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LigaSure Custom Linear Motion Assessment to Improve Performance

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Part 1 – Introduction

Background

Vessel sealing is commonplace in general and specific surgery due to the nature of treatment taking place in the skin, muscle, and organs that are filled with veins and arteries. The industry standard in the vessel sealing marketplace is LigaSure, a product by Medtronic. LigaSure functions via a jaw clamping mechanism that uses electrical current to seal the vessel by generating heat. In order to improve the product, Medtronic plans to implement an accelerometer as a means to relay information to the design team regarding device orientation, mishandling or misuse, and the position of internal components. Since the first two functions of the accelerometer are relatively trivial, Medtronic tasked the team with proving the concept of using an accelerometer as a linear transducer to find the true position of a moving rod inside the device.

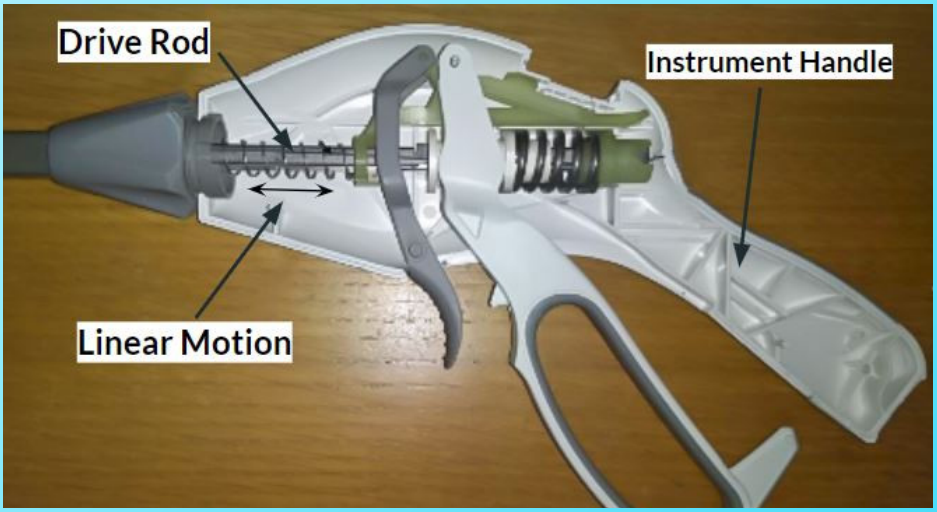


Figure 1: LigaSure Internal Components of Interest

The team created a modular test fixture that simulates the motion of the moving rod of the LigaSure on a larger scale. Because accelerometers only output acceleration data, specific and repeatable vibrations must be sent to the accelerometer that can be interpreted as linear motion. This was accomplished via a vibration-generating feature (VGF) that interacts with the moving components and accelerometer. Finally, software was developed to translate the acceleration data from the accelerometer into a clear linear position output.

Project Requirements and Specifications

1. Build a test fixture that resembles the motion of the drive rod.
2. Design and integrate a vibration-generating feature (VGF) to create distinct vibrations based on linear translation.
3. Create a classification software to interpret VGF output as linear position.
4. Display the calculated versus actual position to verify the accuracy and viability of the final design.
5. Defend the ability to scale down the design to fit within the LigaSure.

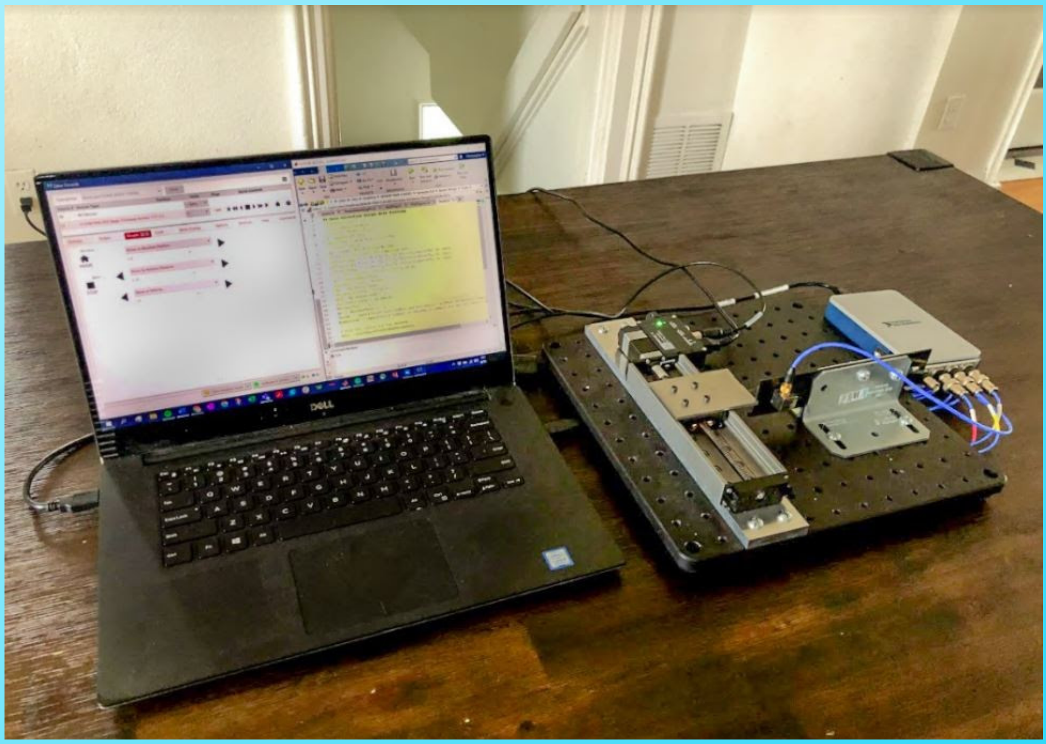


Figure 2: Computer with Data Collection, Test Fixture, and DAQ System.

Project Timeline

September:
Team Matched with Medtronic, Initial Specification Discussions

October:
Scope Definition, Pretotyping, Concept Generation

November:
Initial Prototype Design and Testing, Preliminary Design Review

December:
Data Processing, Critical Design Review, Manufacturing Review, Test Plan Review

January:
Test Fixture Redesign, Part Procurement, Software Plans Finalized

February:
Manufacturing, Testing of Intermediate Designs

March:
Testing New Designs, Software Development, Design Modifications

April:
Final Testing, Finalization of Reports, Completed Whitepaper

May:
Project Completed, Test Fixture Handed Off to Medtronic for Further Advancements

Part 2 – Design Development

Initial Design: Simple Comb

This project's design journey took a great measure of brainstorming, prototyping, and design iteration. The journey began with the simple idea of a comb. In order to track linear displacement, the accelerometer will detect when comb teeth are plucked. Next, each of plucks will be counted in MATLAB to reveal how much distance has been traveled across the comb. Figure 3 shows the test setup for the first prototype of the vibration generation feature.

Figure 3: Accelerometer Mounted to a Comb to Measure Vibrations Caused by Plucking Teeth.

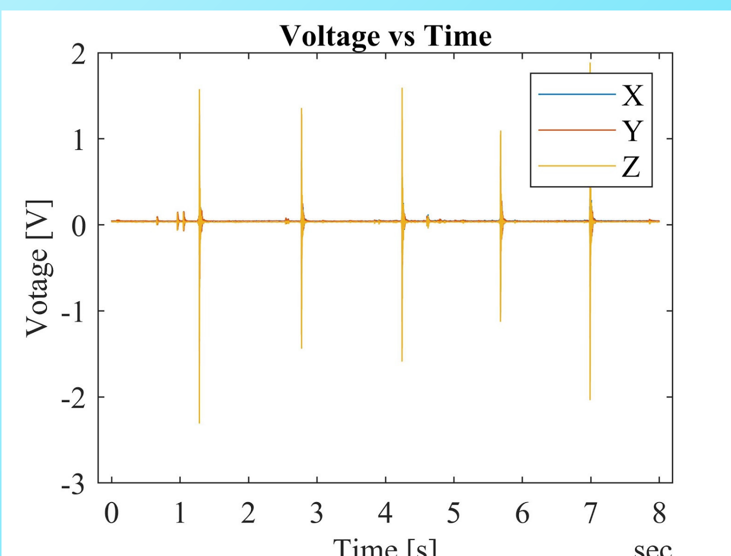


Figure 4: Voltage Response from Comb Plucks.

As seen in Figure 4, the comb generated distinct voltage peaks from the vibrations. However, these peaks only had an amplitude of 2 volts. The signal-to-noise ratio would need to be much higher to ensure noise would not affect the system. To do so, the final design would need to use a material with less elasticity.

Initial Designs Continued

Initial Design: Test Fixture Prototype

Figure 5: Prototype Test Fixture.

The next step was to construct a proper prototype for the test fixture. The prototype test fixture ensured consistent linear motion and held the vibration generation feature secure and aligned with a pick. The team was then able to design the Single Tooth Test in order to understand the signal produced by the vibration generation feature when only a single tooth was struck. The oscillation of this tooth can be seen in Figure 6.

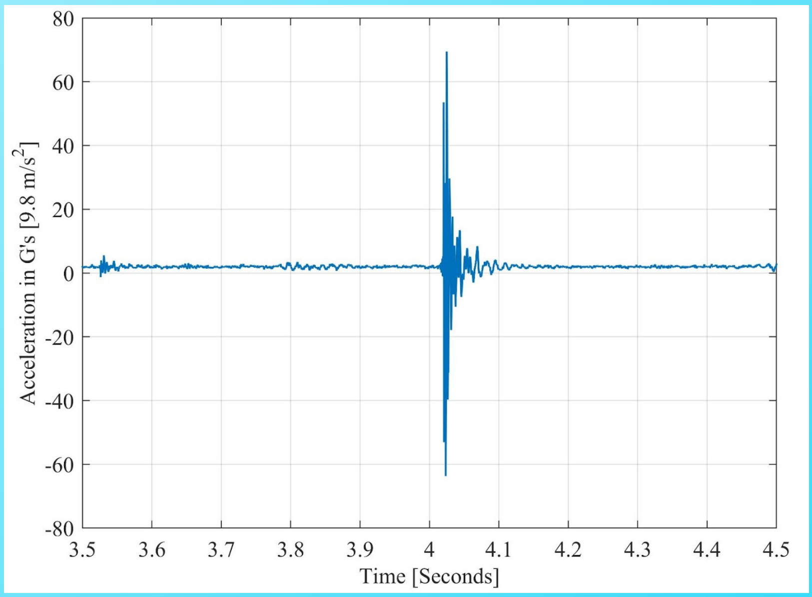


Figure 6: Acceleration Data from an Individual Tooth Pluck.

Through extensive research, the team realized there is no readily available model to determine how the vibrations propagated through the comb to reach the accelerometer. Thus, the team changed the orientation for the final test fixture design, such that the pick was stationary, while the teeth move. Additionally, as seen in Figure 5, the accelerometer is mounted directly to the comb without a repeatable mounting location.

In the next iteration with the changed orientation, the team also acknowledged a need to have specified mounting hole for the accelerometer. By doing so, the accelerometer would consistently be mounted to the same location, and one could better understand how vibration propagates to the accelerometer.

Test Fixture

The test fixture was used to simulate the motion of the LigaSure device drive rod and prove the concept of determining position from the vibration generating features. The test fixture was the team's main deliverable for Medtronic and was designed to test different vibration generating features. After early testing and analysis, the team found that the teeth VGF was the most viable solution for determining position. In order to test the teeth VGF and understand what type of vibration signals it produced, the team designed the test fixture shown below in Figure 7.

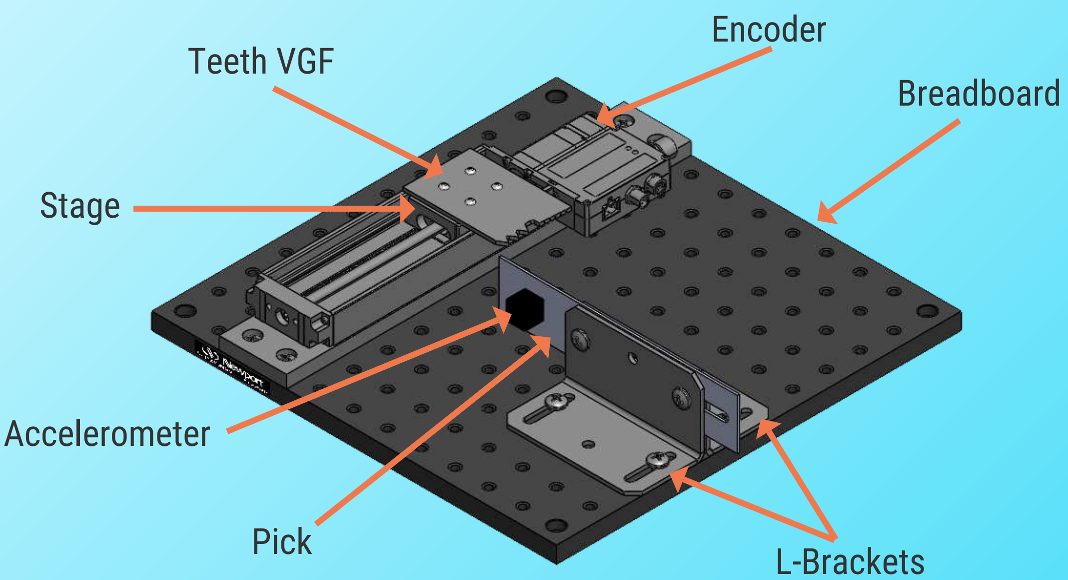
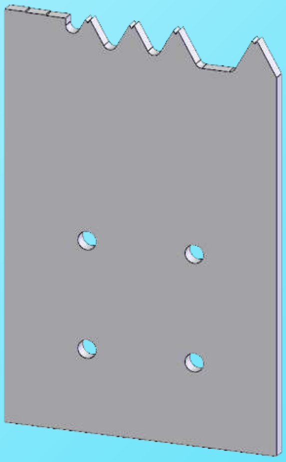


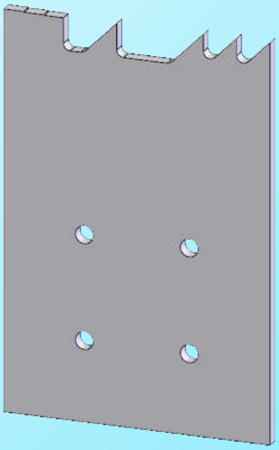
Figure 7: Final Test Fixture Design.

The test fixture consists of a 12” by 12” aluminum breadboard with four vibration damping feet. On top of the fixture, there is a motorized linear stage with an encoder that is mounted to the breadboard. The stage is used to control the speed and direction of the teeth feature as it interacts with a stationary pick, while the encoder provides the actual position values of the stage. The motorized stage software allows us to move the stage at a specified distance or velocity for both single cycle and high cycle testing. The pick is fixed to the breadboard with two L-brackets and allows for length and interference adjustments via slots. The pick component has the accelerometer attached to it and measures vibrations as it is impacted by the moving teeth. The vibrations created by the teeth VGF are read by the accelerometer and analyzed in MATLAB to determine position.

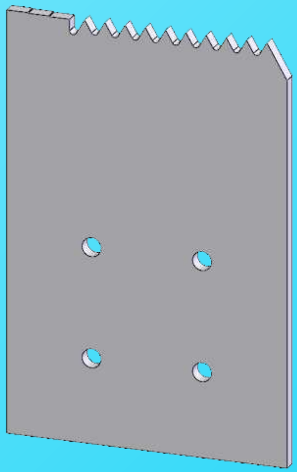
Design Iterations



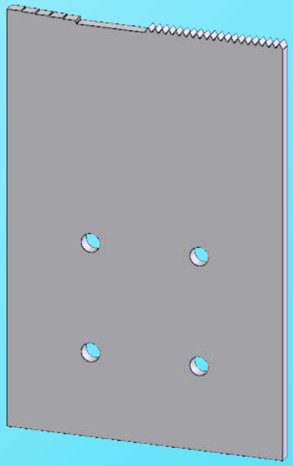
The volcano teeth block (Part 2.3.1) was designed to test if the team could distinguish a small spike prior to a free oscillation. The implications of this design would be the ability to give an indication of a tooth via a large spike before an oscillation. The foreseen challenges of this design were that it would give greater wear on the pick since the small indent is so sharp and impacts the pick very quickly.



The differing angle teeth block (Part 2.3.2) was designed to test whether there would be different amplitude spikes felt from the impact and free oscillations on either side of the tooth. The goal was to find directionality from this different geometry. The worry with this design is that there would be no noticeable difference for free oscillation since the frequency does not depend on force.



The continuous teeth block (Part 2.3.3) was designed to test whether impacting subsequent teeth without free oscillations would provide enough data to draw conclusions on position. It also would help with the space constraint because it could be scaled down faster due to the fact that there is no need for space to freely oscillate.



In the final design (Part 2.3.4), the total travel distance is 0.999 inches and within this distance, there are 20 teeth evenly spaced out by 0.05 inches. At 0.05 inches of spacing between the teeth, the resolution of this design is 5% of the total distance traveled. This design resolution is well within the target of 10% resolution. The testing indicated that this design would provide the best results regarding the goals of this project.

Manufacturing and Material Selection

All custom components were manufactured by Medtronic out of aluminum. The volcano teeth block (Part 2.3.1) and Final continuous teeth block (Part 2.3.4) were outsourced to Weiss-Aug to be laser cut out of stainless steel due to the small geometry of the teeth.

The custom components were made of aluminum due to the fact that it has high machinability and is relatively inexpensive as the team would be changing and modifying designs frequently. As the project advanced, the team noticed that having the teeth blocks and picks made out of the same material was creating too much wear on the pick. After consideration of different ideas on how to reduce wear (force, material, geometry) it was decided that switching to a softer polymer pick would give better results. The team decided to go with Delrin due to its low cost and high machinability. While this did not completely solve the problem of wear it did drastically improve. Moving forward with this specific design the team would recommend a geometry change to more of a rounded tooth shape to reduce wear on the system.

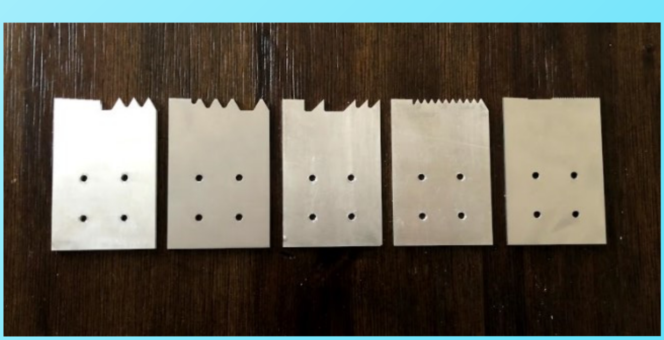


Figure 8: Five Unique Teeth Blocks

Figure 9: Delrin Pick Designs

Part 3 – Testing

Testing Goals

Phase 1

Phase 1 of testing focused on pick-tooth interference, stage speed, and pick length. Each of these parameters was tested separately, while holding all other variables constant. The goal for all three of these tests was to understand how these different parameters affect the output signals.

Phase 2

Phase 2 of testing focused on teeth block geometry, pick material, and five minutes of high cycle testing. The goal for phase 2 was to determine what direction the team needed to aim for in the final stage of testing and design. For the teeth geometry tests, the team manufactured three different teeth blocks in order to understand what type of teeth geometry was optimal for determining position in the system. For pick material testing, the team experimented with Delrin picks of different thicknesses to examine wear and see if a material change had an effect on the signals. The goal for high cycle testing was to obtain a high sample size of repeatable data and ensure that the amplitudes of the signals didn't see a significant decline over five minutes of continuous testing.

Phase 3

Phase 3 testing was the final phase, which aimed to test different pick tip geometries and varying speeds to simulate the random motion of the LigaSure device. For the pick geometry tests, the team manufactured pointed, trapezoidal, and rounded geometries to observe which pick generated the least amount of wear. For the varying speed test, the team used the motorized stage software to randomly adjust the speed of the stage while performing forward and backward motion. The goal for this test was to simulate the regular use of the LigaSure, since the trigger of the device is unlikely to be pulled at a constant speed.

Teeth Block Test Results

Volcano Teeth

The signal created from the volcano tooth block showed a clear spike prior to a free oscillation, which gives an indication that the next tooth is being plucked. In label A on Figure 10, it can also be seen that the amplitude of the initial spike is larger in the negative acceleration than it is in the positive. This observation gives information about the direction the system is moving. The problem with this design is that the free oscillation requires a large amount of space and time.

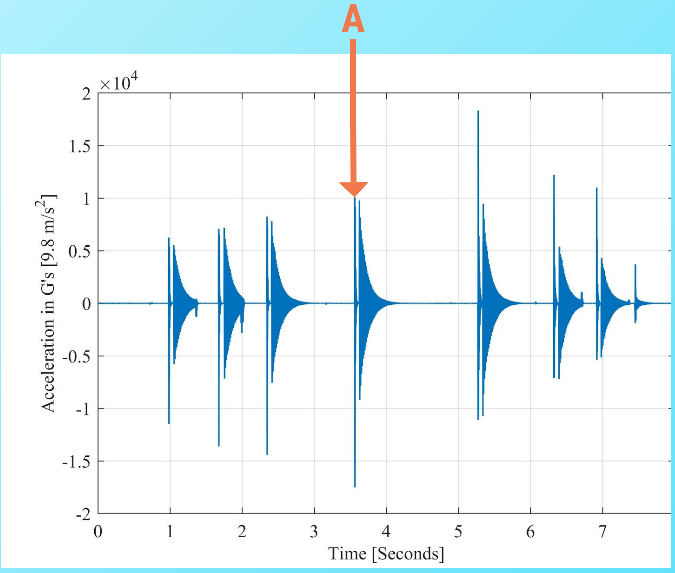


Figure 10: Volcano Teeth Acceleration Data.

Continuous Teeth

The continuous teeth provided the most promising results of the teeth blocks and ended up being the focal point for the remainder of the project. Similar to the volcano teeth, the same positive and negative trend was present from the acceleration spike given the stage motion direction. The results from this design proved that a free oscillation is not necessary to compute position since an amplitude spike alone can be used in our software to determine a tooth pluck. As seen in Figure 11, each amplitude spike represents the impact of the pick against each tooth for both forward and backward motion.

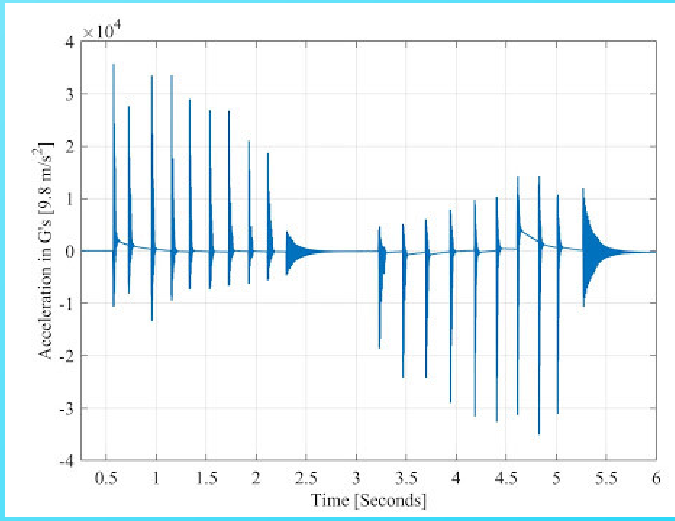
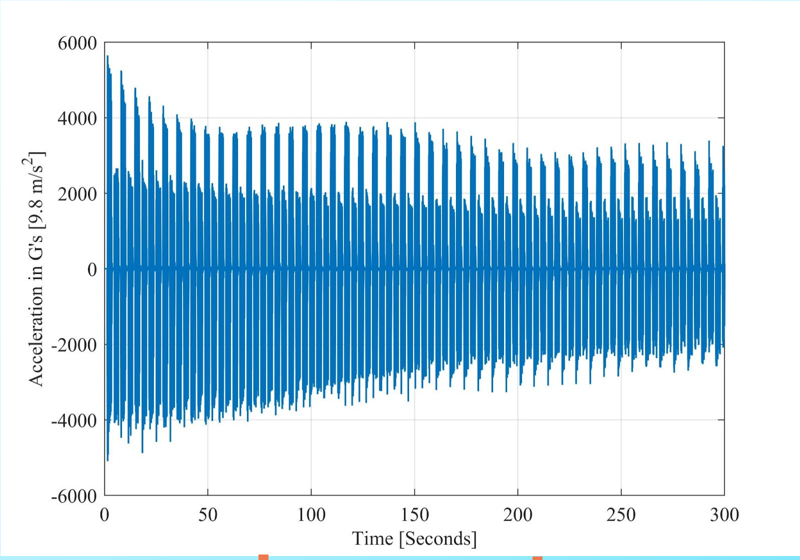


Figure 11: Continuous Teeth Acceleration Data.

Test Results Continued

Final Teeth Design



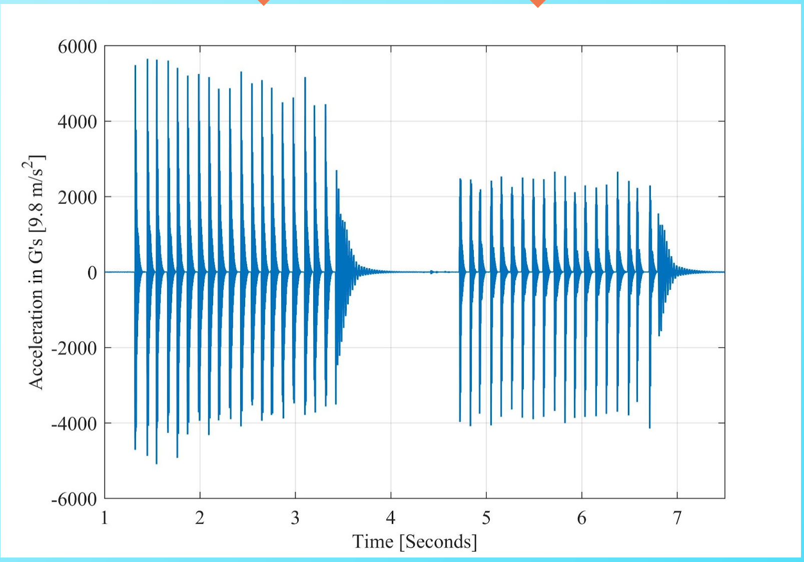
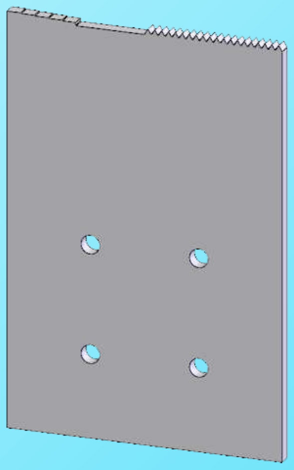


Figure 12: Acceleration data from high cycle testing on the final design.



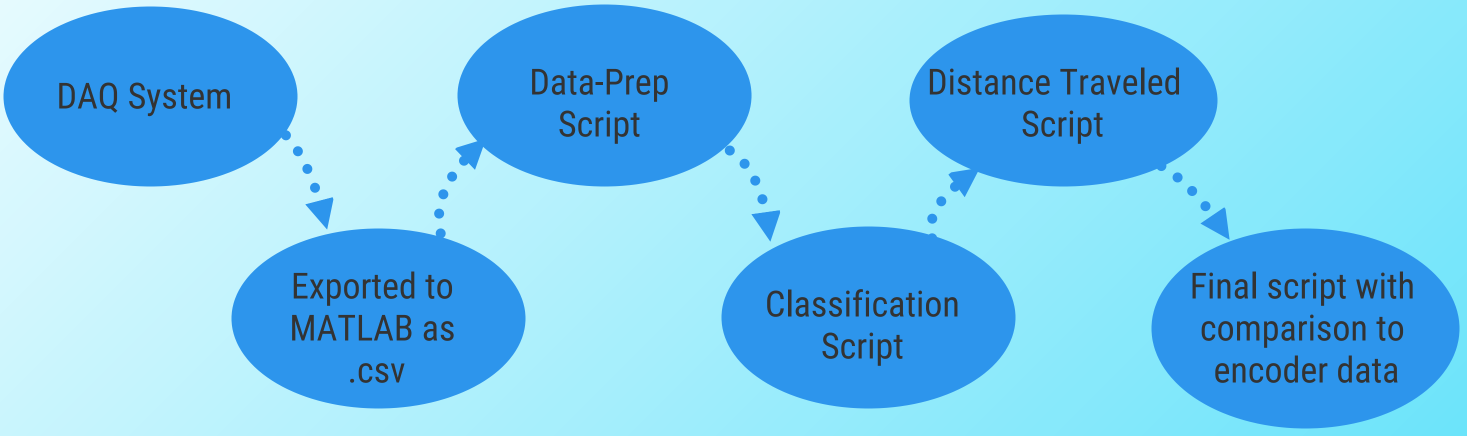
Teeth block features:

- 20 teeth along 1 inch of travel giving a linear translation resolution of 5%.
- Tooth height of 0.043 inches.

Results:

- Higher positive or negative acceleration magnitude depending on the direction of motion.
- Clear repeatable amplitude spikes for each tooth pluck.
- Obvious free oscillation at the end of the teeth range.
- Decay in acceleration amplitude over time from pick-tooth wear.

Project Software



The team started looking at software tools to read the signal from the Vibration-Generating Feature of the test fixture, in the Deep Learning toolbox in MATLAB. The software is used to understand how to obtain the linear position from spikes in the accelerometer data. The team chose to use classification software, which is a type of supervised machine learning in which an algorithm "learns" to classify new segments of data to fit within the provided classifications.

Overall the software has three main scripts. First, the Data-Prep Script converts the data into usable vectors of x, y, z, and time in the MATLAB workspace. Second, the Classification Script classifies the peaks of the accelerometer data based on positive or negative amplitude, indicating forward and backward, respectively. Lastly, the Distance Traveled Script reads the classifications applied to a signal and converts the sequence of classifications into the position of the teeth vs pick position in the test fixture. The thought process of the classification that the Distance Traveled script goes through is displayed in the table below.

Type Of Classification	Physical Interpretation
Forward Spike	+0.050 Inches
Backward Spike	-0.050 inches
Forward Oscillation	At x = 1 inch
Backward Oscillation	At x= 0 inches

Table 1: Classifications and their Corresponding Positional Information

Position Output From Software

The final script simply calls the three aforementioned scripts to attain the calculated position vector and compares it to the actual position read by the motorized carriage's encoder data. The graph below has the calculated position from the software scripts' classified dataset overlaid on top of the encoder data. The softwares scripts output data is the experimental position data and the encoder data is the true position data that comes from the linear carriage in the test table. Comparing these two data sets shows that the experimental output is very accurate. This signal looks like a clipped sine wave because the resolutions bound physically by zero to one inch. This is because the teeth vibration generation feature is an inch in length. This is shown by the boundaries of the red line in the graph below.

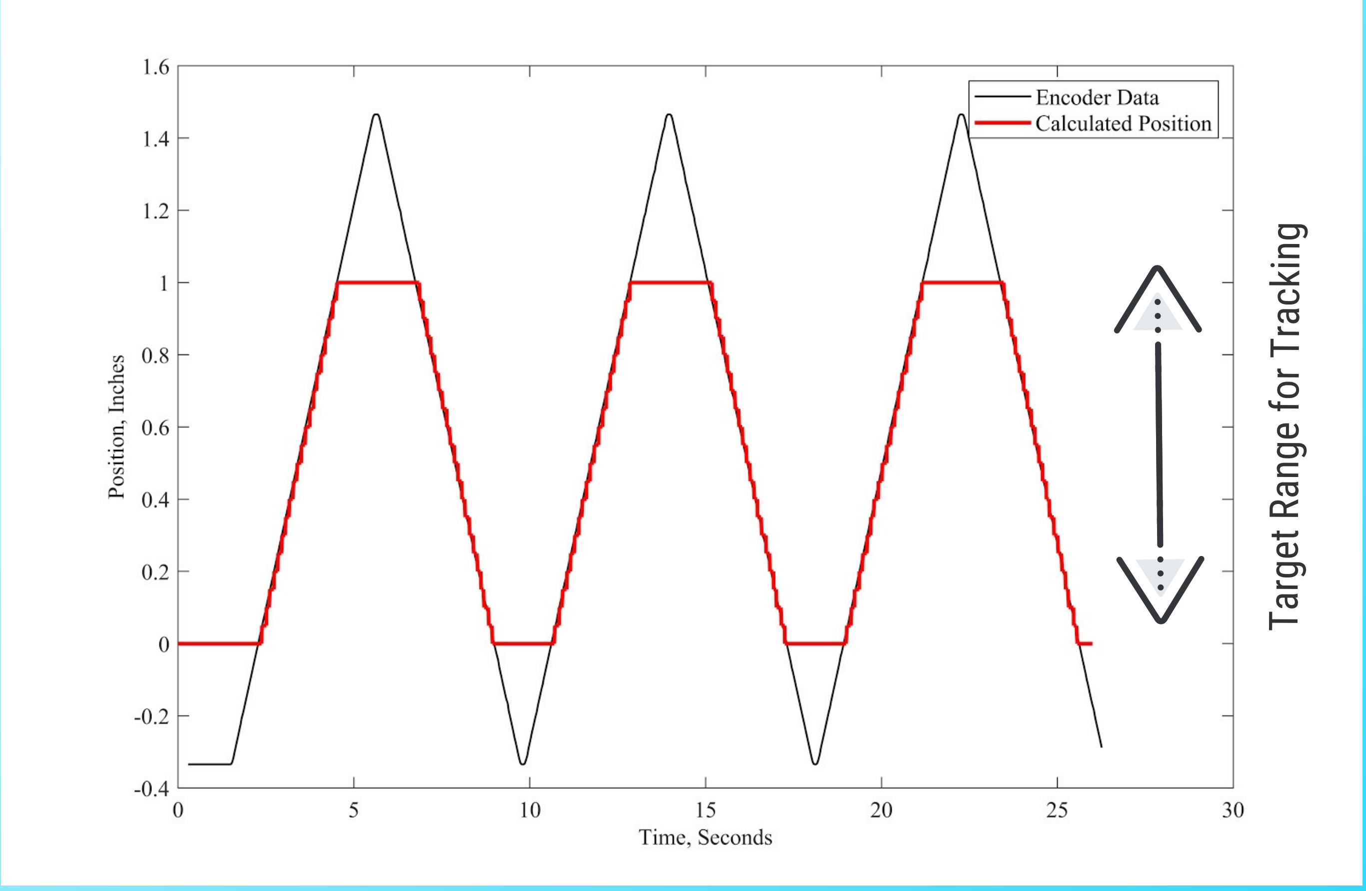


Figure 13: Encoder Data (Black) Plotted Against the Software Calculated Position (Red).

As previously mentioned, the system only has a design resolution of 0.050-inch increments across a one-inch range, which explains the "steps" seen in the calculated position plot.

Part 4 – Conclusion

With the help of the team's director and contacts at Medtronic, we were able to develop our initial ideas into a proof-of-concept design to demonstrate this new technology: using accelerometers to determine linear position via vibration generating features.

- The design was able to identify the linear position of a drive rod with a resolution of 0.050 inches over a one-inch range and display the calculated versus actual position in order to verify the accuracy of the system.
- By proving 5% resolution of the current design, Medtronic can at least scale down to 2X instead of 4X to achieve the 10% goal, without significantly changing the design.

Understanding the position of the drive rod will eventually allow Medtronic to accurately identify the jaw angles of the LigaSure device, the vessel being clamped by the jaws, or even the clamping force exerted upon the vessel, all of which will be useful information for the user to ensure safe and precise surgery. Along with internal component positioning, Medtronic will also pursue using the accelerometer for orientation analysis.

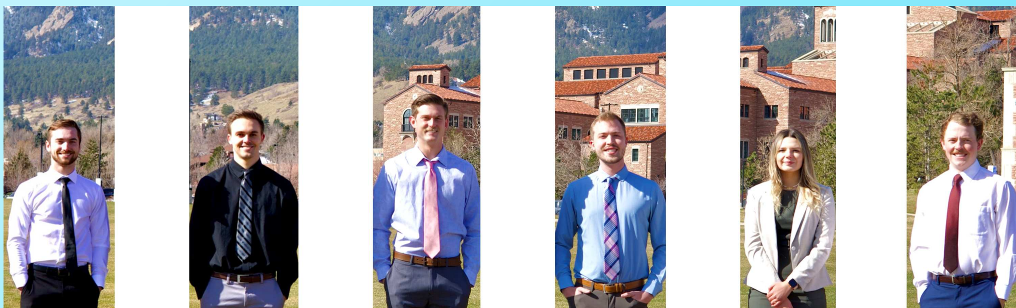
Medtronic has submitted a patent application for the technology developed during this project, indicating the success of our proof-of-concept design. Development of this idea will likely continue either with a new Senior Design team at the University of Colorado Boulder or within Medtronic’s own R&D department.

Acknowledgments

Being a team of young engineers tasked with finding a completely unique solution involved assistance from many people. We want to share our thanks with the following people who helped us achieve success:

- Duane Kerr, JD Allen, and Robert Wham from our client Medtronic for their guidance and support.
- Our Director, Luke Woolley, for his unwavering support throughout this year.
- Michael Cullen at Weiss-Aug for laser cutting several of our teeth designs free of cost, including our final, most successful design.
- Brian Butcher at Medtronic for his exceptionally quick machining of custom parts that were critical to the success of our project.
- Dr. Julie Steinbrenner, Dr. Daria Kotys-Schwartz, and all of the Design Center Colorado Staff.

About the Team



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