

A HYDRAULICALLY CONTROLLED NONOPERATIVE MAGNETIC TREATMENT FOR LONG-GAP ESOPHAGEAL ATRESIA

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ABSTRACT

This paper describes a magnetic, non-operative device and control system designed to treat long-gap esophageal atresia (LEA). This congenital disorder occurs in approximately 100 newborn infants every year [1] and is characterized by a discontinuity in the esophagus between the mouth and stomach. Our device builds upon previous work investigating the use of internal permanent magnets to stretch the proximal and distal esophageal pouches together until anastomosis occurs. We implement a hydraulic standoff device for the proximal magnet assembly to control the distance between the two magnets independent of the esophageal gap size. The standoff allows for controllable, intermittent force between the two pouches and provides a layer of safety from runaway magnetic forces that could potentially damage delicate esophageal tissue. The proximal device comes in two variations: a convex tip for stretching the esophagus and a concave mating tip for meeting the distal end during anastomosis. An LED and phototransistor pair estimate the esophageal gap size for the duration of the procedure, and a fluid pressure sensor enables the force on the esophageal tissue to be calculated. The external control circuitry, physician interface, and pump are described that demonstrate the core functionality of the system.

1. INTRODUCTION

Long-gap esophageal atresia (LEA) is a congenital disorder affecting approximately 100 newborn infants each year in the

United States [1]. In these children, there is a discontinuity in the esophagus between the mouth and stomach long enough to make an immediate primary repair impossible. In this condition, both the upper and lower segments end in blind pouches in the deepest part of the chest. These gaps are usually at least 3 cm in length and can range as high as 6 to 10 cm in extreme cases. As nutrition cannot be provided normally, it must be delivered either through a gastrostomy tube or intravenously [2].

Traditional methods of treatment include replacing the missing esophagus with colon, jejunum, or a tube created from a portion of the stomach [3]. However, preserving and using the native esophagus is felt to create a better “70 year solution” for patients. Work in the 1970's by Dr. Hendren and Dr. Hale [4] and since the 1980's by Dr. Foker [5] has investigated the use of axial tension on the esophageal pouches to induce native tissue growth, allowing the two ends to be approximated [6].

2. NOMENCLATURE

Anastomosis – connection of two tubular structures

Bougie – Long, thin cylinder

Long-gap esophageal atresia (LEA) – A congenital defect in which a discontinuity in the esophagus of greater than 3 cm exists.

Proximal pouch – The esophageal segment connected to the mouth.

Distal pouch – The esophageal segment connected to the stomach.

Stricture / stenosis – narrowing of a structure

3. PRIOR ART

Across the spectrum of esophageal atresia cases, LEA's are the most difficult to treat since an immediate surgical repair cannot be made. Traditional methods such as gastric transposition provide a relatively quick means of establishing a pathway from the mouth to the stomach but oftentimes result in lifelong problems with gastrointestinal reflux disease, precancerous lesions, and other complications. Colonic interposition also limits effective peristalsis and usually requires a corrective surgery every few years [3].

The Foker method was developed at the University of Minnesota in the 1980's and is currently the most popular and successful means of treating LEA. The procedure involves sewing at least 4 traction sutures into the end of each esophageal pouch during a thoracotomy and bringing the sutures through the chest wall to the outside. The sutures on each pouch are then tensioned against the ribcage by a bolster that sits on the skin outside the body, inducing growth of the esophageal tissue. The tension decreases over time, and the process is repeated until the proximal and distal pouches are close enough for surgical repair. Typically, X-ray measurements of gap sizes are made on a daily basis. The procedure maintains the gastroesophageal junction below the diaphragm and does not require any myotomy, leaving most patients with normal esophageal function after treatment.

Several operations may be needed to treat LEA, hospital stays can range from weeks to months, and the complication rate is high. Anastomotic strictures are common, sometimes leading to difficulty swallowing and requiring ongoing operative treatment. Dense fibrosis and leaks at the anastomosis can also be a serious concern.

In 1973 and 1974, a magnetic tensioning method was tested in the MIT Francis Bitter Magnet Laboratory in collaboration with Massachusetts General Hospital [4]. A steel "bullet" attached to a catheter was placed in each esophageal end. The infant was then placed inside an electromagnet device, which induced an intermittent magnetic attraction between the steel bullets. The ends of the esophagus were successfully brought close to one another and anastomosis was achieved surgically. The two infants involved experienced complications related to gastroesophageal reflux and narrowing at the site where the esophagus was joined.

In 2004, Zaritsky et al. conducted a similar procedure at the Hospital de Niños de la Plata in Buenos Aires, Argentina using permanent magnets in lieu of the external electromagnet [7]. A

permanent magnet attached to a catheter was inserted into each esophageal pouch. The esophageal segments were stretched together due to the magnetic force, leading to autoanastomosis after a few days without surgical intervention for any of the five infants treated. The only major complication experienced in this trial was a stenosis at the interface between the esophageal ends. Initial gaps of up to 4 cm were treated.

Magnetic compression appears to be an effective method of anastomosing opposing esophageal ends without surgical intervention. In addition to Zaritsky's ongoing research, Jamshidi et al have demonstrated magnetic compression anastomoses (or magnamosis) without leak in adult pig intestine [8]. Takayasu et al. have also investigated the optimal magnetic bougienage shape to use in treating LEA with an external electromagnet [1].

4. DEVICE REQUIREMENTS

The use of magnetic force in treating LEA is a potentially game changing development for infants with this condition. The procedure can be carried out nonoperatively, allowing patients to avoid multiple surgeries associated with the Foker technique. However, there are some significant risks that must be addressed. The force between two magnets increases exponentially with the inverse of the distance between them. Because of this physical property, the forces involved in treating LEA are extremely weak at long separation distances and extremely strong as the two ends approach. Hendren et al successfully used a stretching force of 0.3-0.4 Newtons during their electromagnetic treatment of LEA [4]. To achieve this force for longer gaps using permanent magnets, larger magnets would be necessary due to the quickly diminishing attraction.

However, larger magnets may increase the risk of tissue damage and tearing as two ends approach each other. Therefore, a method of regulating the magnetic force to a constant, determinable level is necessary. It is also worth noting that high forces may actually be desirable for the anastomosis, since some of the tissue must be crushed and separated from the tissue that forms the sides of the continuous esophagus.

Our project was initiated with the goal of meeting the same functional requirements of previous magnetic approaches to LEA treatment while achieving additional safety and control objectives. An early version of the following list of requirements was presented to the design team by Dr. David Mooney of Children's Hospital Boston.

1. **Non-operative** – No thoracic surgeries should be required. Any device insertion should be through the mouth, nose, or the gastronomy feeding tube incision.
2. **Force Control** – As the two esophageal pouches are brought together, the force applied by the device on the esophageal pouches should be fully controllable.

3. **Physician Interface** – The physician should be presented with a simple interface consisting of one adjustable force value.
4. **Gap measurement** – The system should be able to measure an approximate gap size in real-time and determine if appropriate pouch approaching rates are achieved.
5. **Closed Loop** – The system should achieve the user-specified force value, within a tolerance, through closed loop feedback control.
6. **Fit and Comfort** – Any magnets and enclosures should be as small as possible. The maximum proximal and distal diameters should be 10 mm and 8 mm, respectively. The maximum proximal insertion length should be 30 mm.
7. **Treatable Gap** – The system should work for initial esophageal gaps of between 2.5 cm and 5 cm.
8. **Safety** – Redundant measures should be in place to avoid the possibility of runaway magnetic attraction forces or other system failures.
9. **Temperature** – The highest allowable temperature that may be reached by the components to be inserted into the patient is 40°C.
10. **Magnetic Fields** – Electronic equipment surrounding the patient should not be affected.
11. **Treatment Time** – No more than 4 weeks.
12. **Stenosis** – Anastomosis should not result in a serious esophageal stenosis.

5. MAGNETIC CONFIGURATION SELECTION

Magnets may offer a considerable advantage in treating LEA over pure mechanical solutions like the Foker method since no additional anchoring or suturing is needed to create a reaction force on the esophageal pouches. We considered several non-magnetic approaches involving devices to either push or pull the pouches together, but eventually determined that magnets offered the best overall solution. The force between magnetic bougies is self aligning, meaning that a magnetic device would have a very high chance of achieving autoanastomosis and avoiding complications requiring a thoracotomy. Since controllable force is also a key functional requirement, we considered several potential magnet configurations.

An **External Electromagnet** combined with internal steel bullets similar to the MIT magnet lab experiment could provide controllable force, but it is impractical to set up such a device in a normal hospital environment. Additionally, our system should not interfere with modern hospital room electronics, making large external magnetic fields unacceptable.

Internal Electromagnets are extremely desirable from a control perspective, since force can be quickly adjusted by varying the current supplied to the electromagnets. However, due to the field strength required, a high current would have to be passed through the solenoid of the electromagnet, resulting in significant heat dissipation on the order of watts. Without

active liquid cooling, the device would quickly surpass our imposed heating limit. Early calculations predicted temperatures as high as 60°C for such a device.

We also considered **External and Internal Magnets** in several configurations to produce a stretching force. For instance, a belt of electromagnets around an infant combined with two internal permanent magnets could provide control and avoid heating concerns. However, this approach adds considerable complexity to the system.

Internal Permanent Magnets offer an elegant and simple solution with the only drawback being a lack of force control as the two esophageal ends approach. However, if the distance between the magnet pairs could be controlled independently of the distance between the pouches, the key limitations would be overcome. We have accomplished this by using a stack of ring magnets whose position is controlled via an axially expanding balloon. A casing around the magnets and balloon transmits the force of the magnets to the proximal esophageal pouch.

6. SYSTEM OVERVIEW

Our system consists of 5 modules: the proximal magnet assembly with a hydraulically actuated standoff, the distal magnet assembly, the syringe pump and catheters, the control circuitry, and the physician interface. The design of each module will be covered in more detail in Section 7.

As previously described, the primary objective of the system is to achieve the benefits of simple permanent magnets while limiting risk by adding a closed-loop hydraulic standoff device to control the distance between the magnets independent of the decreasing esophageal gap size.



FIGURE 1 - Proximal Magnet and Catheter

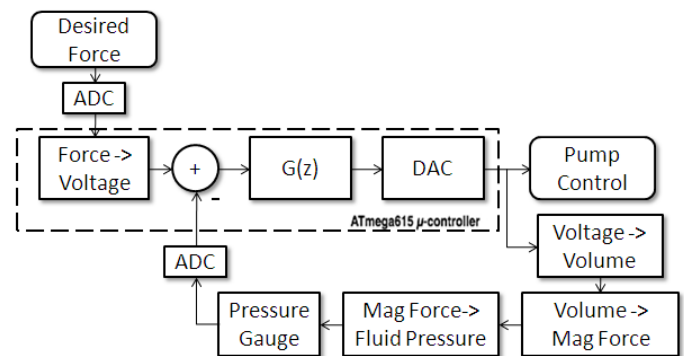


FIGURE 2 - Closed Loop Feedback Control Loop

The final version of this system will implement closed loop feedback control between the modules in order to maintain a requested magnetic force. Figure 2 illustrates the ideal feedback loop of the system as currently designed.

The treatment consists of multiple steps from patient admission until full recovery. Figure 4 illustrates a general overview of the system modules that interact with the patient. The steps can also be divided into 2 phases. Phase 1 is the stretching of the pouches until they are close enough to anastomose. Phase 2 is the anastomosis process. An outline of the steps follows:

Step 1: Insertion of Phase 1 proximal assembly in mouth with minimum balloon standoff. Once the assembly is in the upper esophageal pouch, the balloon is fully inflated to maximize the magnet standoff so that the initial attraction forces are minimized until safety is ensured.

Step 2: Insertion of distal magnet assembly along with feeding tube into stomach. Distal magnet is maneuvered into esophageal pouch using a guidewire. The proximal standoff is adjusted by deflating the balloon until the requested magnetic force is met.

Step 3: The esophageal pouches stretch together over days or weeks under magnetic attraction. A specific constant force is targeted by the physician, but it can be made intermittent in any arbitrary duty cycle to avoid pressure necrosis (Figure 3). An LED in the proximal end and phototransistor in the distal end measure changes in gap length.

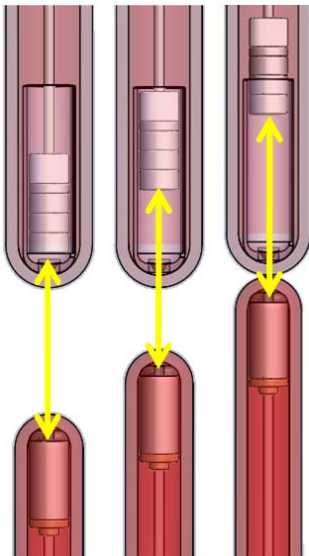


FIGURE 3 - Esophageal stretching process. A constant magnet separation distance is maintained.

Step 4: Just before the two pouches meet, the Phase 1 proximal assembly is removed. The Phase 2 proximal assembly has a

concave mating tip to fit the shape of the distal magnet. It also has no standoff balloon, since a high magnetic force is desired in order to induce anastomosis. The new proximal assembly is inserted into the mouth and anastomosis proceeds.

Step 5: Anastomosis is complete and a guidewire is fed through the distal catheter, passing through the bougies, which are now joined, and out the mouth. The magnets are then removed, leaving the guidewire in place should a dilating balloon be required to open any stricturing of the esophagus.

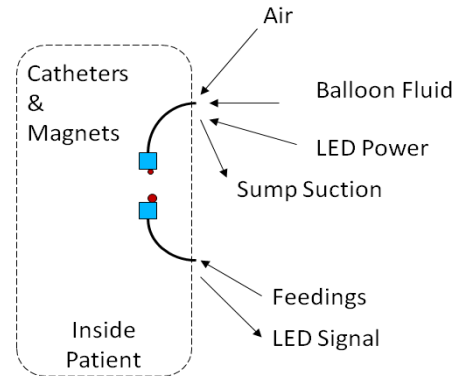


FIGURE 4 - Simplified System Diagram

7. MODULE DESIGN AND ANALYSIS

The system consists of an enclosed set of magnets for the proximal esophageal pouch, an automatically controlled syringe pump, and a magnet with a plastic tip for the distal esophageal pouch. The purpose of the syringe pump is to regulate the fluid in the balloon under the magnets to control their position in the case. Each magnet set is connected to a catheter leading outside the body. A pressure sensor monitors the fluid pressure exerted by the magnetic forces between the magnets, and an LED-phototransistor pair is used to determine the distance between the esophageal ends.

The magnetic force required to approach the proximal and distal ends of the esophagus was determined from the work of Zaritzky et al [6]. The magnets chosen here were sized to provide a comparable force at greater distances (Figure 5). An ideal applied force of 0.08 N was targeted, although this value is not available at all gap lengths (Table 1). If the desired force is outside the range of available forces, the system operates at the closest boundary. Additionally, the number and size of magnets in the distal and proximal assemblies can be varied for individual patients to optimize the available force range. The remainder of this section presents design details of each of the 5 primary system modules.

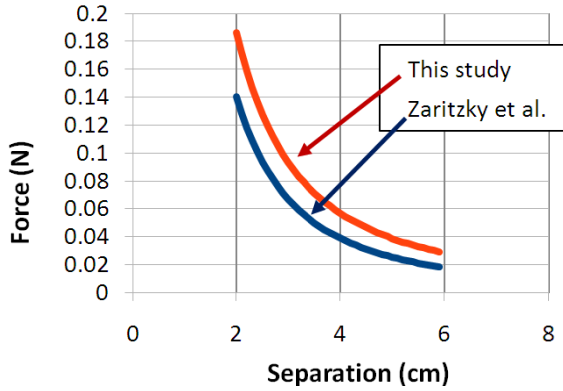


FIGURE 5 - Force-distance curve for magnets

TABLE 1 – Force ranges for various gap sizes based on hydraulic extension range of 30 mm

| Gap Size | Max Force | Min Force |
|----------|-----------|-----------|
| 1 cm | 0.30 N | 0.06 N |
| 3 cm | 0.10 N | 0.03 N |
| 5 cm | 0.04 N | 0.02 N |

7.1. PROXIMAL MAGNET ASSEMBLY AND HYDRAULIC STANDOFF

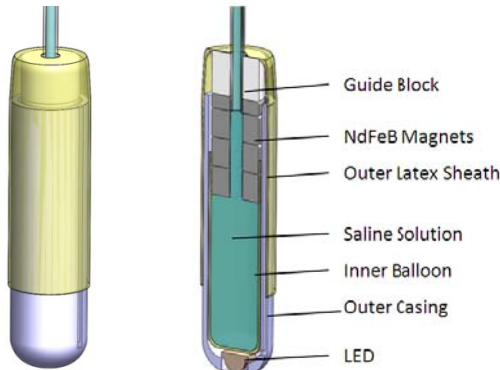


FIGURE 6 - Cross Section of Phase 1 Proximal Assembly

The Phase 1 proximal assembly consists of a stack of NdFeB permanent magnets with a balloon attached to the end. The balloon and magnets are sheathed in a casing of DMS Somos 11122 resin which restricts radial expansion of the balloon. A guide block is glued to the top of the magnet stack to increase the length-to-width ratio of the stack in order to minimize jamming in the casing. The casing was fabricated using a stereolithography (SLA) process.

The shell has an outer diameter of 8.38 mm and length of 30.1 mm (Figures 8, 7). The magnets have an outer diameter of 6.35 mm, and a central hole 1.6 mm in diameter and are allowed to slide up and down within the casing. A catheter is passed through the hole in the magnets to allow fluid in and out of the balloon. A latex sheath secured to the casing and running around the back of the magnets (Figure 6, 7-a) provides the

return force, pushing the magnets forward again as fluid is retracted from the balloon. The tip of the casing is also fitted with an LED (Figure 6).

The DMS Somos resin used here has a tensile strength of 47MPa. The maximum allowable pressure in the balloon was 60kPa; enough to separate the magnets but insufficient to cause harm. With this low pressure, the casing was sized to be robust during handling and insertion.

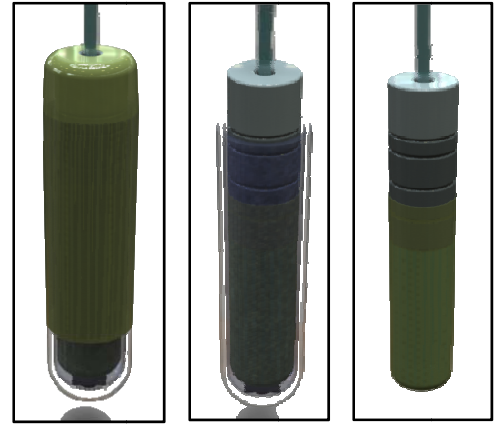


FIGURE 7 - Phase I Proximal Assembly (a) outer balloon over casing, (b) magnet assembly and inner balloon inside casing, (c) magnet assembly attached to fluid-filled inner balloon

Figure 8 depicts the actual size of the finalized Phase 1 proximal casing and magnets before the inner latex balloon and outer latex sheath are attached.

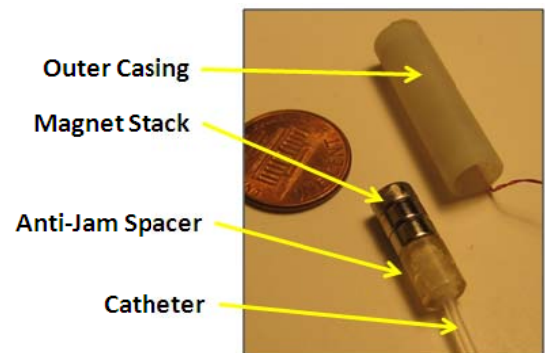


FIGURE 8 - Uncovered case for Phase 1 proximal assembly containing NdFeB Grade 42 magnets

Typical medical balloons are designed to expand radially. For this application, pure axial expansion was required, so custom latex balloons are created via dip molding of liquid latex. The unstretched dimensions of the balloon are a diameter of 4.5mm and a length of 10mm.

The Phase 2 proximal bougie is similar in construction to the Phase 1 bougie except that it lacks all flexible members and the

tip is concave to mate with the distal bougie. There is a central lumen which runs through the entire assembly, allowing a guidewire to be run down the attached catheter. After anastomosis has occurred, a guidewire run along this path could then be used to support additional devices being delivered to the region.

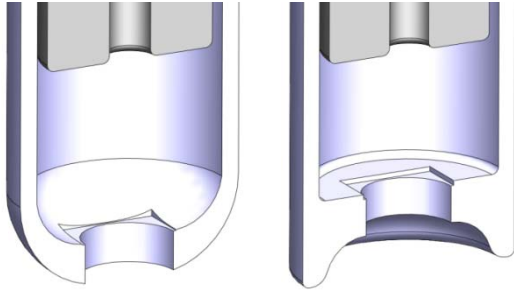


FIGURE 9 - Section view of (a) Phase 1 stretching tip and (b) Phase 2 mating tip

7.2. DISTAL MAGNET ASSEMBLY

The bougie for the distal pouch does not have a casing. Instead, it simply consists of a stack of magnets and a rounded, transparent polymer tip with a phototransistor cast within it. This assembly is also connected to a catheter and, like the phase two proximal bougie, has a central lumen allowing for the passage of a guidewire (Figure 10).

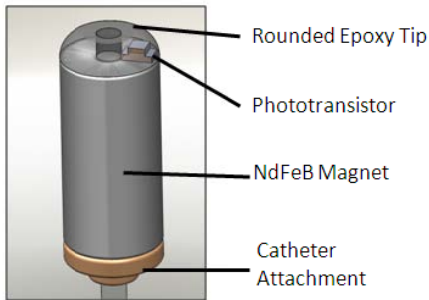


FIGURE 10 - Distal Magnet Assembly

A phototransistor and red LED (Figure 11-b,c) are placed in separate ends of the esophagus and used to determine the current gap distance. The phototransistor attaches to the cap of the distal magnets, and the LED is located in the end of the case containing the proximal magnets.

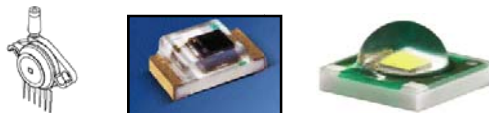


FIGURE 11 - (a) Integrated Silicon Pressure Sensor (b) Silicon NPN phototransistor (c) Xlamp®

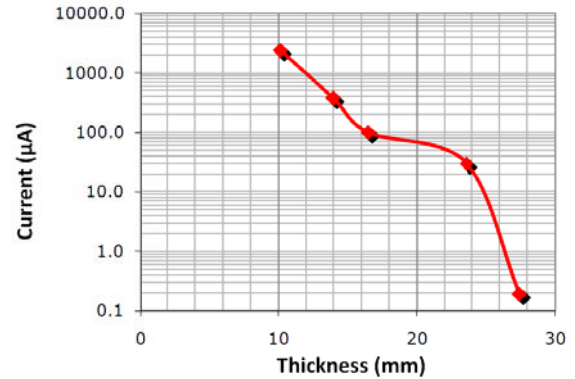


FIGURE 12 - Detection current versus tissue thickness

Using human hand tissue of varying thickness, the LED-phototransistor sensor output is measured (Figure 12). It is most effective at distances under 3 cm and approximately linear for distances under 1.5 cm. This range corresponds to the region for which the magnetic force begins to increase rapidly and detection of the distance is needed to regulate force.

7.3. PUMP AND TUBING

A syringe pump (Figure 13) actuated by a stepper motor is used to regulate the volume of fluid in the proximal bougie balloon. A series of catheters connects the syringe to the balloon through the central holes in the magnets. Only 1 mL of fluid is required to fully inflate the balloon, but to ensure a reasonable inflation speed, a 5 mL syringe is used with the pump.



FIGURE 13 - NE-310 Syringe Pump

A pressure sensor (Figure 11-a) monitors the fluid pressure between the pump and the balloon. As the force between the magnets increases, the pressure in the balloon increases, and this pressure sensor allows the control board to directly calculate the total force on the esophageal pouch.

7.4. CONTROL BOARD AND SOFTWARE INTERFACE

The pump and all other electronics are controlled by a central control board (Figure 14). Onboard is an 8-bit microcontroller (ATmega168) with a 20 MHz clock. This clock speed allows the board to process data and react quickly to events detected by the sensors. There are connectors that connect the control board to the LED, the photo-detector, the pressure sensor, the motor, the power input, and the USB interface to the computer. The on-chip 10-bit analog-to-digital converter (ADC) reads the sensors' outputs at a rate of 6 kHz, which are then processed in

the microcontroller. The LED can be turned on at 4 different power levels, which may be desired at various gap lengths. The photo-detector outputs a current which is an exponential function of the light detected, but that signal is processed by a logarithmic converter chip (Analog Devices, AD8304) to allow for a linear relationship between the voltage read in by the ADC and the detected amount of light.

An FTDI chip – FT232BL – provides for conversion of the UART communications from the microcontroller to a USB format which is easily readable by the computer. The data that is sent back to the computer is a summary of all of the states of the motor and sensors. The motor control chip (Figure 14) – Allegro A3982 – directly controls the stepper motor. It consists of digital logic and 2 H-bridges for precise full-step or half-step control of bipolar stepper motors.

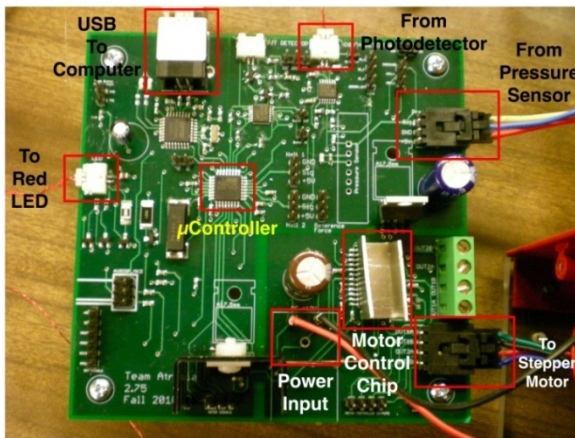


FIGURE 14 - Control board layout

The control board can receive commands from and report data back to a software graphical-user interface running in MATLAB® (Figure 15). Using a custom UART protocol, the software can modify any of the 32 16-bit registers in the microcontroller RAM that define the system's current state. Parameters that can be modified include the strength of the LED and its duty cycle, the ADCs which are ON and recording data, and the refresh speed. The motor can also be commanded to pump fluid in or out of the balloon.

The microcontroller uses this protocol to return 16-bit data to the software via UART. Such data includes the ADC sample values, the actual refresh rate, and the motor position. The software plots this data for the user in real time, gives the option to pause the data acquisition, and the capability to save a snapshot in comma-separated format.

Finally, the panel in the bottom right corner of Figure 15 shows the controls that would be presented to the end-user in the final product. These controls allow the user to specify intermittent force by choosing two force levels, for example, a maximum and a minimum force, along with the time spent at each level.

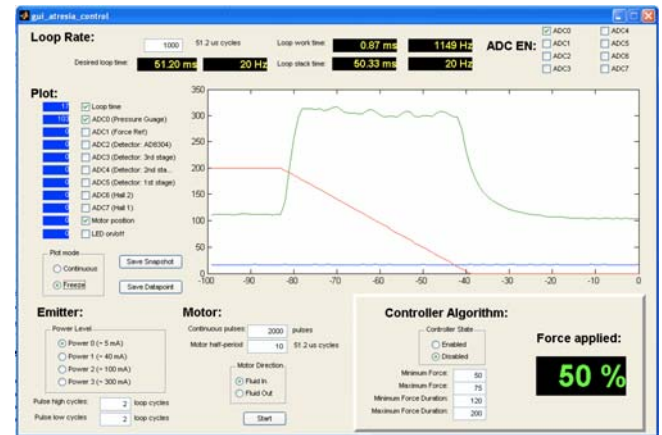


FIGURE 15 - Software interface used to communicate with the control board

8. TESTING

Upon final assembly, the proximal magnet stack was able to obtain a standoff range of approximately 25 mm. According to our measured force curves, this standoff distance would allow for the force between touching proximal and distal bougies to be reduced from 1.5 N to 0.1 N.

We assembled the simulation rigging in Figure 16 as a means to test the standoff mechanism of the proximal bougie. Two latex glove fingers were used to imitate esophageal pouches, and a Vernier Dual-Range Force Sensor (DFS) was set up with Logger Pro™ software to measure the attractive force between the magnetic bougies. The motion of the magnets and sensor outputs were observed during the testing, giving us confidence that hydraulic actuation provides an effective means of varying the distance between the magnets and the resultant force of the esophageal pouches. Despite the DFS confirming a varying force being delivered to the mock pouches, the friction between the proximal magnets and the casing prevented adequate measurement of the delivered force via fluid pressure sensor.

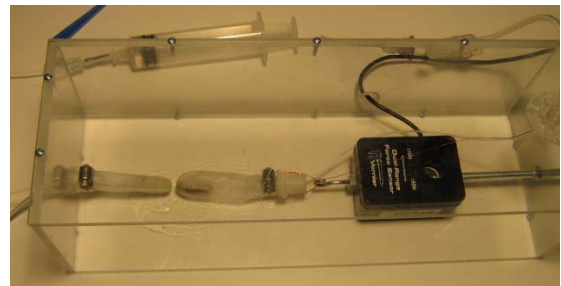


FIGURE 16 - Test rig imitating esophageal pouches with Vernier Dual-Range Force Sensor (DFS) attached to one end

9. FUTURE WORK

Although we have demonstrated an operable system, several

key components must be further developed before we can transition our simulation to an animal model or the treatment of an actual patient.

Our custom-made latex balloons and sheaths were not able to endure sustained inflation and deflation by the pump over multiple cycles without developing leaks, which limited the ability of the device to maintain a fixed standoff. Although these leaks may have been the result of overinflation of the balloons, we believe that the device could be made significantly more robust by working with a professional medical balloon manufacturer.

Additionally, once a robust mechanical system is finalized, we will integrate the real-time sensor data into a closed loop feedback algorithm that will allow for accurate force control by the operator. Specifically, further work is needed to convert the phototransistor output to a reliable tissue thickness metric.

Additional work must also be undertaken to allow a reliable force measurement via the fluid pressure sensor. Firstly, friction in the proximal casing must be reduced to allow the fluid pressure reading to reliably correspond to the balloon pressure. Secondly, the pressure sensor data must further be converted to a reliable force measurement. Finally, the pressure sensor data also requires feed-forward pre-processing to remove pressure perturbations caused by the injection and removal of fluid.

10. CONCLUSIONS

Our system builds upon the work of physicians and scientists who have investigated the use of magnets to nonoperatively treat LEA by inducing growth in esophageal tissue in a similar way to the Foker method. We have designed a device that can hydraulically actuate a magnet stack so as to control the distance between two sets of permanent magnets independent of the esophageal gap size. Distance control enables the system to maintain a constant desired force between the esophageal pouches during the stretching process, reducing the risk that excessive magnetic force could tear or injure delicate tissue. We have also implemented preliminary control circuitry and a user interface that have been used to test the full system and its sensors. Our next steps include iterating on the prototype design to improve reliability and implementing robust closed loop control so that testing on an animal model can proceed.

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