Design for Minimizing Leakage at Gastro-Jejuno Anastomosis of Roux-en Y Gastrojejunostomy

Ethicon-Endo Surgery Project
Cardinal BioInnovations

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I Executive Summary

Ethicon Endo-Surgery, Inc. has requested that the design team find a way to prevent leakage at the gastro-jejuno (GJ) anastomosis after a Roux-en Y Gastrojejunostomy. The Roux-en Y is a bariatric procedure performed on morbidly obese patients. Morbid obesity is a condition characterized by an excessive amount of fat leading to several obesity-related health conditions and a shorter life expectancy. More than one-third of adults in the United States are overweight and an estimated 5 to 10 million people in the United States are morbidly obese.

The Roux-en Y gastric bypass is one of the most effective treatments for morbid obesity; however, leakage occurs in nearly 4% of all patients that undergo the procedure. Initially, the design team ruled that tension was the main cause of leakage at the GJ anastomosis. Upon further study and questioning, the team has decided that the cause of the leakage is not so clear. Thus, the goal has been defined to simply reduce leakage at the GJ anastomosis and not necessarily through the mechanism of tension.

Ethicon expects a working design and prototype to be delivered by the end of the second term. Moving toward this end, the team has selected a final design this quarter that will be further designed, built and tested next quarter. The design is a wrap containing an adhesive substance and possibly additional agents that promote tissue healing. The wrap will be able to be applied in a laparoscopic or open procedure in addition to suturing or stapling of the anastomosis.

This quarter the team defined the scope of the project, performed background research on the procedure and related technology, performed market research, developed design concepts, interviewed surgeons and selected a final design. A summary of this quarter’s work was given in a presentation on Wednesday, March 13; the slides are contained in Appendix A. They provide a quick overview of the progress thus far. Another good summary is the original sponsor project description contained in Appendix F. Although some things have changed in the project description, it still provides a good overview of the initial project requests.

In the next quarter the team will select materials and an adhesive, possibly select a healing agent to incorporate, select an applicator device, perform detailed design on the wrap and applicator, prototype the wrap and applicator and test the wrap and applicator. A working prototype along with design specifications and a testing report will be submitted to Ethicon upon completion of next quarter.
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Project Team

The project team is composed of three ME 282 students, sponsors at Ethicon Endo-Surgery, and a consulting surgeon at the Stanford Medical Center. Student biographies and pictures are given below along with contact information for all team members.

ME 282 Students

Mark, a first year graduate student in mechanical engineering, graduated last May from Iowa State University with his B.S. in mechanical engineering. Over the summer, he worked for Guidant CRM in St. Paul before coming to Stanford. His professional interests are in biomedical design and especially the design of microsensors for biomedical applications. Originally from a farm near Sioux Falls, SD, Mark enjoys sports and outdoor activities in his spare time.

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Jen Cho, a Ph.D. candidate in mechanical engineering, graduated from MIT with her B.S. in ME, in June 2000. Her research focus is in design/fabrication of micro-mechanical sensors and actuators. Originally from Seoul, Korea, she enjoys intensive traveling across the country and Europe. She is very excited with her first class in the biomechanical engineering department.

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Jen Lake, currently a co-term student, is planning to graduate in June with a B.S. and an M.S. in chemical engineering. Previously she has taken a few other courses in the biomechanical engineering department, and is very excited to take a look at the real world problems presented in this class. She is originally from southern California, near LA. She grew up riding horses and now plays on the Stanford Polo Team.

Ethicon Sponsors

The ME 282 design team works with three key people from Ethicon (Rob McKenna, Lyn Freeman and Jean Beaupre) and one primary consulting surgeon (Dr. Pamela Foster). Rob is the primary liaison between Ethicon and the design team; he coordinates most of the efforts and communicates regularly with the group. Jean provides engineering support for the group. Lyn, in her supervisory role, offers suggestions and approves decisions that the group makes. Dr. Pamela Foster provides insight into surgical techniques and offers feedback on design concepts.

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Sponsor Background

Ethicon Endo-Surgery, Inc., is a Johnson & Johnson company with headquarters in Cincinnati, Ohio. Ethicon Endo-Surgery was formed in 1991 to focus on minimally invasive surgery. By 1995 the Company went from being a market share follower to the market share leader in both the laparoscopic and traditional surgery markets. Ethicon develops surgical instruments for minimally invasive surgery and educates surgeons on the use of new instruments. Ethicon works closely with surgeons to develop new innovative procedures and the necessary instruments. Ethicon is currently working in the field of bariatric surgery to improve procedures for treatment of morbid obesity.

Clinical Background

According to information provided by Ethicon, more than one-third of adults in the United States are overweight and an estimated 5 to 10 million people in the United States are morbidly obese. The cause of obesity is not simply overeating. Research has shown that in many cases genetics is a significant factor. Also studies have shown that diet and exercise alone are not effective in providing long-term relief in severe cases (St. John Weight Loss Institute). Obesity surgery has been proven an effective tool in the treatment of morbid obesity.

Morbid obesity is associated with a shorter life expectancy. Obesity-related health conditions include Type 2 diabetes, high blood pressure, heart disease, osteoarthritis of weight bearing joints, sleep apnea, respiratory problems, heartburn, depression, infertility, urinary stress incontinence, and menstrual irregularities (Laparoscopy.com).

Several different gastric bypass surgeries exist. The most common procedure is the Roux-en Y Gastrojejunostomy, the surgery targeted for this project. In the Roux-en Y procedure, the size of the patient’s stomach is reduced to a tenth of the original size to give the patient a feeling of satiety much quicker. The digestive tract is also rerouted to decrease the number of calories absorbed by the body so as to enhance weight loss. The schematic below depicts the result of a Roux-en Y gastric bypass.
In the Roux-en Y procedure, the surgeon first transects and staples the jejunum at a point measured from the ligament of Treitz. The proximal end of the jejunum is then reconnected to a more distal portion of the jejunum, forming the Roux-limb. The Roux-limb is brought up through the mesentery to the stomach. The small stomach pouch is formed using a stapler. The Roux-limb is then connected to the stomach pouch. This gastro-jejuno (GJ) connection is the focus of this project. The anastomosis is either sutured by hand or stapled using either a circular or linear stapler (Advanced Laparoscopic Associates).

**Need / Market Analysis**

Obesity is one of the fastest growing health problems in the United States. The Center for Disease Control estimates that over 20% of the US population is obese [Body Mass Index (BMI) > 30] (Center for Disease Control). Gastric bypass surgery is one of the most effective treatments of morbid obesity. According to Ethicon, about 8 million people in the United States qualify for obesity surgery; however, only around 40,000 gastric bypass procedures were performed in 2000 with another 50,000 procedures in 2001. The number of surgeries performed is expected to increase, but there are several factors limiting the number of surgeries.

One of the reasons for this discrepancy is the shortage of qualified surgeons, as the procedure is technically challenging. Ethicon estimates that currently about 200 surgeons perform 80% of all gastric bypass procedures. Traditionally the surgery was highly invasive with a large incision in the abdomen. Although laparoscopic procedures have
become more common recently, most gastric bypass surgeries are still performed as open procedures since they are easier for the less experienced surgeon.

**Benchmarking and Related Technology**

The Roux-en Y procedure has continually undergone improvement over the past 20 years, and has become a relatively safe and effective procedure. A major cause of complications is the failure of the GJ anastomosis. There are several competitors in the market that have offered current approaches for improving anastomosis techniques.

The Endo GIA Stapler, patented by US Surgical, is currently regarded as the state of the art by most surgeons. It places a triple line of staples in the tissue on either side as it cuts down between the staple lines. Staple sizes vary to accommodate different tissue thickness. Ethicon makes a similar linear stapler and also provides a circular stapler, which puts down a double line of staples in a circle. This stapler can be used to attach parts of the intestine together or to form the GJ anastomosis.

![Figure 2: Endo GIA Stapler (US Surgical)](image1)

![Figure 3: EndoCinch (BARD)](image2)

There is also a wide range of suturing devices. The Endo Stitch, also made by US Surgical, allows sutures to be easily placed. Tissue can be grasped securely between the jaws of the Endo Stitch simply by closing the handles of the instrument. The needle and suture are then passed through the tissue. The Endo Stitch is effective for a wide range of tissues and defect sizes and can be used laparoscopically. Several other competitors have comparable devices, such as Paresurgical’s Quik-Stitch.

The EndoCinch, made by BARD is another suturing device, but has a very specific target use. It is used transorally to place two stitches in the bottom of the esophagus to prevent heartburn. The mechanics of this device, though, may be useful as the Roux-en Y surgery is being driven toward a more transoral surgery.
The AxyaWeld system, made by Axya Medical, delivers a welded AxyaLoop, a suture loop that is secured using ultrasonic energy. The system is comprised of three components: an ultrasonic generator, a resterilizable handpiece and a per-patient disposable welding component.

Some patch-like solutions are available to reinforce both stapled and sutured anastomoses to keep them from leaking. Cohesion has developed a sealant, CoSeal, which consists of two synthetic, biocompatible components. The components are mixed together in the delivery device and applied as a liquid. CoSeal is designed to rapidly adhere to host tissue and inhibit leakage from surgical sites. CoSeal remains intact through the critical wound healing period and then is absorbed and eliminated by the body.

Biovascular has developed Peri-Strips Dry to reduce leaks at staple lines; they prevent staple holes from enlarging and act as a patch. The Peri-Strips Dry can be used in conjunction with any of the linear staplers, but have not been developed for the circular staplers yet.
Covered stents have been used to manage gastroesophageal leak after cancer resection (Roy-Choudhury). Patients treated with stents are very ill, and the stent can help prolong their life for up to a year or two. The long-term use of stents in the GI tract is still under investigation.

The Symmetry Bypass System, a stent-like clamp, has been developed by St Jude Medical to connect vessels without the use of sutures. The Symmetry Bypass System is designed to have the same burst strength as sutures, but is much easier for the surgeon to deploy.

Regardless of the design chosen, the team will need to employ biocompatible materials. Design and creation of new biomaterials is currently underway at many medical companies around the country including Ethicon. The design team will need to use an absorbable material for the final design that has been selected. Below is a chart of absorbable biomaterials and additives from the Kensey Nash Corporation. More research will need to be done next quarter on absorbable materials before the team can select which material will best suit the design requirements.

**Materials**
- Polyesters: Polylactic acid (PLA), Polyglycolic acid (PGA), Polycaprolactone and Copolymers
- Poly(carbonates)
- Poly(anhydrides)
- Poly(amides)

**Additives**
- Synthetic and Natural Polymers
- Ceramics: Hydroxyapatite (HA), Calcium Phosphates, Calcium Sulfates
- Radio-opaque Substances
- Biologics and Drugs
Another biomaterial that the team considered was Dacron. Currently Dacron is used for vascular grafts. These grafts are often coated with protein (collagen/albumin) to reduced the blood loss and antibiotics to prevent graft infection. Dacron is not resorbable, though, and will not be considered for the final wrap design. A Dacron wrap kept on the anastomosis for a long period of time could act to erode the tissue and cause more harm than benefit.

![Figure 9: Dacron graft (Surgical-tutor.org.uk)](image)

Nitinol is a commonly used material in stent manufacturing. Nitinol displays excellent biocompatibility, very high corrosion resistance, and excellent cytocompatibility of NiTi. Its most desirable property is that it has shape memory. The Nickel in NiTi is chemically joined to the titanium in a strong intermetallic bond, so the risk of reaction, even in patients with nickel-sensitivity, is extremely low. Nitinol was considered when the team was looking closely at stent graft solutions. Now that a wrap has been selected as the final design, the team is considering the use of nitinol in an applicator because of its shape-memory characteristics.

Patents were also referenced to help with idea generation and scope the existing technology. A brief list of some of the key patents is provided in Appendix D. Most of the patents that we found discuss the technology presented above or technology that is similar.

**Scientific Background**

Creation and healing of the anastomosis is the key concern for our project. Unfortunately the process of wound healing is very complex and not completely understood. Tension is thought to be a main cause of leakage, but even that hypothesis has not been proven. Numerous studies have been done on comparing suturing methods. Traditional methods include suturing, stapling, and gluing. All three have their pros and cons. Suturing was found to have the highest tensile strength, but suturing requires a great deal of skill and is very time consuming especially in minimally invasive procedures. Stapling is much faster and easier, but staples are associated with a higher stricture rate (Blair), and some surgeons worry about mechanical failure. Leak rates between staples and sutures are comparable (Fakhry). For the GJ anastomosis, surgeons are not comfortable with using glue alone, but many use an adhesive in addition to stapling or suturing.
In 1988 a study at the Kentucky Chandler Medical Center reported the complications from 920 Roux-en-Y gastric bypass procedures. Anastomotic leak occurred in 23% of patients. Complication rate in revisional surgeries was also very high at 50% (Schwartz). In a more recent study done on the laparoscopic Roux-en Y gastric bypass, the GJ anastomosis was identified as a critical, technically demanding, and time consuming step. Of the cases, 2.1% developed leaks at the GJ anastomosis and 27.1% developed stenosis of the GJ anastomosis. The study stated that stapling was much easier than suturing the anastomosis. Stenosis was slightly higher with the stapler while the leak rate was comparable to the hand sewn technique (Mathews).

A study in 1991 by Jansson compared glued, sutured, and stapled anastomoses. The results were that sutures provided the greatest breaking strength followed by staples, followed closely by the glue. There was no significant difference in wall thickness of the anastomosis four days post-op. All three types of anastomoses showed comparable increased blood flow to the anastomosis.

Growth factors and cells can also be added to adhesives or sealants to aid in healing. The healing process is a delicate balance and adding the wrong component can either be ineffective or worse create too much of a reaction which can lead to scaring (Wound Healing). More background research will need to be performed early next quarter to determine if biological stimuli can be added to enhance tissue healing.

**Problem / Needs Statement**

According to Ethicon, leakage at the anastomosis occurs in 4% of the patients, and 1 in 3 leaks result in death.Leaks usually become apparent within 12 hours of surgery, and if detected can be repaired. Leaks can occur up to a week after the surgery, but are not as common. The picture below shows the anastomosis that is of concern.
Initially, tension at the GJ junction was identified as the primary cause of leaks. This tension, while not completely understood, is thought to result from normal peristalsis, spasmodic tissue contraction, the weight of the intestine, and forces from general movement such as standing up or reaching. The forces on the anastomosis could possibly act to peel the jejunum away from the stomach pouch. According to Ethicon, the tissues involved in the anastomosis can only recover up to 60% of the native tissue strength. As a result, excessive tension at the anastomosis could affect the tissue’s ability to heal properly and could cause other complications such as stricture of the anastomosis and necrosis of the surrounding tissue.

Through additional research and discussions with several surgeons, the team learned that tension may not be the main problem causing leakage. Other factors, including poor anastomotic blood supply, poor tissue strength, failure of staplers, patient co-morbidities and surgical technique, are also thought to contribute considerably to leakage.
**Scope of Project**

The major limitations of current Roux-en Y gastrojejunostomy include complexity, invasiveness and the possible leakage of stomach contents. Ethicon’s long-term goal is to devise the easiest and least invasive bariatric procedure while minimizing post-surgical complications. In light of Ethicon’s goal, we have been given the task to find a way to prevent leakage at the gastro-jejuno anastomosis after a Roux-en Y Gastrojejunostomy.

Though initially our immediate focus was on tension relief to lessen leakage at the GJ anastomosis, the scope has been broadened to simply finding the best way to prevent leakage. We will keep in mind the other steps in the surgery (bowel division, Roux limb management) and may modify other portions of the procedure to minimize the invasiveness of our device. However, our project deals with other portions of the surgery only if they impact the leakage at the GJ anastomosis or the invasiveness of our device.

**Project Goals**

In light of the project scope, the team’s goals are as follows:
- Fully understand the Roux-en Y gastric bypass procedure
- Gain in-depth knowledge of existing solutions to similar problems
- Develop awareness of the bariatric market and other potential markets for the anastomotic leakage device that the team designs
- Understand the requirements needed for a good design
- Produce a list of specifications that the device must meet
- Select a final design out of the concepts that are generated
- Create detailed design specifications
- Prototype the final design
- Test and evaluate the final design

The implementation of these goals or a plan for their future implementation is provided in the following sections of the report.

**Customers**

Ethicon Endo-Surgery, Inc., a Johnson & Johnson company, will be the primary customer to the design group. The company manufactures surgical instruments used for minimally
invasive surgery. Customers at Ethicon include the Franchise Development department as well as manufacturing and marketing personnel that will be impacted by the design.

Surgeons and patients will also be customers whose wants and needs must be satisfied. A device should be made that surgeons feel comfortable using and that will be safe and reliable for the patient. Dr. Pamela Foster, a bariatric surgeon at Stanford, is the main consulting surgeon to the design team. Several other experienced bariatric surgeons have been consulted as well.

The design team must regard the FDA as a customer and ensure that the device that is designed will pass their regulatory approval. Also, the payer, which can be Medicare, insurance companies, or the patient, must be consider a customer toward which cost is most important.

**Design Requirements**

The following list of design requirements will be used as a basis for generating specifications with measurable targets:

- **Safe** – The new device or procedure should produce less risk of morbidity or mortality when compared to current methods. Current GJ leak rate is around 4%. Death rates from leaks are around 1 in 3. The device must also be biocompatible and not harm the patient in any way.
- **Effective** – The design objective of reducing leakage at the GJ anastomosis must be achieved.
- **Reliable** – Desired result should be delivered and maintained over time consistently.
- **Minimally Invasive** – Devices must be small enough to fit through a trocar or through a human’s esophagus.
- **Shorten Hospital Stays** - Hospital time is expensive. Current hospital stays average 2-4 days for the current laparoscopic approach.
- **Easy to Learn and Use** – Training should be minimized for users with the possibility of learning in a procedure with minimal pre-training. This can be accomplished by making the device intuitive to use.
- **Deliverable Device** – By the end of the second quarter, the team should have a tangible device that can be evaluated by surgeons and delivered to Ethicon.
- **Simple Design** – Opportunity for mechanical failure (i.e. minimize moving parts) should be diminished. More things can go wrong with a complex design.
- **Universal** – Device should be able to be used on all types of patients and for varying surgical approaches. A device that can be used for multiple procedures is especially useful.
- **Manufacturable** – Ethicon must be able to manufacture a device fairly easily and inexpensively. Ethicon must be able to produce a device at a cost less than 30% of what they sell it for.
Inexpensive – Cost must be diminished to make and sell. Doctors are very cost conscious. If overall cost is not reduced with a new device, it has to add a lot of value elsewhere (i.e. less time or shorter stay).

Appearance – The appearance of the device should enhance its appeal

Minimum Regulation – Potential regulatory issues should be minimized to save money and to decrease the time to obtain market approval.

Requirements vs. Customers

The requirements of the design are listed below and ranked by importance to each customer. The rankings are on a scale from 1 to 10 (10 being most important). The rankings for Ethicon and surgeons are based on numbers provided by both of these customers. The rankings for patients, FDA and the payer were gleaned from information given by Ethicon and various surgeons.

The requirements rankings by the customers were used to evaluate the importance of each of the requirements in the evaluation of designs. The rankings for Ethicon, the surgeons and the patients were weighted more heavily (25% each) than the FDA and payer (12.5% each) since they were considered the most important customers.

Table 1: Requirements vs. Customers

<table>
<thead>
<tr>
<th></th>
<th>Ethicon (25%)</th>
<th>Surgeons (25%)</th>
<th>Patients (25%)</th>
<th>FDA (12.5%)</th>
<th>Payer (Insurance, Medicare, Patient) (12.5%)</th>
<th>Overall Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>9</td>
<td>9.9</td>
</tr>
<tr>
<td>Effective</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>7</td>
<td>9</td>
<td>9.5</td>
</tr>
<tr>
<td>Reliable</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>9</td>
<td>9.9</td>
</tr>
<tr>
<td>Minimally Invasive</td>
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<td>8</td>
<td>8</td>
<td>4</td>
<td>7</td>
<td>7.4</td>
</tr>
<tr>
<td>Shorten Hospital Stays</td>
<td>5</td>
<td>5</td>
<td>7</td>
<td>3</td>
<td>10</td>
<td>5.9</td>
</tr>
<tr>
<td>Easy to Learn and Use</td>
<td>8</td>
<td>8</td>
<td>2</td>
<td>5</td>
<td>1</td>
<td>5.3</td>
</tr>
<tr>
<td>Deliverable Device</td>
<td>7</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Simple Design</td>
<td>6</td>
<td>6</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>4.3</td>
</tr>
<tr>
<td>Universal</td>
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<td>5</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>4.4</td>
</tr>
<tr>
<td>Manufacturable</td>
<td>9</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Inexpensive</td>
<td>8</td>
<td>8</td>
<td>9</td>
<td>1</td>
<td>10</td>
<td>7.6</td>
</tr>
</tbody>
</table>
After ranking the customers’ requirements, the design team produced a list of specifications to provide a way for the requirements to be met. These specifications were then assigned measurable targets to provide a quantitative way to evaluate alternative designs.

**Table 2: Design Specifications**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max FDA regulation</td>
<td>Must pass 510k with clinicals</td>
</tr>
<tr>
<td>Max tension allowed</td>
<td>TBD</td>
</tr>
<tr>
<td>Max GJ leak rate</td>
<td>2%</td>
</tr>
<tr>
<td>Min effective duration</td>
<td>10 days</td>
</tr>
<tr>
<td>Max diameter</td>
<td>21 mm (laparoscopically)</td>
</tr>
<tr>
<td></td>
<td>18 mm (transorally)</td>
</tr>
<tr>
<td>Maximum days for hospital recovery</td>
<td>2</td>
</tr>
<tr>
<td>Max time added to surgery</td>
<td>10 min</td>
</tr>
<tr>
<td>Max # of parts</td>
<td>Minimize. No specific target.</td>
</tr>
<tr>
<td>Min # of different methods it can used</td>
<td>1</td>
</tr>
<tr>
<td>Max cost to produce</td>
<td>$100</td>
</tr>
</tbody>
</table>
Vision / Strategy

The overall strategy that the team employed in the design process was to narrow the scope of the problem and broaden the field of possible concepts. The team took this approach so that focus could be applied to a singular problem while not limiting creative solutions.

Knowledge of the problem was also critical to a successful design; the team put much effort into reviewing literature and the current market and interviewing surgeons. A quantitative analysis was also performed where design concepts were ranked by requirements. Although the knowledge gained and the analyses performed greatly helped in selecting a final design, they were used only to support decisions, not to make them. Final decisions were based more on instinct and overall synthesis of the information than on the rankings and specific studies themselves.

Overview of Work Completed

We investigated several different approaches to reduce leakage, including biological/chemical, mechanical, and direct modification of surgical procedure. A biological/chemical approach involves application of growth factor or fibrin-based sealant. A mechanical approach would aim to reduce the stress at the anastomosis by adding a supporting structure, either intra or extra-luminally. A modification of the surgical procedure would aim to eliminate the source of leakage by implementing alternatives to anastomosis creation or roux limb management techniques.

To better understand each of the approaches, background research was performed. Brainstorming was done on multiple occasions to develop creative design solutions. Surveys were also conducted with surgeons so that we could better understand their viewpoint and discover which options they would employ. The following section discusses the surveys in more detail.

After brainstorming and conference meetings with Ethicon, we narrowed down our design to 4 different concepts. They are discussed in detail in the next section. Our initial leaning was toward an intra-luminal stent graft seal that supports the roux limb and also seals off the anastomosis from the lumen. However, most surgeons we interviewed showed strong resistance to the idea of placing a foreign material inside the lumen. Concerns were raised about patient safety, food obstruction, and whether relieving the downward tension alone could actually reduce the leakage.

Finally, the team selected an extra-luminal wrap for the final design; it will reinforce the staple/suture line and contain the leakage in case of technical failure. Subsequently,
adhesives and growth factor will be investigated and possibly incorporated to our wrap prototype.

**Surgeon Surveys**

The team surveyed five surgeons in order to better understand their viewpoint. In the survey we identified five major areas that are critical to the quality of surgical outcome - leakage at GJ anastomosis, stricture at GJ anastomosis, pouch creation and sizing, GJ anastomosis creation, and Roux limb management (i.e. bringing Roux Limb through mesentery and positioning in place for anastomosis). We asked the surgeons to rank the challenges by importance and by how satisfied they were with their current method of solving the challenge. All the surgeons we interviewed identified the leakage at GJ anastomosis as the most important. However, many of the surgeons were also very satisfied with the results of their anastomosis. This was probably because only experienced bariatric surgeons were interviewed. The results may have been different for a different population of surgeons.

Four of the five surgeons sutured the anastomosis; one of the surgeons stapled the anastomosis with a linear stapler and then sutured over top of it. The surgeons tended to feel more secure with a sutured anastomosis than with a stapled one, but all attributed a steep learning curve to suturing. GJ anastomosis times ranged from 15 min to 1 hr. The surgeons cited tissue failure and the surgeon’s technique as the main causes of leakage; Tension was also mentioned as a cause. The surgeons had not taken many steps to help reduce leakage other than a double row of sutures. Because this was successful for them, they did not feel the need to use the adhesives offered on the market. One of the younger doctors uses fibrin glue, but has no idea how effective it is.

The surgeons were also asked to review the four design concepts in the survey. The feedback on design concepts is discussed in the ‘Evaluation of Designs’ section of the report. The completed surgeon surveys are contained in Appendix H.

**Design Concepts Generated**

Through multiple brainstorming sessions, the group developed multiple ideas for reducing leakage at the GJ anastomosis. Preliminary sketches are attached in Appendix E. From the wide array of design concepts, the group limited the field to four possible concepts that are presented here.

1) **Adhesive/Sealant**
   - Can be applied externally (laparoscopically) or internally (transorally)
   - Similar to fibrin sealants available on market
   - Can be incorporated into circular stapler or applied with separate applicator
Figure 11: Adhesive Design Concept

Figure 12: Adhesive Incorporated with Circular Stapler
2) **Sleeve/Wrap/Seal**
- Can be applied externally (laparoscopically) or internally (transorally)
- Can be incorporated with Fibrin sealant or other adhesive component
- Can be incorporated with circular stapler or implanted with separate applicator
- Can be made of resorbable material (polyglycolic acid, etc.)

![Figure 13: Wrap/Seal Design Concept](image)

3) **Stent Graft**
- Can seal and provide support to anastomosis
- Can be incorporated with adhesive and seal concepts
- Can be applied with circular stapler or with separate applicator
- Can be made resorbable
Figure 14: Stent Graft Design Concept

4) **Stent Stomach**
- No need to staple off stomach pouch
- Procedure easily reversible
- Maintain access to biliary tree
- Saves time
- Need material that is distendable, strong, lubricious and lasts multiple years in GI tract
- Ends will be sealed to prevent leakage
- Can be used with circular stapler or other method
Figure 15: Procedure to Implant Stent Stomach

1) ANASTOMOSIS (GJ)

2) STENT GRAFT - STOMACH LEFT IN TACT
**Evaluation of Designs**

**Design Concepts vs. Requirements**

The four design concepts that were selected were compared with each other on the basis of how well they satisfied the design requirements.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Adhesive</th>
<th>Wrap/Seal</th>
<th>Stent Graft</th>
<th>Stent Stomach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe (11.7%)</td>
<td>9</td>
<td>8</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Reduces Leakage (11.3%)</td>
<td>7</td>
<td>9</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Reliable (11.7%)</td>
<td>7</td>
<td>9</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Minimally Invasive (8.7%)</td>
<td>7</td>
<td>6</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Shorten Hospital Stays (7.0%)</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>7</td>
</tr>
</tbody>
</table>
The adhesive and wrap ideas seemed to be the simplest, safest and most reliable of the designs. Because of this, the designs were also expected to be less expensive and subject to less regulation. The design team felt that the wrap would be easier to deliver by the end of the semester than an adhesive. The wrap could incorporate an existing adhesive, but it would be difficult to develop a new adhesive with the team’s background. The stent ideas were exciting at first because they seemed more novel and innovative. However, uncertainty about their effectiveness and the possible complications that they could cause made them less attractive.

**Feedback from Surgeons on Design Concepts**

The following input given by the surgeons was also used to help evaluate the designs:

?? Surgeons ranked the design concepts in the order of sealant/adhesive > wrap seal > stent graft seal > stent stomach.

?? Surgeons were leary of any intraluminal designs due to the harsh environment in the GI tract. They were afraid that a device in the GI tract would either be moved out of position and cause other problems or would not be able to withstand acidic environment.

?? Due to the current low leakage rate, and high level of satisfaction/comfort with current techniques, most surgeons showed resistance to adopting any drastic changes to their procedure, such as the stent graft seal or the stent stomach.

?? Most of them were in favor of suturing, because it is hard to recognize mechanical failure (“bad staple”) and hard to correct. Some were supportive of the idea of reinforcing the staple line with wrap/seal.

?? Early detection is critical to reduce leakage rate. Most surgeons perform leakage test a day after the surgery by jetting air in and looking for a leak.
Regulatory Considerations

In evaluating the designs, regulatory considerations were also accounted for. The checklist in Appendix G was helpful as a guide to understanding the regulatory status of our design concepts. All of the designs would be considered medical devices. The main regulatory consideration for the devices is in choosing the materials. The devices are all relatively simple and similar to existing products that have been approved (with exception to the stent stomach). Choosing a material that has been approved in a similar device would greatly help any of the design concepts pass through regulation.

The stent designs would seem to require more rigorous regulatory inspection than the wrap or adhesive because they would be left in the body indefinitely. The stent graft design could be made so that it breaks down. However, because this function would be novel and could cause possible complications such as blocking the GI tract, it would be thoroughly screened by the FDA.

Assuming that the adhesive design would not incorporate any new chemicals or materials, the device could pass as a Class II device, probably with a 510k. The wrap would also be a Class II device and may need to undergo a 510k. The stent graft design could possibly be a Class II device since stents have been used in the esophagus and other portions of the GI tract. However, because the application of the device is in a new location, it is quite possible that the device would need to go through a PMA as a Class III device. The stent stomach would probably be classified as a Class III device and require a PMA simply because there is nothing similar to it on the market.

Final Design Selection

The wrap was selected as the final design because it was a solution that the team felt could be safe, effective and accepted by all customers: surgeons, patients, Ethicon, FDA and payer. A brief description follows.

Design Selection : wrap-seal with incorporated adhesive/growth factor

?? External to lumen
?? Can provide better adhesive distribution than adhesive applied separately
?? Reinforces both staple and suture line
?? Incorporated growth factor will shorten the healing time
?? Does not directly relieve tension
Design Specifics

Biodegradable Material
Possibilities include:
  - Natural – collagen based, cellulose, fibrin based, genetically engineered silk, hydrogel, etc
  - Polymer-lactic acid, glycolic acid, monocryl, vicryl, etc

Application - separate applicator compatible with laparoscopic procedure
Adhesive/growth factor – fibrin glue, gel foam, patient’s clotted blood, cultured cells (fibroblast), etc

Preliminary Applicator Design
Wrap is mounted on a catheter-like sleeve, containing a nitinol guidewire
The guide wire originally has a circular shape on its end that has the same size as the anastomosis
The guide wire is inserted into the stiff sleeve making the wire straight (Figure 18)
The catheter and guide wire are inserted into a sleeve in the wrap (Figure 18)
The device, with the wrap mounted on the end, is placed through a trocar to the location of the anastomosis.

As the sleeve is retracted, the guide wire assumes its original shape and helps form the wrap around the anastomosis (Figure 19)
Overview

The design team will have several challenges to face in the next quarter. A project plan has been set forth to help in accomplishing the goals. Detailed design, material selection, prototyping and testing will be the main functions of the team in the next quarter. A timeline and separation of responsibilities will help the team accomplish its goals efficiently. A list of expenses has been estimated to help the team think about the allocation of its available funds; it is contained in Appendix B. A list of resources that has been used and a list of resources that will be needed next quarter are contained in Appendix C.

Deliverables

The following deliverables have been requested by Ethicon:

- Design specifications
- Working prototype by end of Spring term
- Report on prototype tests, including:
  - Leakage tests
  - Materials tests
  - Ease of use tests (conducted with surgeons)

None of the goals stated above have been fully achieved at this time. Design specifications will be completed by mid-term of the next quarter. The working prototype and testing report will be finished near the end of next term.

Methodology

The remaining work required for the project can be divided into the following principle areas:

- Research of agents to promote tissue healing
- Materials selection
- Detailed design of wrap
- Wrap applicator selection
- Detailed design of wrap applicator
- Selection of healing agents
- Building and prototyping of both wrap and applicator
- Testing and Validation
The project will be continued next quarter with research of healing agents, materials selection and selection of a wrap applicator design. After healing agents have been studied, the team will select which healing promoters will be incorporated. Once wrap materials have been specified and an applicator design is selected, prototyping will begin. Detailed design of both the wrap and applicator will occur concurrently with prototyping; dimensions and other constraints realized in prototyping will help in finalizing the design. Shortly after prototyping, testing will begin and may warrant further designing and prototyping if time permits.

**Reliability and Validation**

**Evaluation of design**

Preliminary evaluation and validation of the design will be performed through surgeon interviews to determine its ease of use and appeal. Details in manufacturability and marketability will be discussed with Ethicon so that the team produces a device that can be feasibly made and sold.

**Testing**

Testing will be performed in the following areas:

?? **Application**

- Carried out with Dr. Foster on pigs
- Determine ease of use, how well it can be applied laparoscopically and how well the device seals around the anastomosis.

?? **Leakage measurement**

- Anastomosis will be created with pig tissue
- Stapled anastomosis will be tested because they are easiest to create
- Leakage will be induced in anastomosis by removing staples
- Wrap will be applied to the anastomosis
- Anastomosis will be inflated with air and submerged under water to identify leaks still occurring after wrap is applied

?? **Material property**

- Observe absorption of wrap in an in vitro environment
- Make qualitative judgments on how well material can seal during critical two week period

**Major Hurdles**

Several challenges will appear throughout the design process. Some that we have identified already are listed below.

**Choosing a resorbable material** – It may be difficult to find material with proper elastic and resorbable properties. If the proper material does not exist or if it hasn’t passed regulatory approval, it could force us to reconsider the design.
Although the team has not researched material options very much, we are fairly certain that a suitable material will exist and so we don’t feel a fallback plan is needed at this time.

**Understanding tissue healing** – It will be difficult to gain an understanding of the tissue healing process to know what will be best to incorporate to aid healing. If it becomes too complicated to add agents that promote tissue healing, we could go with something that exists on the market (fibrin glue) or leave this out of the design.

**Accurate testing** – It may be hard to prove the effectiveness of our design through testing. We think that the testing method outlined will be an effective way to prove that the device works. If the testing does not provide us with the information, we will search for another test method to evaluate the designs.

### Timeline

Below is the timeline provided in the last report showing the progress that has been completed at this time.

![Figure 20: Updated Initial Timeline](image)

The timeline includes key milestones and deliverables for both quarters. The timeline was an excellent tool in keeping the team focused on its goals this quarter. Over the past quarter, the team worked on many aspects concurrently – background research, surgeon surveys, developing design concepts. The spring quarter will require the same parallel planning so that the team can achieve results. Below is a more detailed Spring Quarter timeline:
Individual Responsibilities

Areas of focus were divided among the team members during the first quarter. These areas of ownership, while being shared with the entire group at times, indicate where each member has provided some leadership.

Mark Bly – project management, building and prototyping, regulatory
Jen Cho – detailed design/CAD, material selection, budget/finances
Jen Lake – biology/anatomy, benchmarking, testing

In the next quarter, the same general responsibilities will be assumed. Mark will work on project management and ensure that the project is proceeding according to the timeline set forth. Mark will be in charge of the building and prototyping since he has the most shop experience in the group. He will also advise on any possible regulatory issues since he is part of the regulatory committee.

Jen Cho will be the lead person for detailed design. She will coordinate materials selection efforts and work on creating a computer model of the final design. Jen will also remain in charge of the budget, ensuring that we do not exceed our limit.

Jen Lake will take the lead on tissue healing agents and adhesives. She will ensure that the group selects the appropriate healing promoters and adhesives. With her chemical engineering background, Jen is best suited for this role among the group members. Jen will also lead testing efforts.


Schwartz RW, Strodel WE, Simpson WS, Griffen WO. Gastric Bypass revision: Lessons learned from 920 cases. Forty-fifth Annual Meeting of the Central Surgical Association, Columbus, Ohio, March 10-12, 1988.


Appendix A: Presentation Slides
Appendix B: Expenses
The following list was generated initially as an estimation of expected overall expenses:

<table>
<thead>
<tr>
<th>Items</th>
<th>Overall Expenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shop licenses</td>
<td>$340</td>
</tr>
<tr>
<td>Relevant products in market</td>
<td>$600</td>
</tr>
<tr>
<td>Outside services</td>
<td>$700</td>
</tr>
<tr>
<td>Prototyping materials</td>
<td>$1300</td>
</tr>
<tr>
<td>Communications with sponsor</td>
<td>$160</td>
</tr>
<tr>
<td>Testing (facility rental/ equipment)</td>
<td>$400</td>
</tr>
<tr>
<td>Pig Lab</td>
<td>$0</td>
</tr>
<tr>
<td>Existing Ethicon product</td>
<td>$0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$3500</strong></td>
</tr>
</tbody>
</table>

The following expenses have been incurred thus far:

<table>
<thead>
<tr>
<th>Items</th>
<th>Expenses for Winter Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design Sketchbook</td>
<td>$9.47</td>
</tr>
</tbody>
</table>

**Total** $9.47

The following expenses are expected for next quarter:

<table>
<thead>
<tr>
<th>Items</th>
<th>Expenses for Spring Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shop licenses</td>
<td>$270</td>
</tr>
<tr>
<td>Materials (Nitinol, absorbable polymers, adhesives)</td>
<td>$1300</td>
</tr>
<tr>
<td>Cultured cells, growth factors</td>
<td>$1500</td>
</tr>
<tr>
<td>Porcine Tissue</td>
<td>$500</td>
</tr>
<tr>
<td>Testing (facility rental/ equipment)</td>
<td>$800</td>
</tr>
<tr>
<td>Pig Lab</td>
<td>$0</td>
</tr>
<tr>
<td>Existing Ethicon products</td>
<td>$0</td>
</tr>
<tr>
<td>Communications with sponsor</td>
<td>$130</td>
</tr>
<tr>
<td>General Supplies</td>
<td>$200</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$4700</strong></td>
</tr>
</tbody>
</table>

The budget for next quarter has been expanded to include more money directed for cultured cells, animal tissue, and testing fees and equipment. The team does not expect to meet or exceed the expenses listed above, but the guideline will provide an idea of how much we can allocate to certain portions keeping in mind other costs for the project.
Appendix C: Resources
Resources for the Ethicon Team

The following resources have been helpful to the design team this quarter:
  - Animal lab on Stanford campus
  - Dr. Foster and OR
  - Various bariatric surgeons
  - Ethicon sponsors
  - Lane library

We will need to acquire and develop the following resources and contacts to complete the project:
  - Air pump for inflating anastomosis for testing.
  - Place to obtain porcine tissue for testing (possibly Monfort Biological)
  - Staplers – provided by Ethicon
  - Nitinol – provided by NDC, a Johnson and Johnson Co.
  - Absorbable materials – some provided by Ethicon, others may need to be purchased
  - Possibly a resource for stitching fabric for wrap
  - PRL will be used for other prototyping needs
  - May try tensile tests if time permits – facility in Veterans Hospital will be used

Resources for 003 Design Room

We would like the following items in the design room to help us complete our project:
  - Scissors, tape, rulers, and general office items
  - Fax machine (can use one in BME office, though)
  - Fully-stocked fridge
Appendix D: Patent Search Information
Multiple patent searches were conducted over the course of the quarter and printed out. The printed patents were not included in the report, but can be provided on request.

Some of the more useful patents that we used include:

USPT# 5,104,025: Stapler with detached anvil (Ethicon)
USPT# 6,309416: Medical anastomosis apparatus
USPT# 6,146,416: Medical stents for body lumens exhibiting peristaltic motion
USPT# 6,329,337: Adhesive for biological tissue
USPT# 6,241,774: Artificial esophagus
Appendix F: Original Sponsor Description
Appendix G: Regulatory Checklist
Appendix H: Surgeon Survey