Table of Contents

Abstract

Tubal sterilization is a relatively inexpensive and effective form of birth control. By physically closing off 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 M. Julian, secures a band around the fallopian tubes, closing the tube to block the egg's pathway. This device often tears the tube and releases the bands improperly. He asked us to address these issues when we redesign the device. We developed a design for a device that includes a suction mechanism to secure the tubes more gently, a more gradual band release mechanism to achieve a better accuracy, as well as a band separator to ensure that only one band is released on each fallopian tube. Last semester we created an enlarged prototype to test the fundamental concepts of our design and then made a couple alterations. This semester we made a 2:1 scale prototype, tested the suction mechanism on sheep fallopian tube tissue, and tested the band release function with and without the separator.

Introduction

Tubal Ligation is a surgery, and although it is minimally invasive there are risks and chances for complications. Complications occur up to 20% of the time with the current product, which is far too high in a surgical procedure. The fallopian tube 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 is damaged. Another problem with the device is the band release. The procedure involves placing an elastomer band over the fallopian tube to create a mechanical blockage, but sometimes the 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 prolongs the procedure 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; however, 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. These procedures alter 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 prohibits the eggs from reaching the uterus for fertilization. Some versions are the Pomeroy technique, coagulation, clipping, and banding (1).

Figure 1: The Pomeroy technique (1).

Figure 2: The coagulation technique (1).

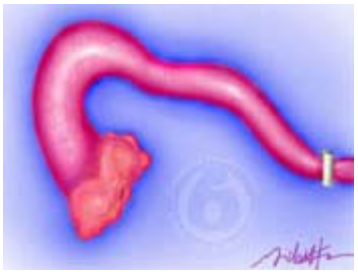


Figure 3: The clipping technique (1).

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).

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).

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).

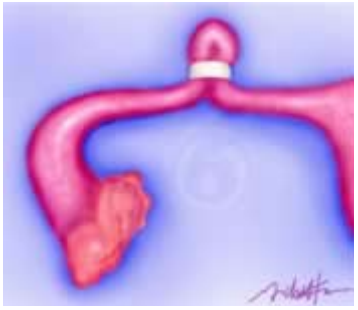


Figure 4: The banding technique (1).

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).

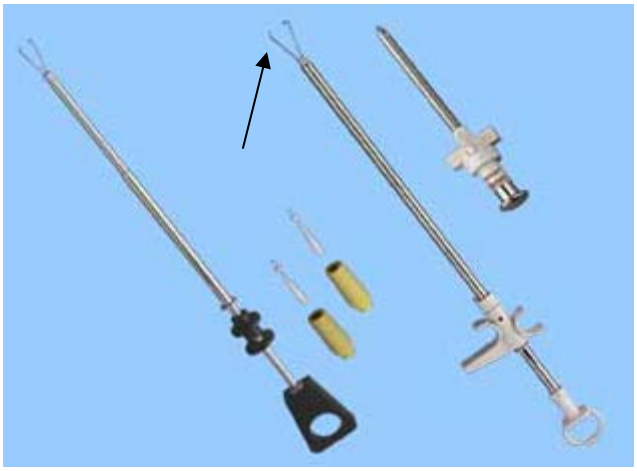


Figure 5: The Falope-Ring band, produced by ACMI Corporation (2).

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 approximately $400 for the device and bands. 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 transversing 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).

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 trochar; 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) and be approximately the same price ($400 or less).

III. Design

This device, shown in Figures 6 and 7, 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, corp. This includes thumb tabs to eject the syringe from the device next to the fallopian tube, a finger grip that will pull on the suction of the syringe

to secure the tube, and a threaded knob to gradually push the silicone elastomer band off the end of the device onto the tube. The column section that extends into the body is approximately 40cm long, 8 mm in diameter, hollow, and composed of stainless steel.

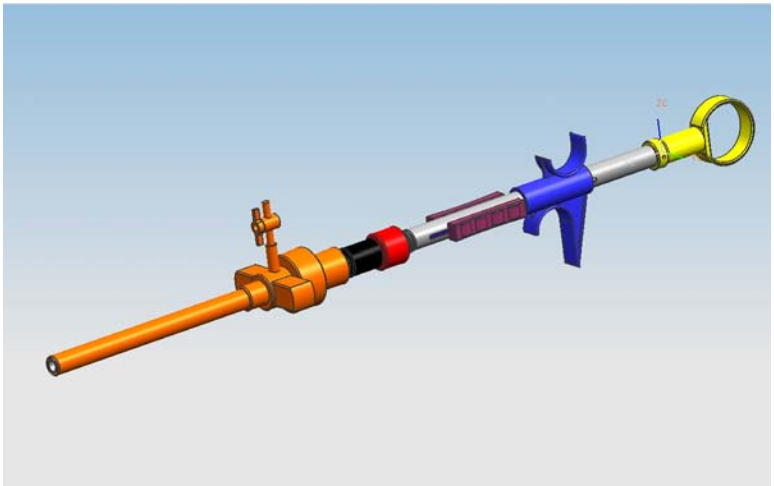


Figure 6: CAD model of prototype inserted into the laparoscopic port (orange). Threaded knob for band release (red), thumb tabs for movement of syringe (violet), finger grip for creating and releasing suction (blue), and end handle (yellow).

The securing mechanism operates using a small syringe that will hold the fallopian tube in place. The thumb tabs slide forward, compressing a spring and allowing the tip of syringe to be exposed and to be placed in contact with the fallopian tube. Suction is then created when the finger grip is pulled back. The bands are released when the push rod is moved forward just far enough so that one band is released off the device onto the fallopian tube. At this time, the surgeon should release the suction on the fallopian tube by releasing the finger grip. Next the syringe is pulled back into the main column of the device, and the device is removed from the abdomen.

To ensure that only one band is released at a time, we designed a gelatin ring to be placed between the bands on the device. This physical separator has an inner diameter of 8.2 mm, and an outer diameter of 9.8 mm (for 1:1 scale). Once in the body, the gelatin should dissolve and not

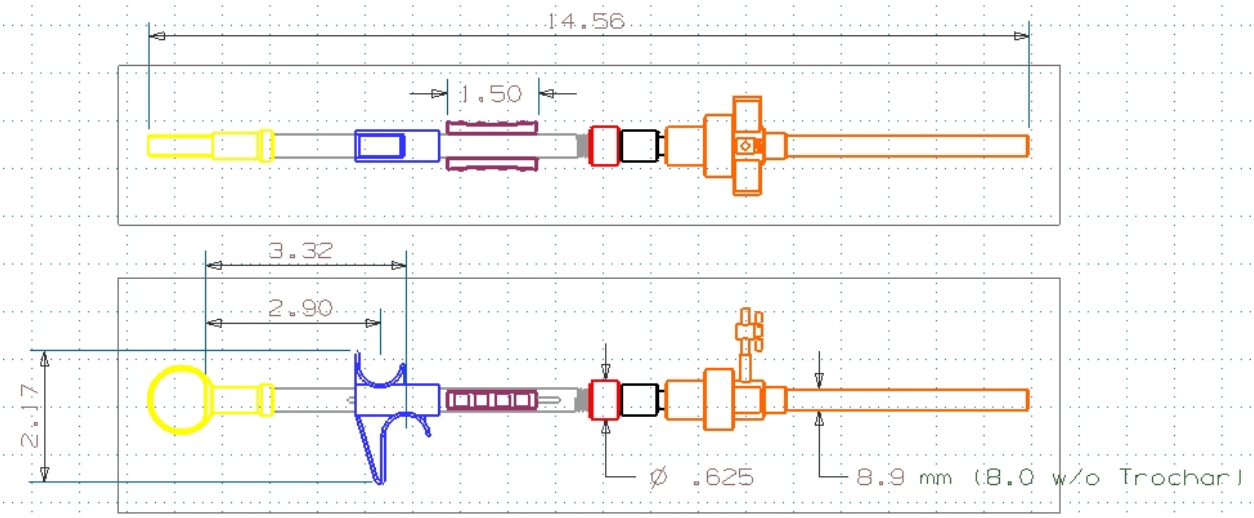


Figure 7: 2D side view of thumb tabs and spring controlling syringe mechanism, threaded knob controlling band release.

cause harm to its surrounding environment.

There are several advantages to this design. Because the handle is similar to the current device used, the surgeons will not have to learn many new procedure steps to perform the surgery and will thus be more likely to use the device. The suction mechanism of securing the fallopian tube will be gentler on the tube, and the method of releasing the bands onto the tubes will also be more reliable than the in current device.

IV. Prototype and Testing

This semester we constructed a 2:1 scale prototype so that we could verify that our altered design concept works. The main shaft of the instrument was machined from delrin, while the band push rod was constructing using green nylon. The total length of the device including the attached handle is 14.56 in (1:1 scale length) and the outer diameter of the instrument shaft, where bands will be positioned, is 0.647 in (approximately 16 mm; 2:1 scale diameter). Parts that would require production via plastic molding were supplied by Biomet, Inc. in the form of rapid prototypes which were created based on three dimensional CAD drawings. A mold for creating gelatin rings that would act as physical separators between bands was also machined using nylon. While the final prototype could not be constructed in a true 2:1 scale model due to lack of appropriate tools and fixtures, we believe that our model accurately demonstrates proof of concept and serves as a functional, physical representation of our design.

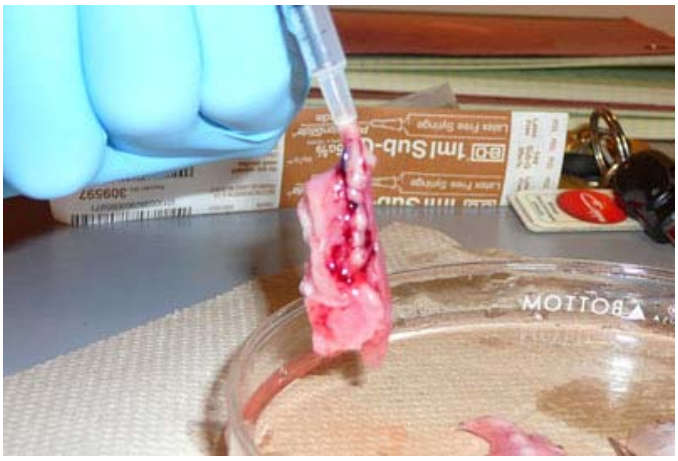


Figure 8: Testing of syringe mechanism. Suction is created.

Before we constructed the prototype, we first tested the suction mechanism on cooked spaghetti by using a 1 mL syringe. Unfortunately, the syringe was unable to secure the noodles without breaking them. We next tested the suction mechanism to secure sheep fallopian tubes provided to us by graduate student Ben Sprague's laboratory research. We observed that very little force was necessary to attach the fallopian tubes to the end of the syringe and lift them off the Petri dish, and that no visible damage or physical changes were made to the fallopian tubes (shown in Figure 8). Only after 0.20 mL was drawn into the syringe did damage occur, in the form of a circular indent in the fallopian tube tissue. Later we performed a second set of tests on the suction mechanism to more precisely find the volume of fluid necessary to secure the fallopian tube. We tested various volumes 10 times and found a success rate of 90% (9 out of 10 times the fallopian tube was secured and pulled into the column) for volumes equal to or less than 0.10 mL. A success rate of 100% was achieved with a volume of 0.15 mL (see Figure 9).

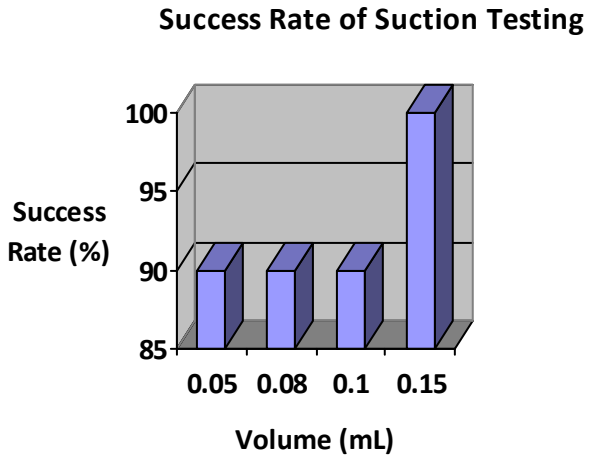


Figure 9: Success rate of suction mechanism testing.

To test the band release mechanism, we acquired rubber bands with an outer diameter of 9mm, an inner diameter of 6mm, and a thickness of 1.5mm. We loaded the bands and gelatin separator onto our prototype and released the bands onto latex gloves. We discovered that even the densest gelatin separator made was too soft. The bands slid over the separator and off the end of the device. We also tested the band release mechanism without the separator and the bands released separately 100% of the time.

V. 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.

VI. Future Work

Now that we have completed our 2:1 scale prototype and ordered and received materials for the 1:1 scale prototype, next semester we will construct the actual size prototype. This may be difficult due to the limitations of the machine shop tools and the precision required for a smaller device. We will also find bands that are the appropriate size and test the band release mechanism on non-biological materials. Because the gelatin separator failed to slide off the device between the two bands, we may look into a more solid yet resorbable material such as a salt ring. If we are able to build more than one prototype, we will use one to test the sterilization procedure on a sheep's (or another animal's) fallopian tube tissue. Specifically, we will measure the success rate

of several attempts at banding the fallopian tubes. Successful trials will be characterized by full blockage of the fallopian tube, percent success of securing fallopian tube, and percent success of band release. Due to the difficulty in sterilizing the device after it is used on animal tissue, our device must be single use only in testing. In respect to obtaining a patent, we plan to submit an Invention Disclosure Report to WARF.

We are currently working with our client and advisor to apply for a research and development grant through the UW hospital. If we are awarded the grant, a couple of us would be able to continue the project this summer and the following fall semester. The funds would be used to pay for custom mesomachining, materials and specialized tools, animal tissues for testing, as well as our work hours and advisor's involvement.

VII. Conclusion

Last semester our client presented us with the problems associated with the ACMI Falope-Ring Band device that he currently uses for sterilization procedures. This product is dangerous and traumatic, with a failure rate of 20%. Last semester we designed and constructed a large-scale prototype to test the concept of our design. This semester we made modifications to our design, performed testing on our suction and band release mechanisms, and constructed a 2:1 scale prototype. We also made gelatin ring separators and performed more testing on sheep fallopian tubes. We are applying for a research and development grant to continue the project after this scholastic year. Next semester we intend to build one or more 1:1 scale prototypes and perform testing of the device. If all goes well, we will take the necessary steps to bring our device into use in hospitals.

Appendix A: 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>.

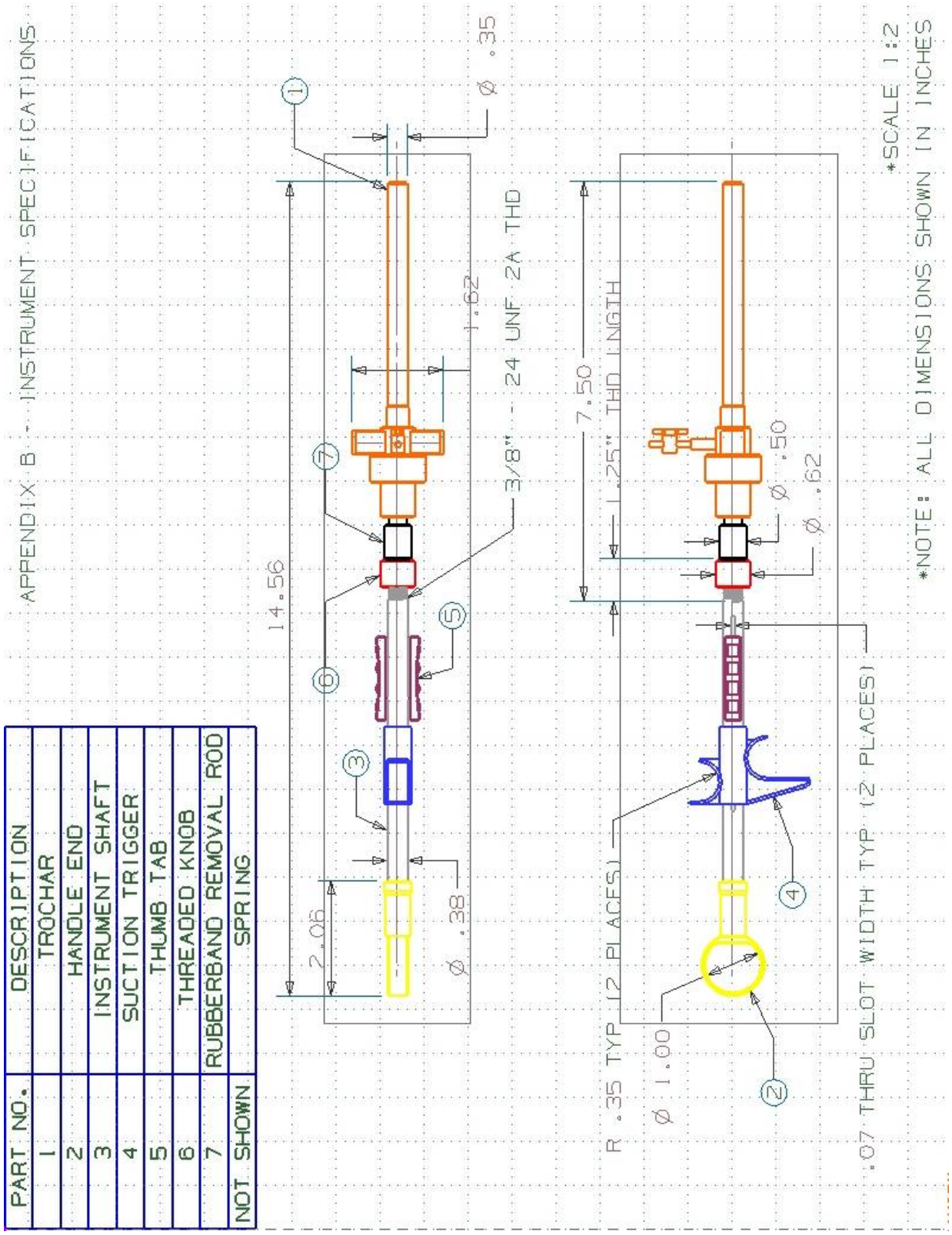
(3) Julian, Thomas M.D. Personal Communications. 2007.

(4) "Laparoscopic surgery." Wikimedia Foundation, Inc. March 7, 2007. Wikimedia Foundation, Inc. <http://en.wikipedia.org/wiki/Laparoscopic>.

Special thanks to…

- the UW Perinatal Lab and Ron Magness, Ph.D, the Director of the Perinatal Labs and Dept. of Ob/Gyn for donating sheep tissue for testing.
- Biomet Orthopedics for manufacturing several pieces of the prototype
- Ben Sprague for helping us during testing of the sheep tissue

Appendix B: Instrument Specifications



Appendix C:

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.

d. *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.