Laparoscopic Banding Device for Tubal Ligation in Women

K. R. Feyereisen; A. M. Moeller; G. E. Stuessy; T. D. Witt

The aim of our research was to design and construct a laparoscopic device for tubal ligation in women. We focused our design around the banding method, in which a small silicon elastomer band is placed on the fallopian tube, occluding the pathway of the ova. Our device uses a modified syringe to secure the fallopian tube with suction. The bands are pushed off with a pushrod that is attached to a threaded knob for accuracy. Testing with sheep fallopian tubes has shown the device to secure the fallopian tube 97% and release the bands individually 100% of the time. We have secured a research and development grant from the Department of Obstetrics and Gynecology so that we may continue commercialization of the device and conduct further testing on live sheep. We are also pursuing a patent at this time.

Introduction

Tubal ligation is a form of permanent birth control in which the fallopian tube is blocked or cut to prevent passage of the ova from the ovaries to the uterus, preventing pregnancy. The banding technique is popular because it is gentle and easily reversible. It blocks the fallopian tube by placing a silcon elastomer band around the folded fallopian tube, much the same way kinking a hose will occlude flow of water. Because the fallopian tube is not intentionally cut during this procedure, it is much gentler and more easily reversible than other methods, which may damage tissue in order to occlude the fallopian tube.

The most common instrument currently used for the banding tubal ligation (Falope Ring Band® made by ACMI, Corp.) has been found to be unreliable, releasing bands properly only about 80% of the time. It is also common for the instrument to cause damage to the tissue, making reversal of the procedure difficult[1]. Additionally, tearing of the tissue by the instrument can lead to excessive bleeding and a longer and more painful recovery from the procedure. After inspection of the instrument, we decided a gentler way of securing the fallopian tube was needed, as well as a more accurate way to release the bands to ensure they released reliably and separately.

Materials and methods

Materials

As previously stated, currently available surgical instrumentation for use in tubal ligation operations has proven to be clinically unreliable. In addition to the issue of consistent reliability, there also exist problems involving post-operative scar tissue formation which has the potential to result in infection, patient discomfort, and irreversible damage. Our research team has incorporated a series of instrument revisions with the intention of alleviating these problems associated with reliability and scar tissue formation.

The proposed instrument design is a modification of a similar device currently manufactured by ACMI, Corp. and is comprised of a fully cannulated instrument shaft, suction mechanism, band release mechanism, and handle end (Figure 1). The instrument shaft houses a spring-loaded

Figure 1: 3D CAD model of fully assembled instrument featuring proposed design modifications (above). Constructed instrument shaft prior to assembly (below).

syringe that, once extended from the shaft, is used to secure the fallopian tube by generating suction to form a seal between the tube and the syringe. Operation of extending/retracting the syringe and creation of suction is controlled by a trigger and thumb tabs located on the periphery of the instrument shaft. Once the fallopian tube has been secured, the band release mechanism is used to complete the operation by individually unloading a predetermined number of bands. This is accomplished by turning a knurled handle over a threaded segment of the instrument shaft. The procedure is completed by releasing suction on the fallopian tube and removing the instrument assembly from the laparoscopic incision.

To ensure the individual and sequential release of each band, we have chosen to incorporate a resorbable ring to be positioned between the bands prior to release. While the exact material properties of this separator have yet to be determined, biocompatible compounds such as gelatin, salt, and other similar biomaterials will be researched for this specific use. Following insertion, the separator serves no functional purpose and will be absorbed.

Selected dimensions and material composition of functional instrument components are outlined below:

- Resorbable Separator – 8.2 mm ID, 9.8 mm OD
  Material: TBD

- Instrument Shaft (Including Handle End) – 14.56" (37 cm) overall length, .310-.375 OD
  Material: Stainless Steel

- Handle End, Trigger, Thumb Tabs – See Figures 1 for component placement
  Material: Poly (e.g. delrin, radel, etc.)

- Band Release Threaded Handle – .625" OD over knurled section
  Material: Stainless Steel

- Internal Syringe – .266" OD
  Material: Medical Grade Poly

Specific to our invention, the suction mechanism designed to secure the fallopian tube is less invasive than the current method which uses protruding metallic pinchers to "grab and pinch" the tube. The seal generated between the fallopian tube and the instrument will decrease occurrences of scar tissue formation.

Finally, the instrument's overall ease of use is thought to be increased by incorporating the spring controlled mechanism for extending and retracting the internal syringe. Fine threads located on the instrument shaft, in conjunction with a resorbable separator placed between each band, have been included to increase operative efficiency and effectiveness by allowing the operating surgeon greater control during band release.

Method of Validation

In order to test the effectiveness of the new device, two different types of tests were performed. The first tested the suction mechanism and the second tested the band release mechanism. For both tests a Petri-dish was half filled with water and then two sheep fallopian tubes that were extracted from a sheep were placed into it. The ends of each fallopian tube were secured to the bottom of the Petri-dish. This allowed the fallopian tubes to be raised off of the bottom of the dish no more than one inch. After this was accomplished the two respective tests were performed.

Suction

First, the tip of the syringe was extruded from the device. Two different types of trials were conducted, either with the syringe touching the fallopian tube, or by holding the syringe near the fallopian tube (within 1mm). The fallopian tube

was approached by the syringe from five different angles to test the importance of contact angle and success of the suction. These angles were 30°, 45°, 60°, 75°, and 90°, each tested six times for a total of 30 trials. The 90° trials were all completed with the syringe touching the fallopian tube since there was not enough water in the dish to cover the fallopian tube, making it impossible to test the 1mm distance trials.

After suction was activated, the fallopian tube was lifted ¼" to ½" off of the Petri-dish for approximately 10 seconds to test the how well the suction would hold. A successful trial was if the suction was created and if the seal held for the 10 seconds. After the time trial, the suction was released and the fallopian tube was inspected for damage. Five levels of visible damage were recorded: no damage, a faint indentation, a suction circle from the syringe tip, a deep suction circle, and tearing of the fallopian tube.

Banding

To test the band release mechanism the tip of the syringe was extruded and placed in contact with the fallopian tube. Suction was created and then the syringe and a portion of the fallopian tube were drawn back into the shaft of the instrument to create a bend in the fallopian tube. The first band was then released and the number of turns (approximately 180° of rotation) required to push off the first rubber band was recorded. The tip of the syringe was then extruded again and suction was released. The fallopian tube was then visually inspected to see if any damage was inflicted on the tube beyond that seen in the suction testing.

Next, the tip of the syringe was either placed on a different place on the same fallopian tube, or on the second fallopian tube in the Petri-dish, suction was created, and the fallopian tube was drawn into the device. The second band was then released and the number of turns needed to release it was counted. The tube was then visually inspected again for any further damage. A successful trial was when the bands were released individually and no tears were seen in the fallopian tubes. This procedure was repeated 30 times.

Results

Suction Mechanism

The success rates of the suction mechanism, tested at various angles (30, 45, 60, 75, and 90 degrees) for the thirty trials are shown in Figure 2. Adequate suction was created in all but one of the trials. For this trial, the device was held at an angle of 75 degrees from the horizontal, and the suction was tested with the tip of the syringe starting at a position not in contact with the fallopian tube. The tester believes that this trial failed because the tip was too far from the fallopian tube (more than one millimeter away). There was usually not significant visible damage to the fallopian tubes. In most trials we noticed either a small indent (12 trials) or a slightly raised circle (14 trials) on the fallopian tube

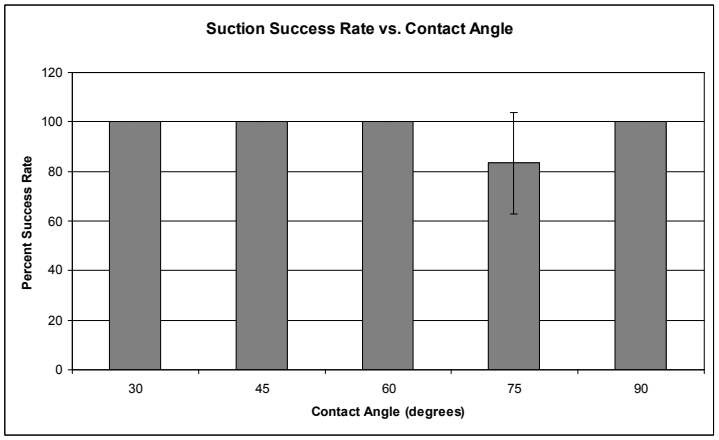

Figure 2: Success rate of the suction mechanism vs. contact angle in testing. Overall success rate of suction mechanism was found to be 97%.

tissue due to the contact with the syringe. Within minutes, these effects were no longer visible. A more prominent suction circle was formed three out of six trials at a device angle of 90 degrees. These circles also faded within minutes. There was never any tearing of the fallopian tissue.

Band Release

The band release testing had a success rate of 100%. This means that the bands released separately and that there was no additional

visible damage to the fallopian tubes beyond the indents left by the suction mechanism. The first band was released from the device in an average of 1.425 turns (where a turn is defined as a 180 degree rotation of the push rod) and a standard deviation of 0.43 turns. The second band was released in an average of 1.433 turns with a standard deviation of 0.46 turns. During four of the thirty trials, the tester accidentally pulled back on the device after the band was released, which caused the suction seal to break due to the fact that the fallopian tubes were secured onto the Petri dish. These events were solely due to human error and it is believed that they had no relationship to the band release function of the device.

Discussion

We are very pleased with our test results and believe that they show our device meets the goals of the client. Our device is gentler on the fallopian tubes, as shown by the lack of significant damage or tearing to the tissues. It is important to note, however, that a deeper indent is seen with a syringe contact angle of 90 degrees compared to shallower angles. The band release testing showed that the bands can be released individually, in only a few turns of the threaded knob. This should allow for reliable and easy band releases.

Summary and conclusions

We have designed, constructed, and tested a new device for laparoscopic tubal ligation. We have shown that it is gentler than the current instrument on the market, as well as more reliable. We will continue to commercialize the design until it is ready to be marketed.

Acknowledgments

We would like to thank M. Tyler, N. Chesler, T. Julian, R. Magness, B. Sprague, as well as Biomet Orthopedics for their support of our project.

References

1. **T. Julian.** Personal Contact [2007]