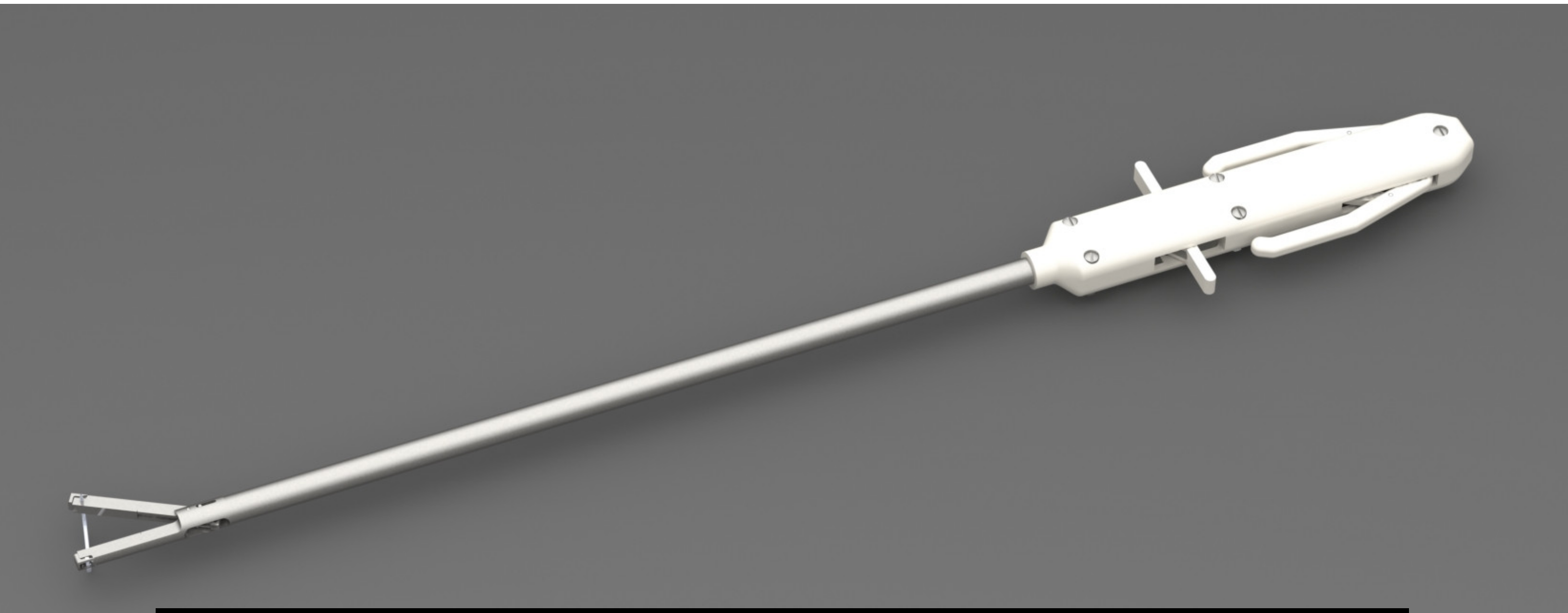

Medtronic Stitcher

Design Center Colorado Sponsor:Medtronic

Overview

This project focused on the development of a medical device capable of repairing medium sized abdominal hernias with diastasis tearing. Our client came to us with a basic idea for what was needed. The team conceptualized a prototype product to embody the idea. A novel solution to this problem was first identified and then developed into a workable prototype over several iterations. Our team used a series of engineering techniques to ensure the product was reliable, function, met our clients specification, and held to the highest of standards. This proof of concept leads to new potentials for surgical repair of larger defects in the body through a less invasive laparoscopic procedure. As a team of mechanical engineering students, this project pushed us to further our understanding of biomedical devices, design for manufacturability, and work in industry.

Starting the Project

The Problem

Ventral hernias are a problem faced by many people across the world. The most common causes are pregnancy and obesity. A hernia is when an organ pushes through the tissue or muscle holding it in place. The hernias can range from small to large and with or without diastasis - a condition where tearing forms in the abdominal wall. The presence of this additional diastasis can pose difficulty for repair. Current methods of repair vary by size. For the smallest hernias many current devices are sufficient, but for larger sizes and ones with diastasis, there is a clear lack of a simple device capable of repair. The goal of this project was to create such a device. That device should be able to be used with one hand, go through a laparoscopic port (a type of less invasive surgery), and be able to use a large enough needle to pass across a medium hernia with diastasis.

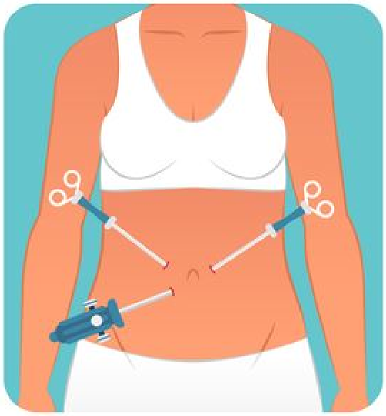

Fig 1: An example of laproscopic surgery
https://www.craigranchobgyn.com/services/laparoscopic-surgery/

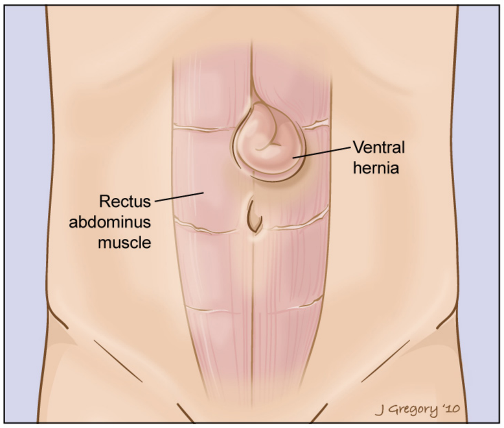

Fig 2: An example of a ventral hernia
http://www.athensherniaclinic.com/ventral-hernia-repair/

The Team

Fig 2: From left to right: Chris Bautista, Shayne Albertson, Alex Grocholski, Taron Lard, William Jackson Bowen, Kyle Sherman, and Theodore Chamberlain

The project is composed of seven senior mechanical engineering students from the university of Colorado. Their collective experience spans a variety of topics from electrical focuses to biomedical. Each of them has a passion for engineering and a desire to expand their knowledge of engineering through this project.

Shayne Albertson: CAD Engineer ✚ Christopher Bautista: Test Engineer ✚ William Bowen: Project Manager ✚ Theodore Chamberlain: Finance Manager ✚ Alexander Grocholski: Logistics Manager ✚ Taron Lard: Manufacturing Engineer ✚ Kyle Sherman: Systems Engineer

Approaching a Design

Humble Beginnings

While some members of the team had some biomedical experience at the start, as a team of mechanical engineers with little overall medical experience, the challenge initially proved daunting for us. Much of the first couple months was spent in brainstorming meetings trying to understand the challenge at hand. As we improved our understanding of the relevant surgical concepts, so too did our designs improve. What started off as simple ideas made from cardboard transitioned into 3D printed prototypes and finally into a realizable design made out of metal. A final device made out of metal was optimal for satisfying sanitation requirements and getting something that looked nice and like a final design.

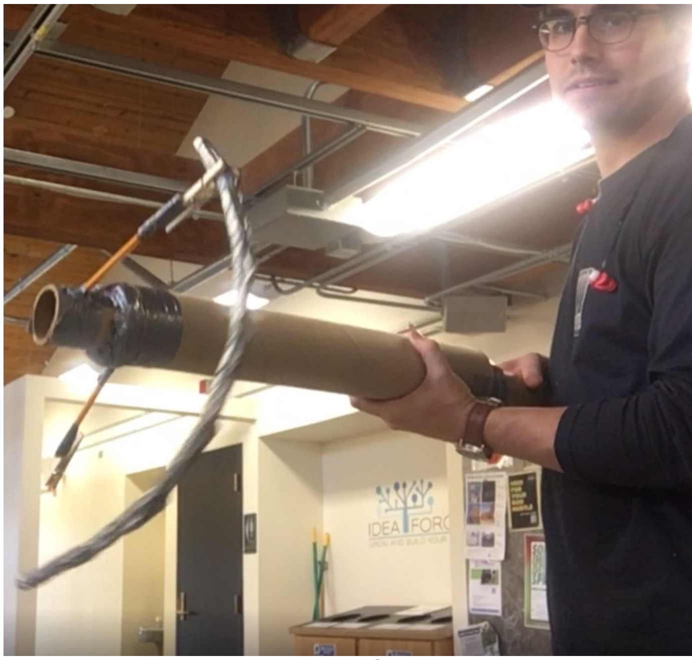

Fig 4: An early example of a rotational design

The First Of Many

After going back and forth between a couple different overarching designs, we settled on what would later be developed into the final design. The basic idea was to have something that could open up once in the body and capture a needle on its outside faces. The process would involve first grabbing the needle with one jaw, passing the needle through the the defect, grabbing the needle with the other arm, pulling the needle back and tightening the suture, and resetting back to the initial position by passing the needle between the arms again. The ultimate goal was to simplify the process for a surgeon, and to give the surgeon the ability to do the whole procedure with one hand.

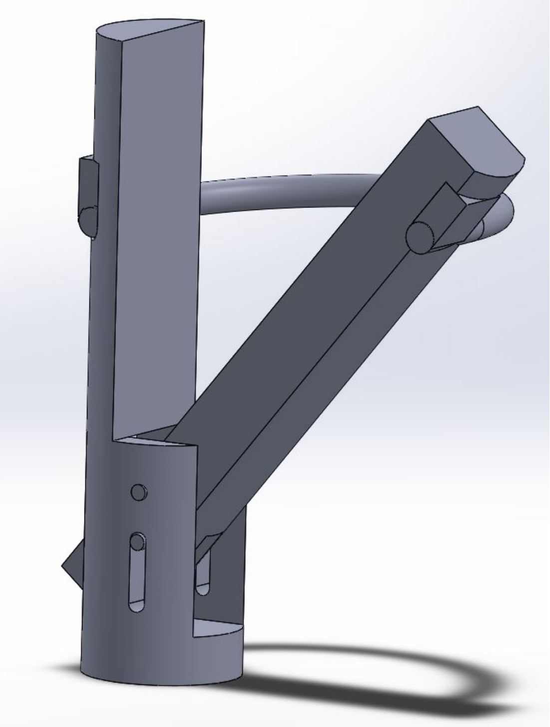

Fig 5: The overarching design we settled on

Iterating

Rapid Prototyping

While the first design had the overarching motion down, it had to be defined more. How would the jaws operate? Would they grab by pushing outwards or pulling inwards? Was the slot right for the swing arm? Would this be manufacturable? All of these were questions we needed to answer, but CAD wasn't enough, so we transitioned to 3D printing prototypes. These were crucial for us in developing our ideas further. Many problems that weren't apparent in the CAD became very clear. Our most pressing problem was making a design that could be machined. With the complicated geometries present, we had to make sure that every feature we imagined was something we could do. This required over 10 iterations from our initial design to final 3D printed prototype. After a couple of tests and a few full head assemblies, we had something that we could make out of metal.

Fig 6: a 3D printed prototype

Moving to Metal

Fig 7: a metal prototype

With the design now machinable, we sought the help of a rapid manufacturing shop. Our geometries were complicated, and it would be difficult for us to machine ourselves, especially as we continued to iterate. With their services, we were able to iterate fast, with turnarounds of under a week at times. They would use a CNC machine, a computer controlled milling device, to accomplish all of our complex faces. This phase finalized the jaw design, a part we had spent many months on. These jaws could grip the needle and hold it at just the right angle for operation. While we didn't yet have a handle, we could operate the device with cables and a metal push rod, which gave us our first look at how the device would look in operation. We went through a couple more metal prototypes, iterating on smaller tolerances and more precision extrusions, before we settled on a final design. This final design had to be iterated multiple times because of manufacturing errors.

Final Design

A Head That Can Pass the Needle

Our final head design improved on many of the failings of earlier designs. The most prominent features are the needle-grabbing jaws. These jaws bite down on the needle at an angle to allow the operation of the device. The design allows for consistent 3-point contact between the jaw and needle. This 3-point contact is used to make sure mating with the needle is consistent and strong, and this will be the main force used for driving, so this is crucial.The arms sit in plane and capture a needle greater than half an arc, which allows the re-gripping of the needle on the other side. These jaws, along with the slotted swing-arm, allowed for the motions we envisioned that would allow the device to complete the procedure.

Fig 8: a render of our final design

A Handle That Can Switch Jaws

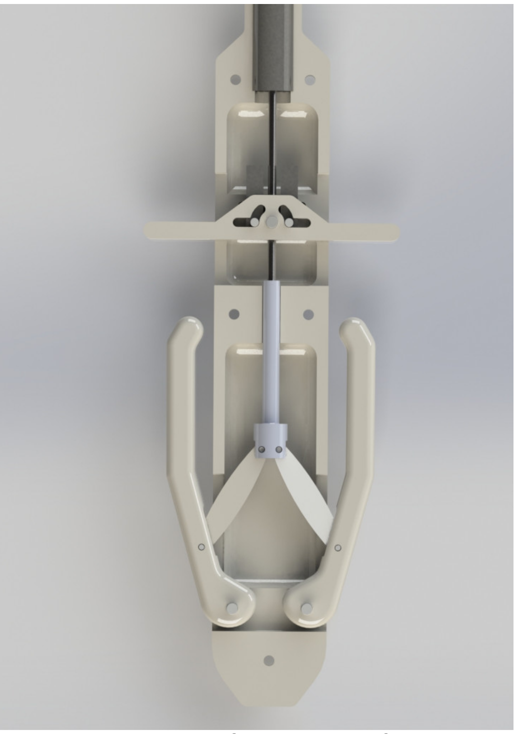

Fig 9: a render of the internals of our handle design

While we had been developing ideas for a handle interface in the background for much of the project, the focus remained on getting a completed head design. Once that was settled, we went ahead on getting a working handle. We wanted something that would allow us to switch which jaw was open and which one was closed in one motion instead of individual actuating them. The solution to that was a lever. When one jaw was pulled down, the other was released by the lever motion. When fully working, this created a simple switch for the user to control both of the jaws of the device, and made motion simple and efficient. With the addition of a squeeze-able handle to swing the arm out, a surgeon could properly operate the device with minimal operations to achieve the ventral hernia repair at hand. All-in-all this turned 11 possible motions into just three needed ones.

Closing Out

Testing Goals

Although formal testing could not be completed by the end of this project's scope due to COVID-19, our team did have some preliminary suggestions of what this test could look like and what it would solve. The main concern with this project was the ability for the device to hold the needles through all possible surgical functions during this procedure. Our team created a testing box that would mimic the torso of a patient. Inside of the box a series of testing situations could be mimicked. These tests would range from force of suturing, material being sutured, and angle of the suturing process. Our hopes would be to improve the design so that all of these tests could be passed with satisfaction.

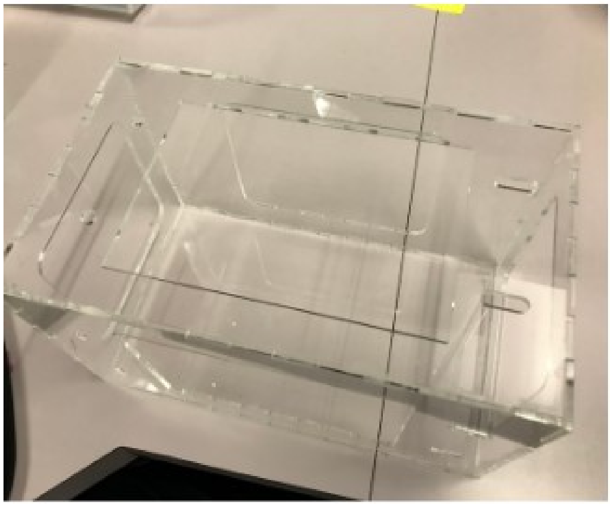

Fig 10: our preliminary testing box made from acrylic

Conclusion

With the help and funding of the people of Medtronic, we have successfully designed a single handled device that is able to repair defects that weren't previously repairable with one. The process of design involved many sessions of brainstorming and design iteration to get a realizable device. The journey has been full of many challenges, but overcoming those challenges has greatly improved our engineering understanding. This project has been a great experience for everyone on the team and we are all satisfied with what we have accomplished. Throughout this process, we have become very familiar with the iteration process, progressively incorporating new understanding into our designs. From initial ideas to final design, this process has greatly enhanced the engineering understanding and applied skills of our team.