A. Cover Sheet

PI Name: Thomas M. Julian
Division: Gynecology
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Proposal Title: Research and Development Grant-Laparoscopic Banding Device for Female Sterilization
Have you identified any other extramural support or other funding to submit the completed proposal? No
If "yes", please enter name of agency/program below and attach a copy of the request for proposal or program announcement:
If "no", please list potential sources of funding that might be appropriate for your proposal. I do not think that there is another available source for small grants in this area to which I have access.

Assurances:
Yes No Pending
Approval
Human Subjects—not necessary
Animals –not necessary
Biological Safety—not necessary

Certification:
In applying for a Research and Development grant from the Dept. of Ob/Gyn, I agree, if awarded funding to all of the terms as stated in the R&D grant guidelines and to submit to the R&D Committee a report detailing the progress made on the project within the time period specified.
Signature Date

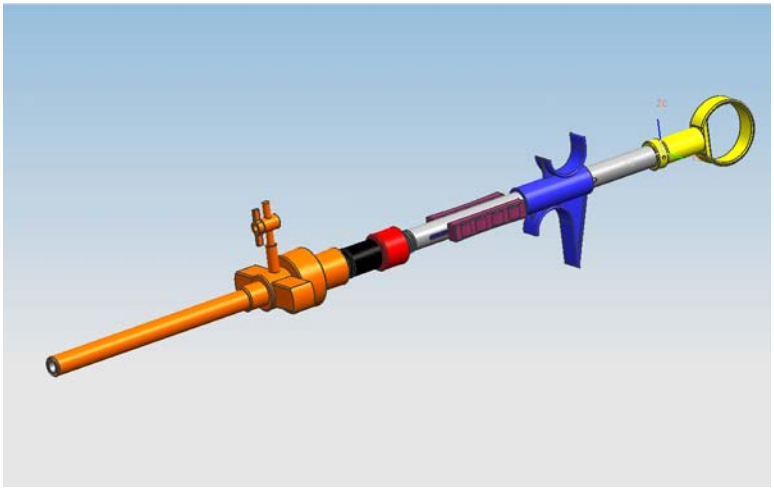
Electronic signature: Thomas M. Julian 11/13/07

B. Project Description

Background

The medical instrumentation currently used to perform female tubal ligation (sterilization) surgeries through the banding technique is both inadequate in function and promotes the likelihood of tissue injury. These problems are directly associated with the Fallope-Ring Band manufactured by ACMI Corporation. Our team of engineering students is developing a device that is potentially capable of eliminating operative damage caused to the tissue due to poor instrument design, as well as improving overall ease of use for the surgeon.

Dr. Thomas Julian first approached the Biomedical Engineering Design Program with the hope that we could solve the problems the current laparoscopic banding device presented. He stated that complications occur up to 20% of the time with the current product, which is far too high in a surgical procedure. Furthermore, the fallopian tube can be torn or otherwise damaged during the procedure causing excess internal bleeding and the formation of scar tissue. These complications reduce the chance that the surgery can be successfully reversed since more of the fallopian tube is damaged. Another problem with the device is the band release process. The procedure involves placing an elastomeric band over the fallopian tube to create a mechanical blockage. Sometimes, however, the band does not release correctly, requiring application of the second band, or two are placed on the same fallopian tube, requiring the physician to withdraw the device and load another band on it. This prolongs the procedure and requires more work for 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. We believe that this can be accomplished by developing a new and better device to perform this procedure.



CAD model of prototype [shown inserted into the laparoscopic port (orange)]. Threaded knob for band release (red), thumb tabs for movement of syringe (violet), trigger for creating and releasing suction (blue), and thumb-ring handle (yellow).

New Design

We have developed an instrument that allows for a gentler procedure for the patient and a more reliable band release for the surgeon. This device, shown in the figure to the left, consists of a handle, a long outer shaft 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 Corporation. This includes thumb tabs to exposes the tip of the syringe to make contact with the fallopian tube. A trigger will generate suction to grab secure the fallopian tube. The syringe is then retracted to bring the fallopian tube inside the device for banding. A threaded collar attached to a push rod will gradually release one band onto the fallopian tube. The collar will require no more than 4-5 rotations to release one band. The instrument shaft that extends into the body is approximately 40cm long, 8 mm in diameter, hollow, and composed of stainless steel. To ensure that only one band is released at a time, we have designed a gelatin ring to be placed between the bands on the device. Once in the body, the gelatin should dissolve and not cause harm to the surrounding environment.

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 syringe to be ejected from the device.

Suction is then created when the trigger is pulled back. The bands are released when the pushing rod is moved forward just far enough so that one band is ejected off the device onto the fallopian tube. At this time, the surgeon should release the suction on the fallopian tube by disengaging the trigger. After both tubes are banded, the syringe is pulled back into the main column and the device is removed from the patient's abdomen.

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 procedural steps to perform the surgery and will thus be more likely to use the device. The suction mechanism of securing the fallopian tube is gentler on the tube as compared to the pair of 'fingers' employed on the current AMCI device, and the method of releasing the bands onto the tubes will also be more reliable than the in current device.

Current Status

The project is in the prototype construction and testing phase. In the Fall '07 semester the team constructed a 2:1 scale prototype so that we could verify that our design concept works. Before we constructed the prototype we tested the suction mechanism to secure sheep fallopian tubes provided to us by Ron Magness, Ph.D., director of the UW Perinatal Labs, and graduate student Ben Sprague. We observed that very little force (0.25 N) was necessary to create a vacuum and secure the fallopian tubes to the end of the syringe and maintain a high level of suction**.** No visible damage or physical changes were observed to the fallopian tube until excessive force was applied (0.27 N)**.** We obtained a 100% success rate for securing the fallopian tubes before any damage was observed. To test the band release mechanism, we acquired rubber bands with appropriate dimensions and loaded both the bands and gelatin separator onto our device. In order to assure proper function of our design, the bands were then released onto a latex glove. We also made a gelatin ring that fits on the device column between the two bands to facilitate improved reliability of the band release.

While testing, we discovered that even the most dense 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 individually 100% of the time.

Planned Research & Development

In the Spring semester of 2008, with the assistance of this grant, we plan to construct a 1:1 scale prototype and test all of the mechanisms together as an integrated system. We will also research an alternative material that is more suitable to be used as a band separator. We plan on creating a band loader to make this process more efficient since there have been complaints about the difficulty in loading the silicone elastomer bands onto the device before use. Over the course of the summer we will need to manufacture several prototypes to test on animal fallopian tubes and perform then testing with the fully functional device. For this phase, applications would need to be filled out and submitted to the IRB for approval of testing on live non-human animals. Specifically, we hope to obtain animal tissue and 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. In respect to obtaining a patent, we plan to submit an Invention Disclosure Report to WARF.

C. Budget

DETAILED BUDGET

LIST ALL KEY PERSONNEL	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED *(omit cents)*			
NAME			ROLE ON PROJECT	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
			Principal Investigator			

Thomas M. Julian, M.D. serves as a project client and provides evaluation of prototype from the standpoint of a medical professional. No salary or fringe benefits are requested.

Role of all the following are student engineers:

Kailey Feyereisen (engineering student) No salary or fringe benefits
Gina Stuessy (engineering student) Salary in the summer but no fringe benefits. Summer salary is $17/hr for 20 hr/wk for 8 wks = $2720.00
Anna Moeller (engineering student) Salary in the summer but no fringe benefits. Summer salary is $17/hr for 20 hr/wk for 8 wks = $2720.00
Tyler Witt (engineering student) No salary or fringe benefits

Mitchell Tyler Faculty engineer adviser Salary in the Summer but no fringe benefits. Requests ½ month salary for summer advising = $3385.00

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SUBTOTALS

EQUIPMENT *(Itemize) $1200 for shop fees and for custom mesomachining*
SUPPLIES *(Itemize by category) $770 for supplies to design and construct the bander prototype. It will go into metals, machining, design modification, trial of materials. An exact amount cannot be given because much of this will be trial and error. Also for disposal of any animal tissue we acquire.*
TRAVEL *(Itemize by Domestic & Foreign) none*
PATIENT CARE COSTS none | INPATIENT none
OUTPATIENT none
OTHER EXPENSES *(Itemize by category) none anticipated*
TUITION REMISSION none anticipated

TOTAL DIRECT COSTS **$10,795.00**

D. Research Support

To date, Dr. Thomas Julian has funded the design team by allocating a total of $500 for project costs to be used over the course of three semesters. Of this initial project fund, $340 is remaining. This will not, however, be sufficient for the upcoming and iterative fabrication and testing process that will be necessary to evolve the design to a fully functional ready for clinical testing. Throughout the next six months Mitch Tyler will be overseeing the progress of the design and acting as the technical advisor on the project. This is necessary to ensure that the final product is made to the full potential. It will also help in avoiding any unnecessary errors.

E. Regulatory Issues

Since it is unlikely we will be testing on any humans without a patent, or FDA approval, we would like to test on animals. So far we have used sheep fallopian tubes that were already sacrificed in order to not waste any part of the animal. Working with these types or tissue require one to take precautions including wearing a face mask so that diseases will not be spread. If we are unable to obtain these sheep fallopian tubes in the future, we plan to go to the veterinary school and ask for fallopian tubes from sacrificed or dying animals. We will also make sure to take all appropriate measures to ensure the safety of everyone involved.