Gastric Band Slippage Detector

BMEN 3151 *Medical Device Practicum*

Advisor: Dr. Steven Saliterman
Team members: Matthew Steigauf, Tran Lu, Aaron Liu

Clinical Problem

Bariatric surgery is an effective method for treating severe obesity in adults. Done correctly, it can improve many issues severely obese patients face, such as type 2 diabetes, high blood pressure, heart disease, etc. A common type of bariatric procedure is the laparoscopic adjustable gastric banding (LAGB) which is a band fit around the stomach filled with adjustable amounts of saline. LAGB is one of the three most common bariatric procedures, with a higher prevalence in the UK than other countries. The most common complication for the gastric band is slippage, defined as the fundus of the stomach migrating above the band. Cases of gastric band slippages are typically presented with abdominal pain, food intolerance, regurgitation, and in extreme cases, gastric necrosis. The slippage is confirmed using either an X-ray or a contrast swallow test, which can lengthen the amount of time the band is miss-positioned. A normal band will typically sit at 30°—60° from the horizontal plane.

Need Statement

There is a need for the early detection of gastric band slippage and partial deflation system to reduce chances of major complications from LAGB surgery and improve patient quality of life.

Market Analysis

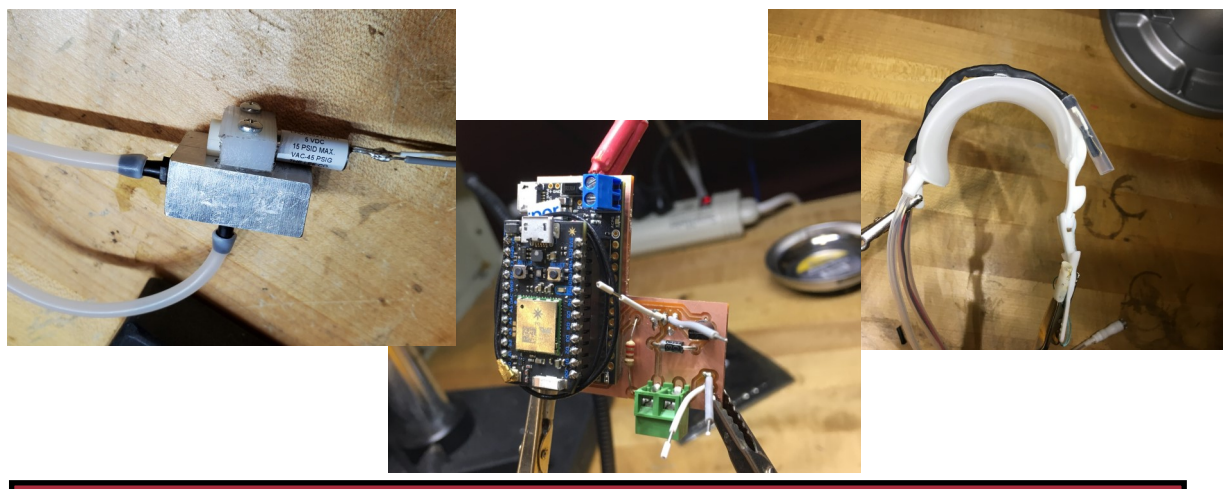
Bariatric surgery has seen a significant worldwide increase since first being introduced to the market. According to the International Federation for the Surgery of Obesity (IFSO), the number of bariatric procedures increased from 146,300 procedures in 2003 to 634,897 procedures in 2018. LAGB consists of approximately 10% of all bariatric procedures done. Several articles list the complication rates of the gastric band procedure range anywhere from 15% - 25%. The price of the LAGB procedure differs depending on which country you are collecting data from. The US lists a range of $10,004 ± $4,749 for the cost of the primary procedure from an article published in 2013. The cost of a revision surgery is higher than the primary procedure and is on average $14,153 ± $10,227. The revision surgery cost is highly dependent on the complication and its severity. The total market value for this product is approximately $225 million.

Medical Device Solution

As defined earlier, band slippages occur when the fundus of the stomach migrates above the band. Our device would need to detect major movement of the band relative to the location on the stomach. Our prototype does that by using a Particle Photon IoT device that connects to a Lee Company miniature 3 port solenoid, a custom made manifold, a PCB, and a system of always open magnetic reed switches.

The always open reed switches are used to detect distance from a magnet. If the sensor comes within range of a magnet, the switch will close. Our prototype uses 5 reed switches in parallel, when one or more switches detect a magnet, the switch closes, thus completing the circuit. This information is fed back to the Particle Photon board which will activate the solenoid once it receives a reading from the switches. The solenoid will then open into empty tubing, which will allow the pressure and the saline from the band to be dispersed.

The final device is intended to be fully implantable. The reed sensors are placed on the back of the gastric band and connected through tubing to the Particle Photon board and miniature solenoid near the saline port. There will be an encased magnet sutured on the part of the stomach that the band is on. The prototype has a safety feature that ensures a certain amount of time must pass where the reed switches do not detect the magnet before the band is deflated. The Particle Photon, solenoid, manifold, drainage tubing, PCB, and batteries would all be encased with stainless steel. The components of our prototype were chosen because of their small size.



Team Photo