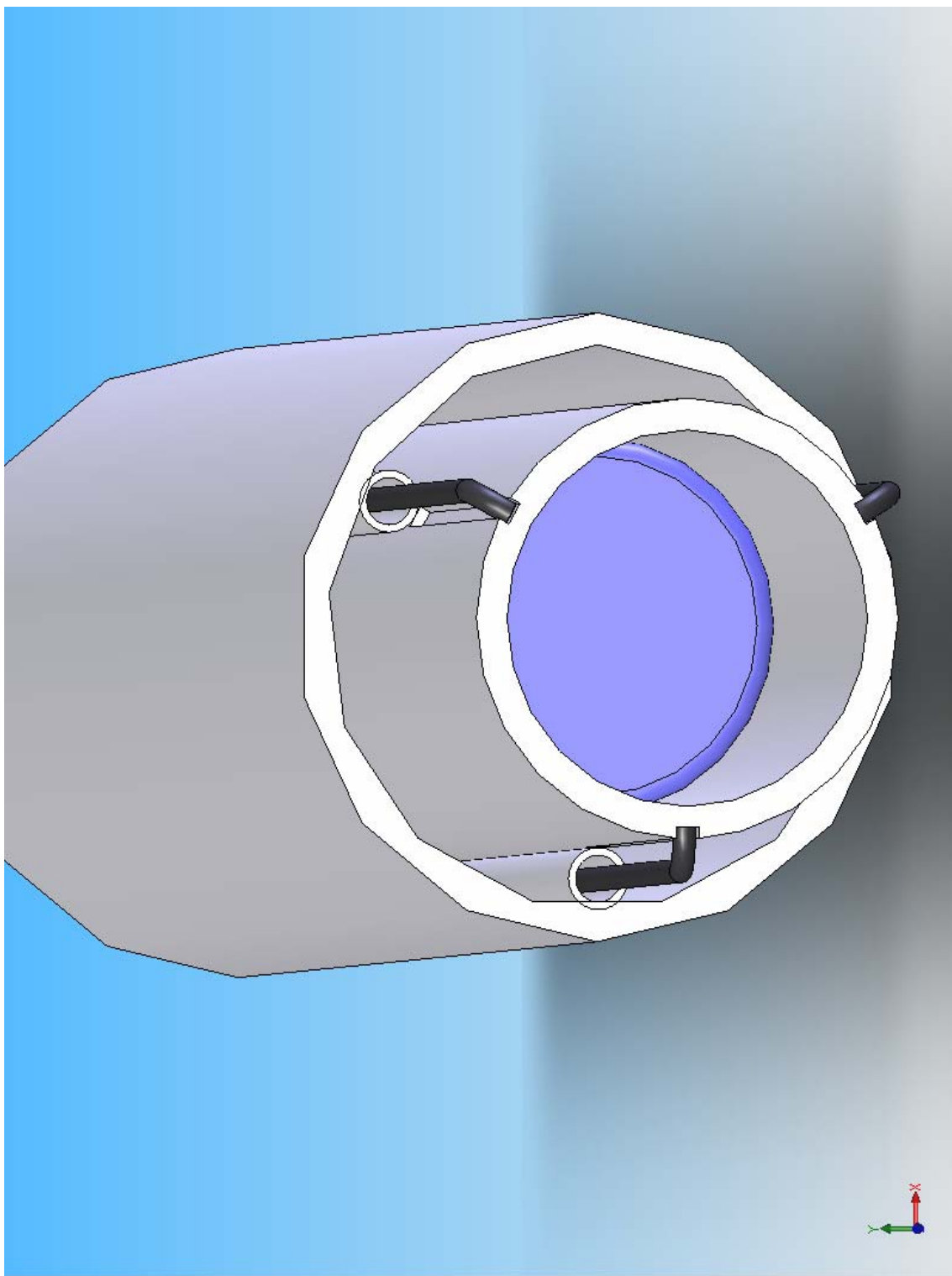
This semester our client presented us with the problems associated with the ACMI Falope-Ring Band device that he current uses for sterilization procedures. This product is dangerous and traumatic, with a failure rate of 20%. We came up with several design alternatives that would hopefully be safer and release the bands properly. From these designs, we chose one to develop and constructed a large-scale prototype. After testing our prototype, we realized that it did not work properly and several changes were made. Our final prototype is a device that uses metal probes/fingers to push the bands off one at a time, with physical feedback so that the user will know when the first and second bands have been released. In future semesters we will construct a smaller, to-scale prototype and, if all goes well, take the necessary steps to bring our device into use in hospitals.

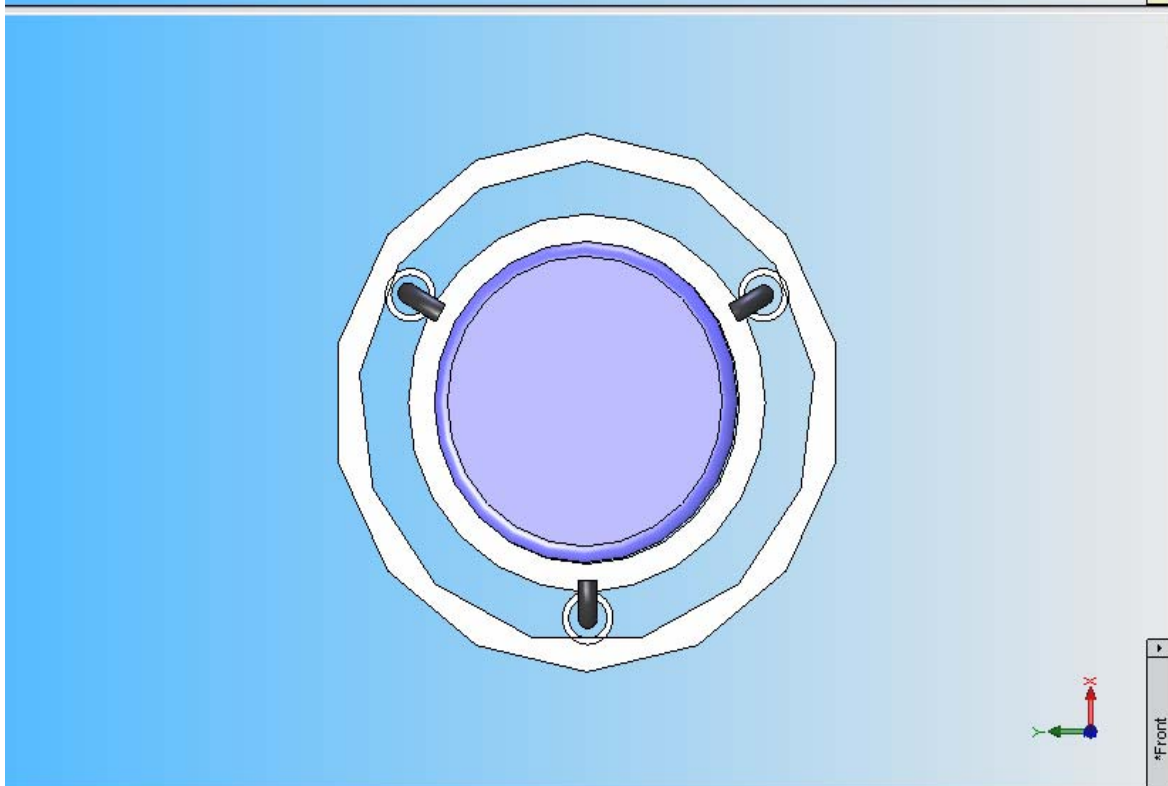
Appendix A: Final Design and Prototype Figures

(All dimensions are in inches)









Appendix B: Product Design Specifications

Laparoscopic Banding Device Product Design Specifications

February 9, 2007

Gina Stuessy – Team leader / BSAC
Anna Moeller – Communications
Kailey Feyereisen – BWIG

Function: Design a laparoscopic banding instrument for tubal sterilization that is less traumatic and more dependable than current, cumbersome, rough, inaccurate product.

Client Requirements:

- Load bands more easily
- Release bands safely, accurately
- Must work with existing trocan
- Training on device should be minimal

Design requirements:

1. Physical and Operational Characteristics

- a. *Performance requirements:* Device must be accurate for one-time use, ergonomically similar to current product.
- b. *Safety:* Device must not tear fallopian tubes while releasing bands and must be kept sterile before use.
- c. *Accuracy and Reliability:* Device must release band onto bent tube the first (and only) attempt with a failure rate smaller than that of the current device (20%).
- d. *Life in Service:* Entire product will only be used for one surgery before it is discarded.
- e. *Shelf Life:* Device should be stored at room temperature (approximately 20-30 °C) in a clean and dry environment. Shelf life of materials (stainless steel, plastic) is many years, and as long as sterile package is not compromised, the device should last that long.
- f. *Operating Environment:* The product is designed to enter the human body. Device must be able to withstand normal temperature range (approximately 15 – 50 °C) and exposure to internal organs and tissues without corroding within the given time frame.
- g. *Ergonomics:* Device should be easy and intuitive for surgeon to handle. Grip must be easy to use within normal range of hand size which is approximately 150 – 250 mm in length. Product should indicate when band has been ejected from device, and the force exerted for ejection of band should not exceed the forces required on the current device.

- h. *Size:* Device should measure approximately 360mm in length, with a handle of approximately 100mm. The outer diameter of the neck of the device to be inserted into the body must not exceed 75mm. Current bands used have an outer diameter of 4mm and an inner diameter of 1mm.
- i. *Weight:* Weight of device should not exceed a few pounds because device should be easy for operator to handle and maneuver.
- j. *Materials:* Product should be made of stainless steel and plastic. Care should be taken that any other materials used in the device are not toxic. Bands used in the current device are made of silicone elastomer.
- k. *Aesthetics, Appearance, and Finish:* Device should be as similar to the old device as possible so that the surgeons do not have to learn a new procedure.



This is a picture of the current device. There is more information on it in US Patent 4,226,239.

2. Production Characteristics

- a. *Quantity:* The specific number requested is not specified, but we need to build at least one prototype.
- b. *Target Product Cost:* The target cost is as little as possible. The current product costs roughly \$400 and we hope to make a cheaper alternative. We also do not have funding at this time and will need to present a design before we can get funding.

3. Miscellaneous

- a. *Standards and Specifications:* FDA approval is required if the device is determined to be a plausible alternative to the current laparoscopic banding device. They approve all medical devices.
- b. *Customer:* Bands for device should load more easily, and ejected properly. Device should indicate when each band is ejected. Device should not tear the fallopian tube of the patient.
- c. *Patient-related concerns:* The current product is a single use device. If we create a multiple use device it will have to be sterilized at the hospital. For the patients' safety we should create a device that does not tear the fallopian tubes if possible to decrease the amount of unnecessary bleeding.

Competition: The current product is produced by the ACMI Corporation and is the only mechanical device used in laparoscopic banding surgery that our client has ever used or seen (US Patent 4,226,239). There are many other ways to permanently sterilize a woman. Our client prefers this method because of its simplicity and reversibility.

Appendix C: References

- (1) Berger, Gary S. M.D. "Tubal Ligation." Chapel Hill Tubal Reversal Center. March 11, 2007. Chapel Hill Tubal Reversal Center. <<http://www.tubal-reversal.net.htm>>.
- (2) "Falope-Ring® Band: Gynecology " Gyrus Group PLC. July 20, 2006. Gyrus Group PLC. <http://www.acmicorp.com/acmi/user/display.cfm?display=cat_menu&maincat=Gynecology&catid=9>.
- (3) Julian, Thomas M.D. Personal Communications. 2007.
- (4) "Laparoscopic surgery." Wikimedia Foundation, Inc. March 7, 2007. Wikimedia Foundation, Inc. <<http://en.wikipedia.org/wiki/Laparoscopic>>.