CU Senior Design Team 11 for Medtronic
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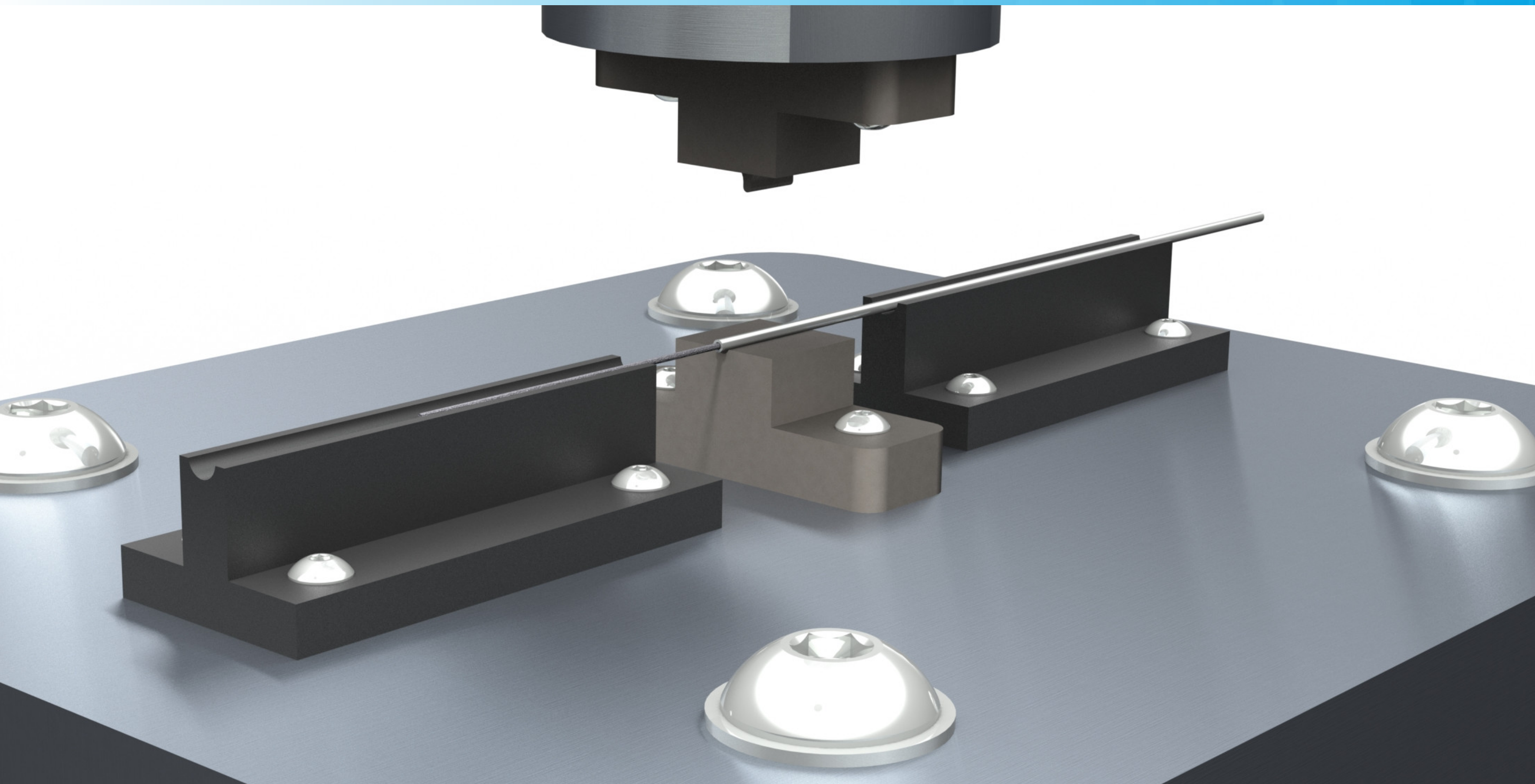
Optimization of Hypodermic Tube Crimps used in Medical Devices

Maintaining the highest constant pull force to ensure safety and security of medical devices and patients



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Brief Introduction to the Project

Multiple tungsten wires crimped to steel tubes fit inside the body of the device. Here is a crimped sample for reference.

Medtronic currently produces articulating medical devices that allow a surgeon to manipulate body tissue. These devices require cables to maneuver the functional end of the device. Steel tubes are joined to the cables to control the motion of the cables.

The cables within the devices experience dynamic loading. Therefore, the connection between the tubes and the cables is critical to maintaining control of the device during operation.

Medtronic currently uses a large servo press to crimp the steel tubes to the articulation cables, however, the servo press operates at incredibly high forces and consumes significant floor space.

Team 11 was asked to optimize the process of joining the steel tubes to the articulation cables by exploring alternatives to the press. The team also investigated ways to improve the performance of the press by altering some of its key parameters.

Project Requirements and Goals

The primary objective of the project was to investigate different methods of creating the connection between the articulation cable and the steel tubing in Medtronic's articulating medical devices while maintaining a pull strength above a required safety limit. In addition to a minimum pull strength, the connection also had to fit within tight dimensional constraints in order to function properly inside the medical device. The team also considered how a process for creating the connection could be implemented on a production line. After deliberations with Medtronic, there were four primary factors to address.

1) A minimum tensile strength of 60 pounds is required to avoid device failure

2) The connection can not exceed a diameter of 0.065 inches to be able to fit inside the device

3) The tube can not be bent excessively as a result of the joining process

4) The process must have a duration of less than 30 seconds

To satisfy these project requirements, as well as the time constraints of the project, the team eventually chose to explore the potential of mechanical crimping. The compressive force required to create a mechanical crimp is a key factor in determining the size, shape, and cost of the equipment needed to produce the crimp on an assembly line, so it was chosen as a primary variable by which the other factors could be evaluated. Other factors the team chose to consider include variations in the shape of the dies used to create the crimp, variations in the dimensions of the steel tubes used, and modifications to the tube ends.

Throughout the duration of the project, the team identified a few other objectives that they felt were important enough to establish as stretch goals.

1) The connection must be highly repeatable to ensure scalability for device production

2) The process should lower production costs overall

Medtronic Project Timeline

September
Initial Consult

Team 11 matched with Medtronic and team roles were established.

October
Scope & Design Inquiry

Client objectives ironed out.
Spec and Planning Report and Presentation.

November
Research & Initial Design Concepts

Initial research phase of different methods.
Preliminary Design Review to share ideas with client.

December
Team 11 focuses on Mechanical Method

Design and finalization of mechanical method and project direction.
Comprehensive Design Review
Manufacturing Review
Test Plan Review

January
Project Setup w/ Logistics

Final Design ideas Presentation
Material Purchasing
Spring Semester Planning
Design of Experiments

February
Material Allocation

Received Materials
Manufactured in-house components at CU Boulder

March
Testing

Received final materials
Testing Phase
Data Analysis
CO-VID Pandemic

April
Project Wrap-Up

Finalized Project reports and presentations
Completed White Paper

May
Project Completed

Final project reports presented to Medtronic, all hardware returned

Research Phase

The first phase of the project involved researching a wide variety of different ways to join the articulation cable to the steel tube. Mechanical, chemical, and thermal methods were all considered before ultimately choosing one method with which to conduct physical testing. The following are just some of the methods the team considered.

Thermal and Chemical Crimping Methods

Hot Crimping

Hot crimping is a combination of spot welding and mechanical crimping. A hot crimper runs electrical current through the metal it is crimping, causing the metal to heat up and ultimately melt. As the metal melts, the compression of the mechanical crimp forces the metal together. The metal is then allowed to cool, forming a solid bond. This method showed great promise after some preliminary testing, but further testing did not fit within the scope of the project.

Heat Expansion

This method is based on the well known physical principle that objects expand when heated and shrink when cooled. The process involved selecting steel tubing with an inner diameter slightly smaller than the outer diameter of the tungsten cable. The steel tube would then be heated until it expanded enough to fit around the cable. The cable would then be inserted into the tube, which would contract around the cable as it cooled. Unfortunately, new equipment would have had to have been purchased to pursue this method.

Glass-to-Metal Weld

A research team at Heriot-Watt University developed a method for joining glass to metals. The process uses tiny "balls of lightning" to heat the metals and the glass between them. The result is a vacuum tight, electrically insulated seal. This method was not pursued because glass and stainless steel have different thermal expansion coefficients. Additionally, extensive training would have been required of the team as well as the purchase of a high precision laser machine.

Soldering

Soldering, much like welding, is based on the principles of melting and cooling metal to form a solid bond. In the soldering process, liquified metal is added across both materials being joined. The metal then cools, forming a solid connection between the materials. The team decided not to pursue soldering because soldered connections are only as strong as the strength of the solder itself, which is commonly much weaker than the strength of the materials being joined.

Glue Adhesion

There are many kinds of glue that are readily available and easy to use. As such, using glue had the potential to be cheap and easy to implement. However, this method was not investigated because most strong glues have drying times much longer than the time limit outlined in the project requirements. Additionally, the team had concerns about the repeatability of a process that utilized liquid glue.

Research Phase

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Mechanical Crimping Methods

Rotational Compression

Similar in concept to an English Wheel or bead roller, this design concept crimps the tube to the articulation cable by compressing the tube between two rotating disks or ‘anvils’ separated by a fixed distance. Each 'anvil' has a concave pressing surface to conform the steel tube around the articulation wire without damaging the wire. This concept would have added significant complexity to the process, and as a result, the team decided that this method was not worth pursuing further.

Hydraulic Tube Crimp

The machine that crimps fittings to high-pressure hydraulic hoses utilizes several triangular shaped press heads with curved tips to crimp the fitting from all sides. These triangular press heads from a circle around the fitting and slide against each other to press the fitting around the hose. The team thought that a process similar to this could be applied to the project, but it was ultimately decided that the complexity of this system outweighed its benefits and it was not pursued further.

Composite Braids

Braided structures typically have higher resistance to tensile failure. This is because, if one strand breaks, the woven structure distributes the loading force across all of the other strands. The team considered using braided cylindrical structures similar to 'Chinese finger traps' to join the steel tube to the articulation cable, or even to replace the steel tube altogether. It was eventually decided that this method went beyond the project scope and it was not pursued further.

Magnetic Pulse

The idea behind magnetic pulse crimping is to use a repulsive magnetic force to crimp a metal tube. A powerful circular electromagnet is placed around the tube. This magnet is then used to create a short pulse of magnetic force directed at the tube, compressing the tube from all sides. Unfortunately, the team did not have access to equipment with the capability to generate the large magnetic force required to investigate this technique.

U-Bracket Crimps

Many electrical crimps involve crimping U-shaped connectors around the wire. Crimping such a connector will collapse the sides of the 'U' and pinch the wire, creating mechanical crimp. The team decided that adding a third component to use as a connector added unnecessary complexity. However, the team later investigated how modifying the steel tubes to create a similar shape could reduce the force required to generate a crimp. This is further discussed in the variables section of this report.

Research Phase Conclusion

Ultimately, the team decided to pursue mechanical crimping processes for the remainder of the project. To do this, the team chose to use a servo press as a base and modify other crimp parameters.

Servo Press

At the conclusion of the team's research, it was decided that the best way to meet the project objectives was to further investigate mechanical crimping. By creating new die shapes of varying geometries, the team felt confident in the project scope and their ability to provide Medtronic with valuable data. To do this, the team opted to use Medtronic's servo press as a base platform but alter crimp die shape, crimp force, tube dimensions, and tube end modifications.

The press that Medtronic uses is a Promess 12 kN EMAP servo press. This press allows operators to control the press force, the press distance, or even the press speed. The press is also incredibly precise, allowing the team to carefully control each aspect of the crimping process.

In order to use the press effectively, the team designed a unique interface between the press and the crimp dies. This interface allowed the team to precisely align the dies within the press, but it also allowed the team to change out dies quickly without having to realign the press.

Promess Servo Press
https://www.promessinc.com/category/blog/page/3/

Design Phase

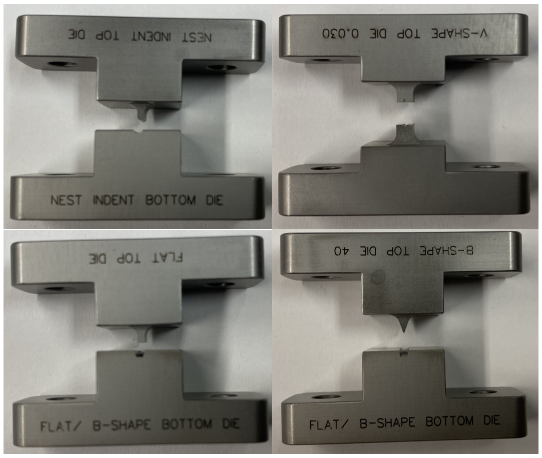
At the conclusion of the research phase, the team decided to further investigate mechanical crimping. The strength of a mechanical crimp is heavily influenced by the shape of the die used to create the crimp, so the team designed four die shapes to investigate. Each die shape is unique, but all dies are interchangeable and can be quickly changed without re-calibrating the press.

Die Shapes

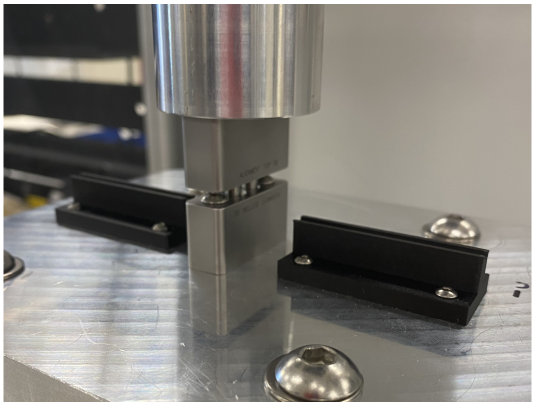
In order to investigate the effects of die shape on crimp strength, the team designed four basic die shapes. The V-shape and B-shape were designed with multiple variations that had slight changes to one specific feature of the die for a total number of eight die shapes. The team also made a set of dies for aligning the press, but these dies were not used for crimping.

In order to minimize the setup time before and during crimping, the dies were designed to be interchangeable. This way, the press only had to be aligned once, and the dies could be quickly changed without having to re-align or re-calibrate the press. To accomplish this, the dies were designed to be held in place by two dowel pins and fixed to the press with two small screws.

Before designing each die shape, the team started by selecting the cross sectional shape of the crimp they wanted to investigate. From here, the top and bottom halves of the dies were designed, working backwards from the desired crimp cross section to create the features of the die. The following pages contain more information on the design process of each specific die shape.



The four basic die shapes after manufacturing

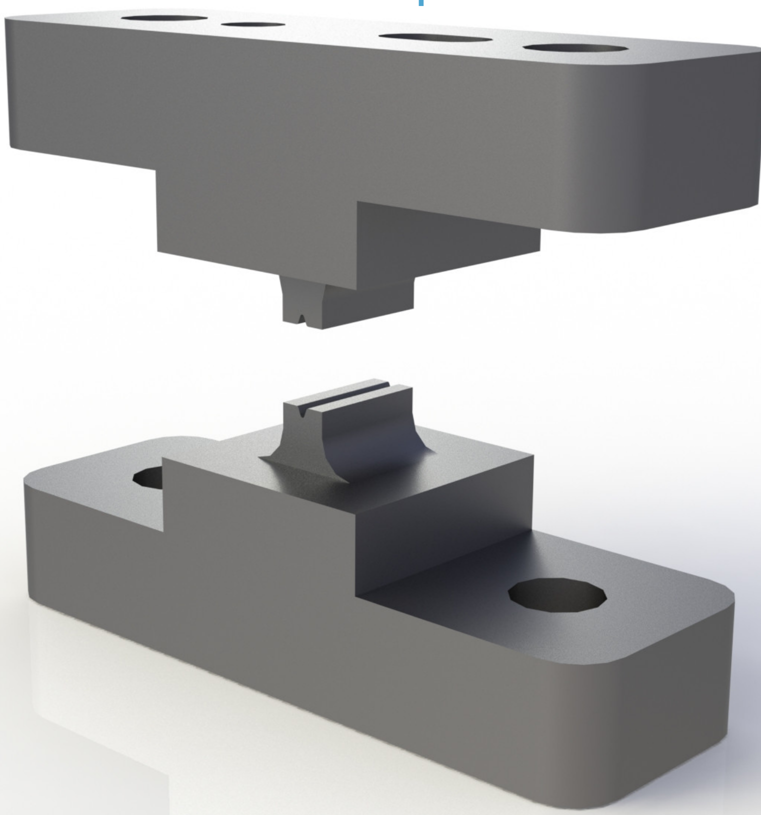


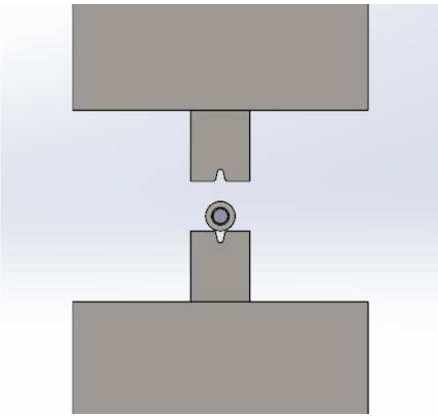
The Alignment dies in use

Die Shapes

The V die shape was designed to be similar to a die configuration Medtronic currently uses. The top and bottom dies are identical and have a “V” shaped cavity.

V Shape





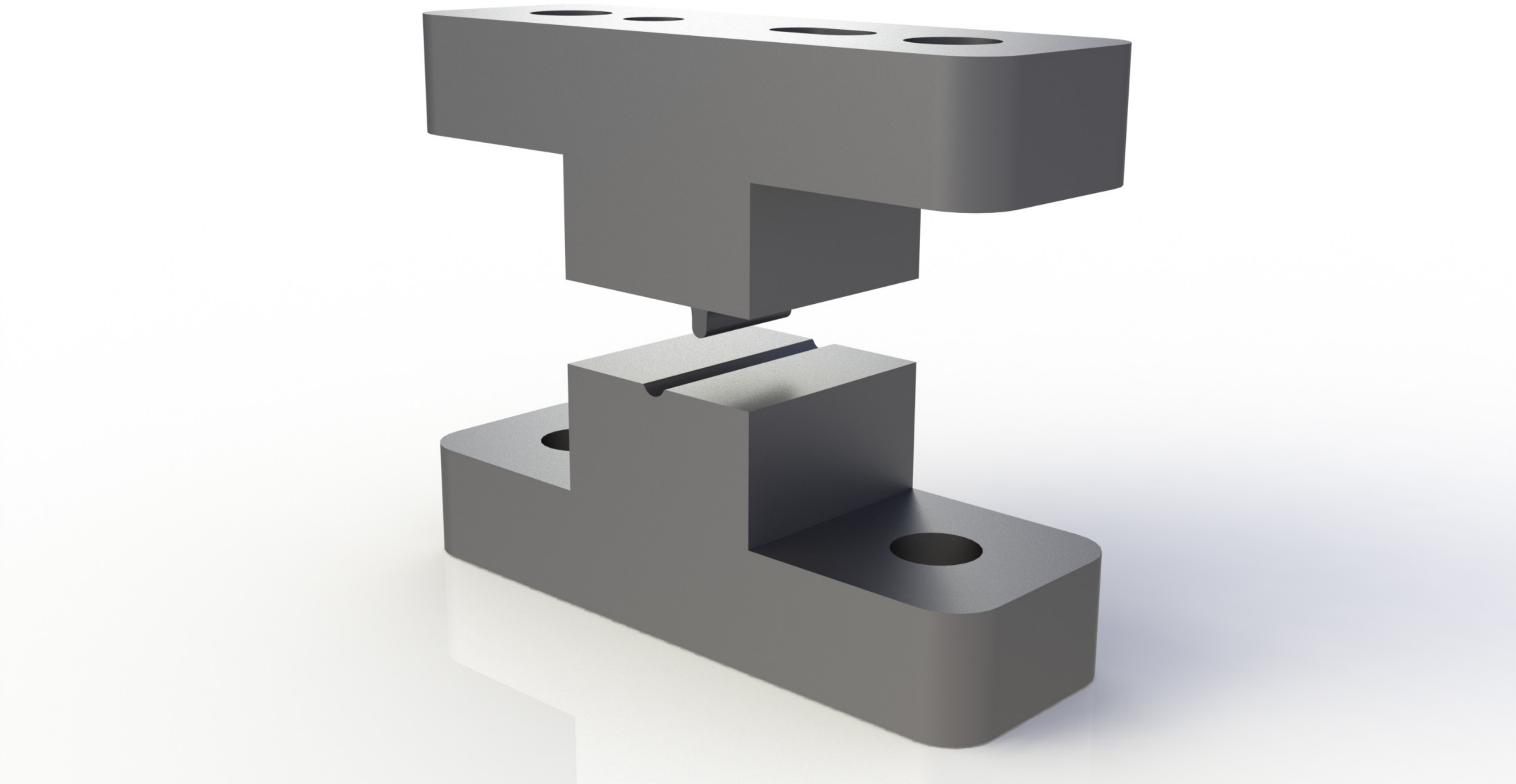
Cross-section view of V die shape with tube and cable for reference

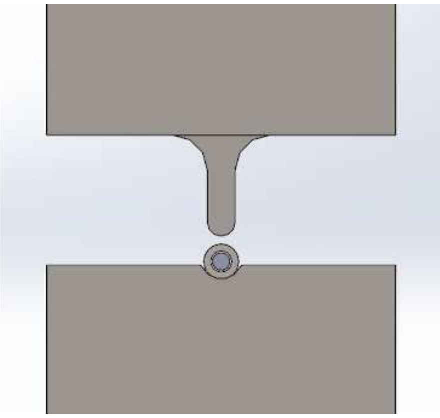
The team further explored the potential of the basic shape by manipulating the clearance spacing of the “V”. Three variations of the basic shape were created. The first variation has a cavity width of 0.025 inches to match the diameter of the tungsten cable. The second variation has a cavity width of 0.030 inches to match the inner diameter of the original tube diameter. The final variation has a cavity width of 0.035 inches to investigate the effects of a cavity width large enough to encompass the inner diameter of the tube.

Die Shapes

The idea behind the Nest and Indent shape was to create a die shape with a large amount of contact surface area, but with a convex top shape to allow the tube to deform freely.

Nest and Indent





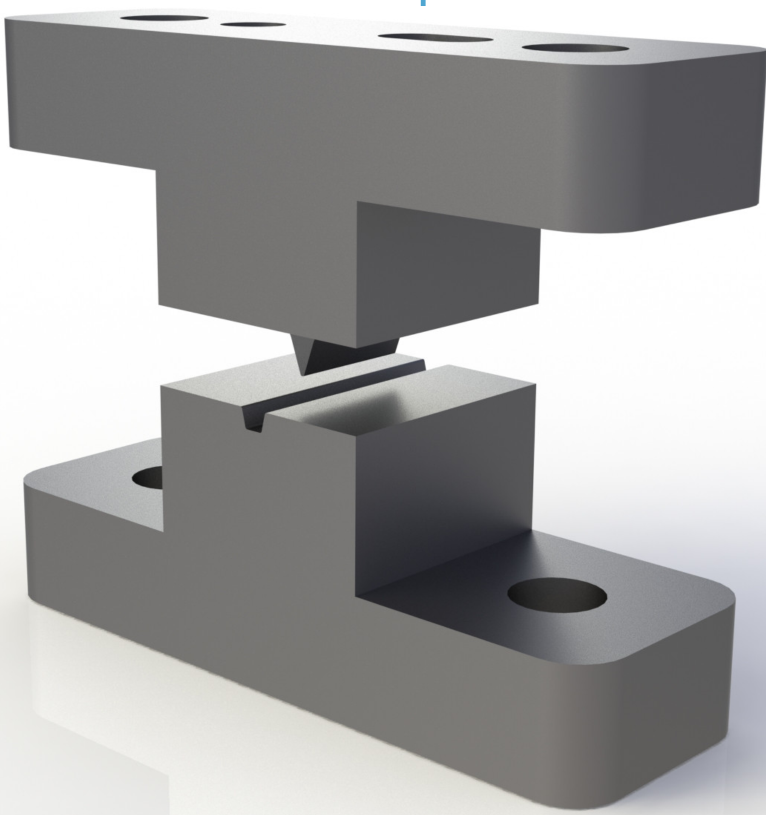
Cross-section view of Nest and Indent die shape with tube and cable for reference

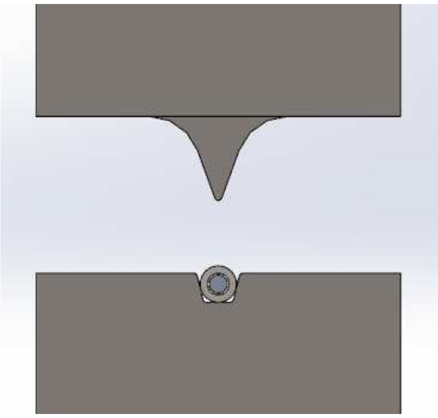
The top die was designed to be curved and have a diameter smaller than that of the hypodermic tube in order to concentrate the crimping force at the center where the cable would be. The bottom die, on the other hand, was designed to be curved with a diameter greater than that of the tube to allow for the tube to expand while deforming during the crimping process. The height of the cavity in the bottom die was set to be a relatively shallow 0.020 inches so that the cavity would be shallower than the height of the tube, allowing the tube to be taken out easily after crimping.

Die Shapes

The B die shape is named not after the shape of the crimp dies, but rather the shape of the crimped tube that they create. When the flat surface and centered wedge form a crimp, the result has the appearance of an uppercase letter 'B'.

B Shape





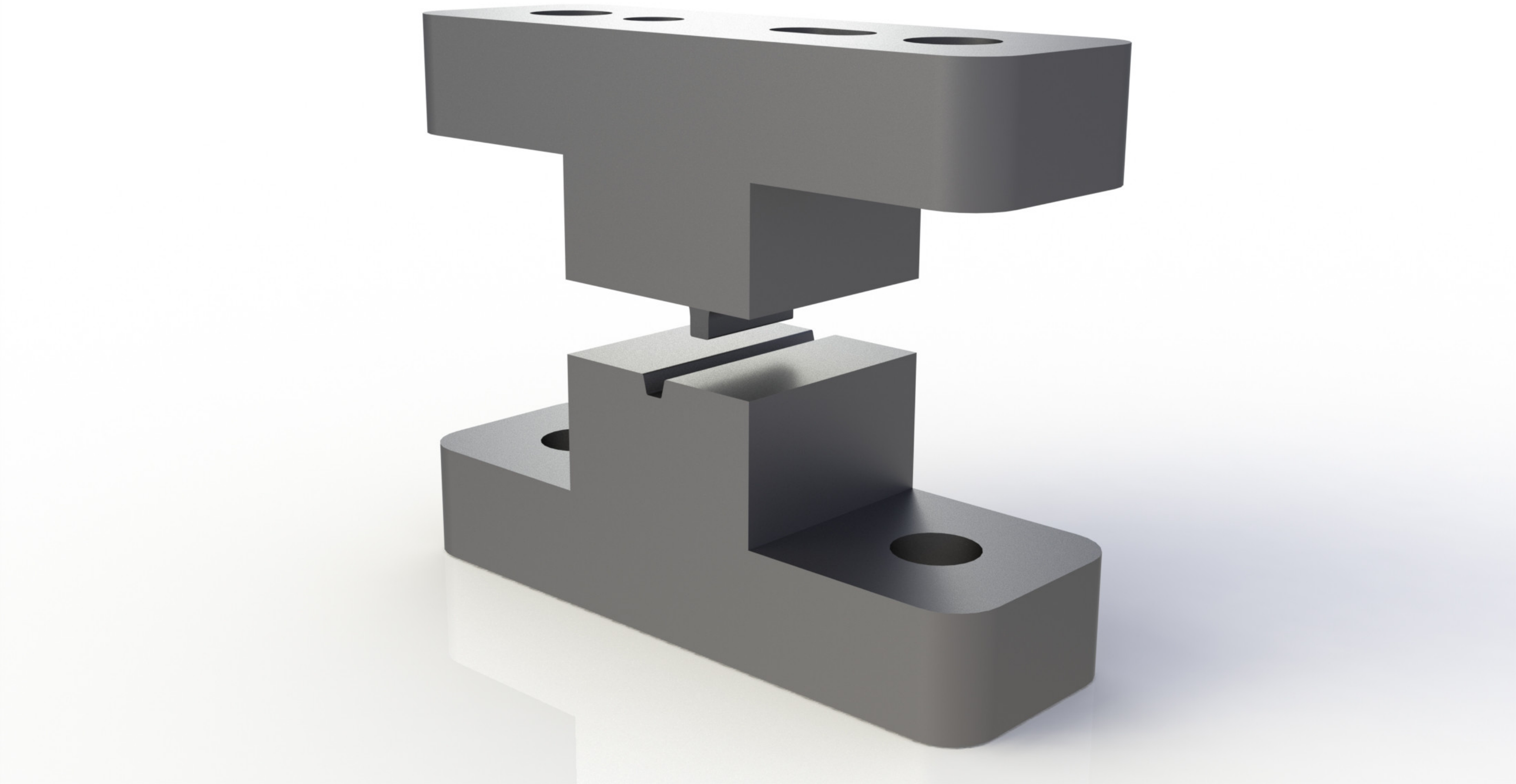
Cross-section view of B die shape with tube and cable for reference

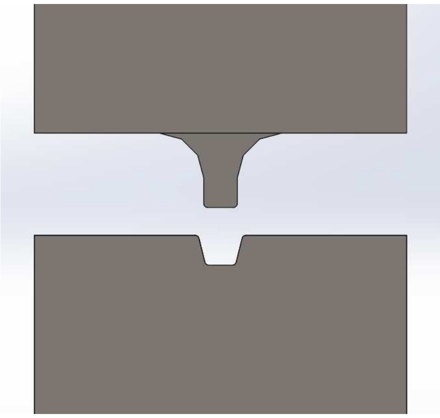
Three variations of the top die were made, with the angle between the two faces of the wedge set to 20°, 40°, and 60° to test the effect of the wedge angle. The point of the wedge was designed to have a semicircular shape to reduce the possibility of cutting through the tube. The bottom die was designed to have a trapezoid shaped cavity with fillets on each of the corners to reduce the possibility of the tube becoming stuck to the bottom die after crimping. The height of the cavity was set to be smaller than the original tube size to reduce the possibilities of interference between the top and bottom dies.

Die Shapes

The Flat die shape is as simple as its name implies. It was created as a baseline for testing the effects of contact surface area and complex die geometry on crimp strength.

Flat





Cross-section view of Flat die shape

The Flat die shape was designed to have a flat rectangular shape with rounded corners to prevent damaging the tube. The upper die was designed with a width of 0.04” and the bottom die was designed to be exactly the same as the B-Crimp bottom die. The top die was wide enough to cover more than the width of the tungsten cable diameter (0.025”) and the bottom die was small enough to maintain the crimped tubing area maximum diameter limit.

Outsourced Manufacturing

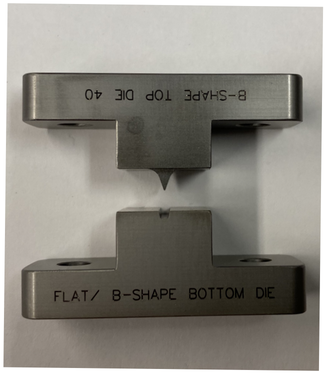
The final project design consisted of both in-house and outsourced manufactured parts. The die shapes and tube modifications were outsourced through JBJ Precision Industries. Medtronic recommended them to the team and they were able to bring our ideas to fruition with high precision despite small size constraints.

Die Shapes

Imperfections during the manufacturing process of the dies could cause crimp misalignment, damaged samples, or increased wear. To prevent this, the dies were made of A2 Tool steel and underwent a hardening process after being machined. The incredibly small features of the die were machined using wire Electrical Discharge Machine, or wire EDM. A wire EDM uses an electrically charged wire as small as the diameter of a human hair.

B Die Shape CAD Model

The machinists at JBJ transformed CAD models and part drawings to finished products.



B Die Shape Finished Product

Tube End Modifications

The team chose to test two different options for modifying the ends of the stainless steel tubes as shown on the right. The maximum diameter of the tubes was 0.050" so a wire EDM was the best option. The modified tube ends either had two slits or four slits.

Tube End Modifications Design

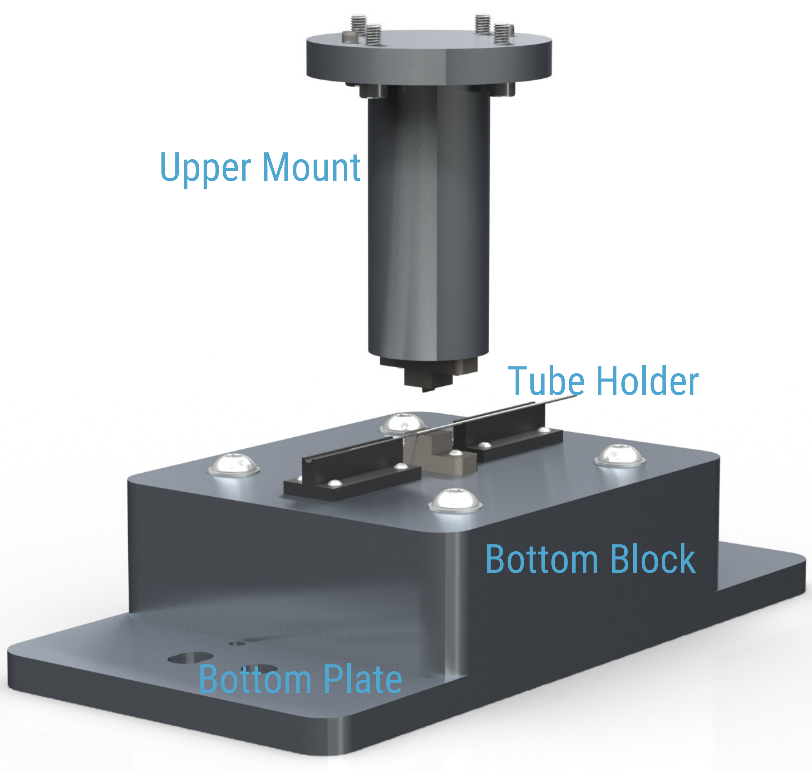
In-House Manufacturing

The final project design consisted of both in-house and outsourced manufactured parts. The team wanted to gain valuable experience working in a machine shop, so all components that did not require high levels of precision were made by the team.

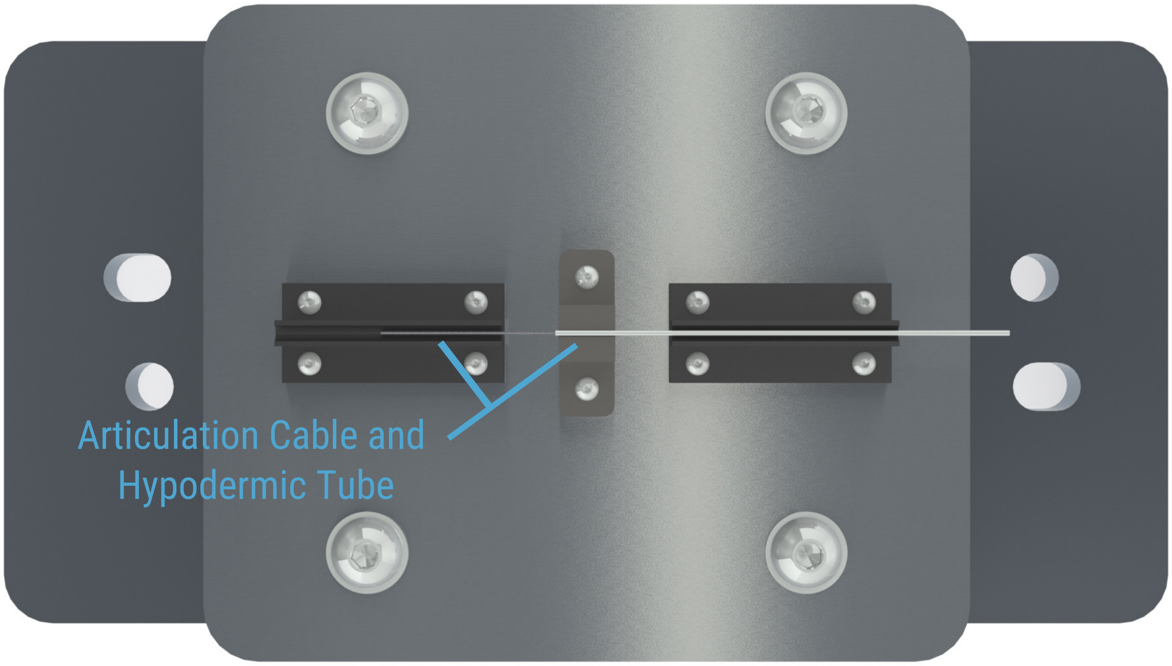
The upper mount was manufactured using a lathe. It attaches directly to the servo press. It is a longer component to account for distance between the top of the servo press and the bottom block.

The bottom block and bottom plate were machined on a mill, and their design allows for slight adjustments during the setup process. By using oversized screw holes on the bottom block, the bottom block could be moved in both the x- and y- directions to match the orientation of the upper mount.

The tube holders were fabricated with a Markforged 3D printer.



Servo Press Assembly Components



Top view of bottom block and bottom plate

Variables Chosen to Manipulate

There were four primary categories of variables that the team focused on while investigating mechanical crimping.

Crimp Force: The compressive force that the servo press applies to the crimp directly affects the strength of the crimp. However, the lower the crimp force, the cheaper and simpler the equipment required to create the crimp can be. Crimp forces from 3.5kN to 6.5kN were investigated, in 500N increments.

Die Shape: The shape of the dies used to create the crimp also plays a large role in determining the strength of the crimp. The team designed four basic die shapes, two with multiple variations, for a total of eight die shapes. These shapes included V-shape, Nest and Indent, B-shape, and Flat.

Tube Dimensions: The team investigated three different sizes of the stainless steel tube used in the crimp.

- Tube 1, currently used by Medtronic, 0.050" OD, 0.030" ID
- Tube 2, thinner wall thickness, 0.050" OD, 0.038" ID
- Tube 3, smaller diameter and wall thickness, 0.039" OD, 0.027" ID

Tube End Modifications: Based on research the team did on "U-brackets", the team decided to investigate making small cuts on the end of the steel tubes. The idea behind this was that these cuts would not only change the way that the tube deformed when crimped, but also reduce the force required to crimp the tube. Three variations were tested; no slit, one slit, and two slits.

Constraints were placed on the testing process in order to fit comprehensive testing of all of the above variables into the timeline of the project. These constraints included not only time constraints but also limits on the number of samples to be tested. In order to navigate these constraints while still acquiring enough data to support a conclusion, the team created a Design of Experiments (DOE). The DOE that the team developed provided the framework of the testing process that is described in detail later in this report.

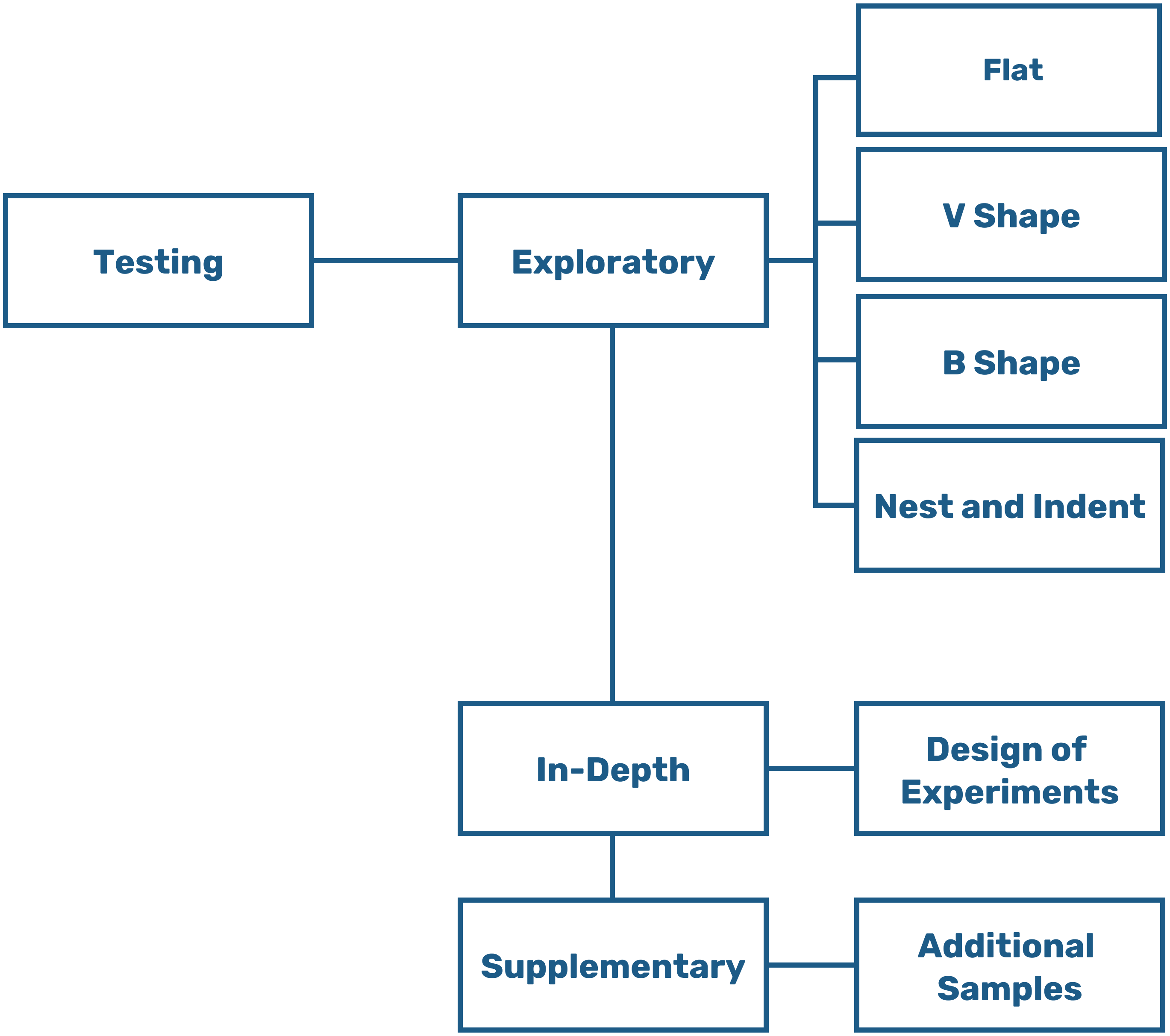
Testing Phases

Our team split testing into three phases: Exploratory, In-Depth, and Supplemental.

The exploratory phase focused on establishing primary relationships between variables for each die shape.

The in-depth phase aimed to utilize a Design of Experiments to collect data with a limited number of samples.

The supplementary phase was intended to collect extra data to verify previously established results.



Testing Procedure

Setup

Alignment of Upper and Lower Dies

Our design components were fabricated with adjustability in mind. Proper alignment is crucial to collect accurate data and create the strongest crimps. Our manufactured parts were designed so alignment only had to occur once.

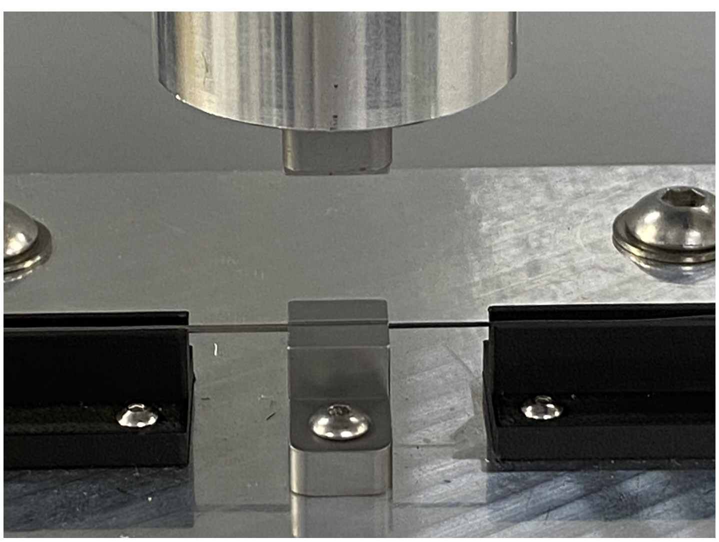
The first step is to select the proper die shape and install both components to the upper mount and the bottom block and verify the alignment.

Crimping Process

The Tungsten wire is placed within the stainless steel tube and placed on top of the die and tube holders as shown below.

Once this step is completed and the proper force is entered, the servo press crimps the two materials together.

Two tubes are crimped through this process, one at each end of the cable.

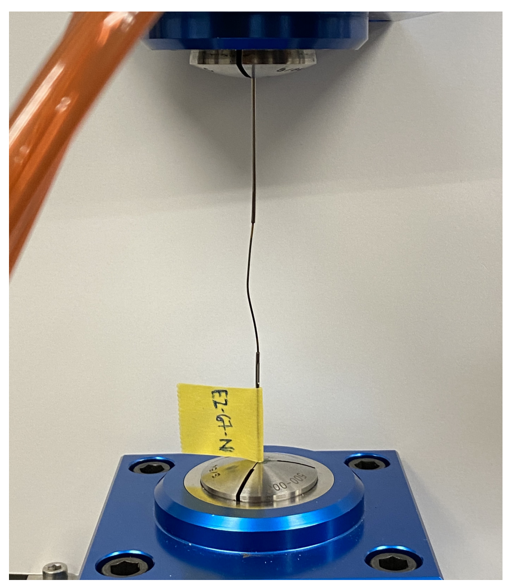


Servo Press Tube and Wire Alignment View

Pull Test Process

Each fully crimped sample is then placed in the pneumatic collets of the Instron machine as shown below. It was important not to pinch the tube where the wire was located so the data would reflect only the crimp strength.

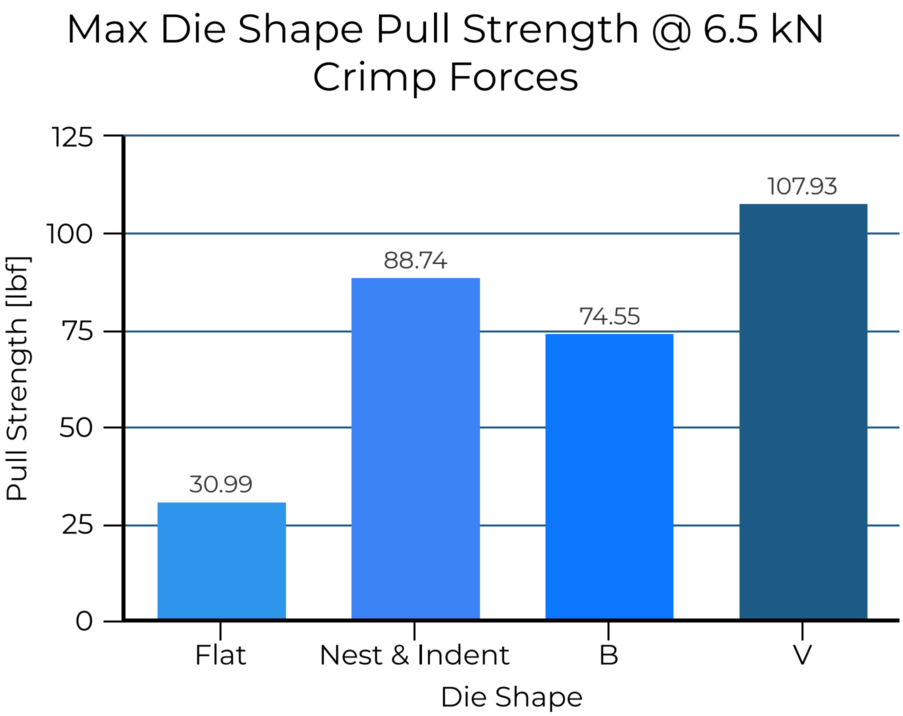
Each sample is pulled to ultimate failure where the cable slips out of the tube or the wire breaks and unravels. The results of these tests are shown on the following pages.



Instron Machine Crimped Sample Setup

Testing Results Overview

Tested crimps passed at 60+ lbf pull force to satisfy the device safety regulations.



During the exploratory phase, each die shape was tested with the standard tube and no end modifications with crimp forces up to 6.5 kN.

Due to the poor performance of the Flat shape, it was eliminated from further rounds of testing.

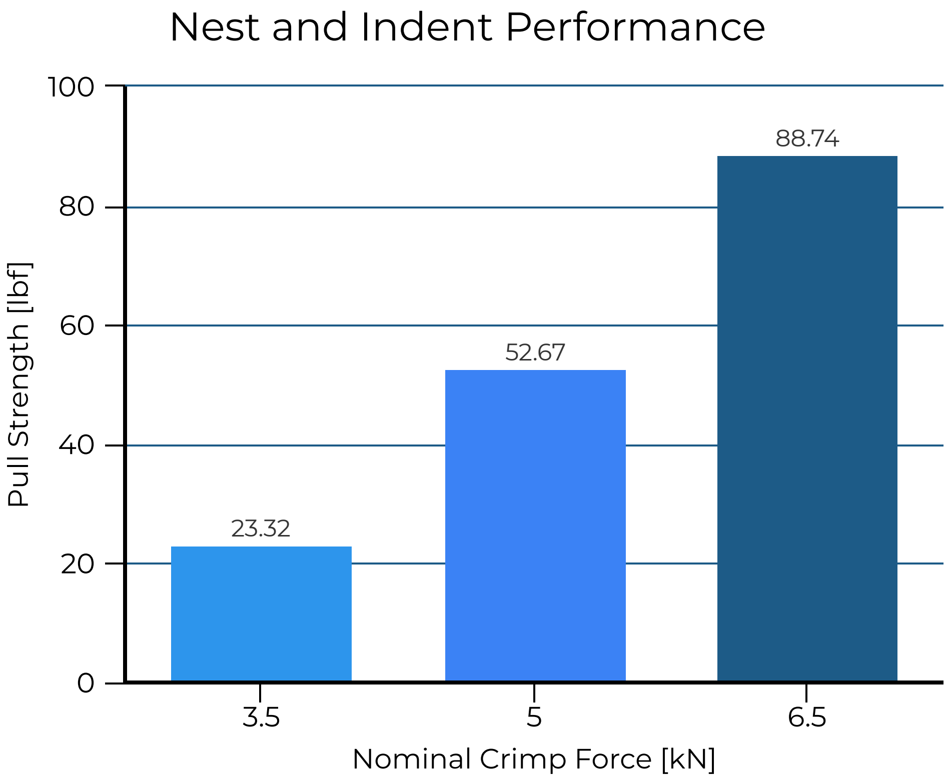
Die Shape	Optimal Crimp Force	Optimal Die Variation	Optimal Variation	Further Tests Required
Flat	No crimp force yielded a successful result.	Not Applicable	No tube variation yielded a successful result.	No.
Nest and Indent	6.5 kN	Not Applicable	No tube variation yielded a successful result.	Yes. Samples at 5.5 kN and above expected to pass.
B	4.5 kN and above	Larger Angles	No tube variation yielded a successful result.	Yes.
V	6 kN and above	Large Clearances	Tube 1 or Tube 3	Yes.

This table illustrates the initial performances of each die shape with the variable modifications.

Nest & Indent Die Shape Results

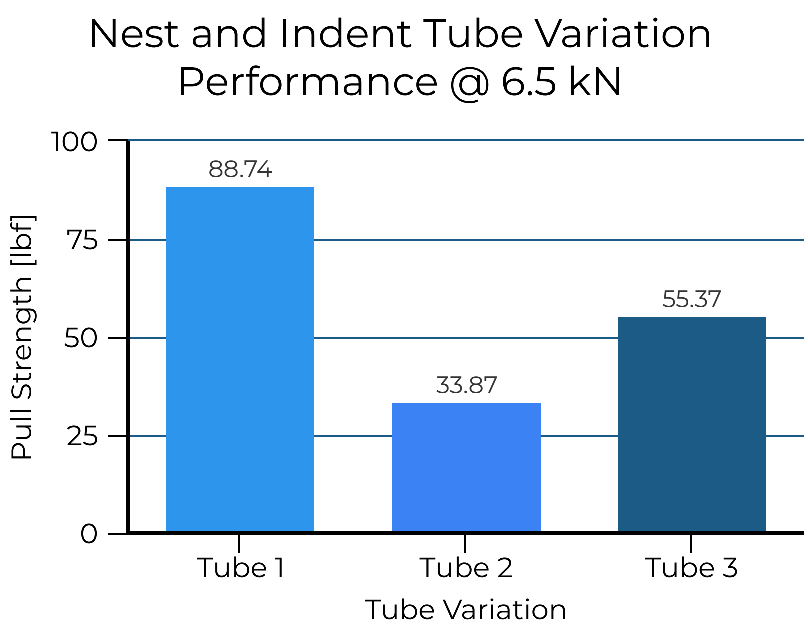
The Nest and Indent Die Shape produced successful crimps at 6.5 kN crimp forces. The tube variation showed Tube 1 as the best combination with this die shape.

Tested crimps passed at 60+ lbf pull force to satisfy the device safety regulations.



The Nest and Indent shape was only tested at three crimp forces. This allowed the team to develop an understanding of the die performance without testing a large number of samples.

The Nest and Indent shape performs better with increased crimp forces when crimped with tube 1. Crimps performed on tube 2 and tube 3 did not yield successful crimps. Tube end modifications also did not yield successful crimps.



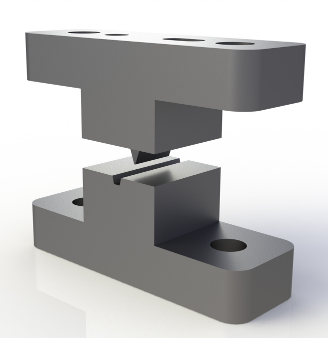
Tube 1 - 0.050" OD, 0.030" ID
Tube 2 - 0.050" OD, 0.038" ID
Tube 3 -0.039" OD, 0.027" ID

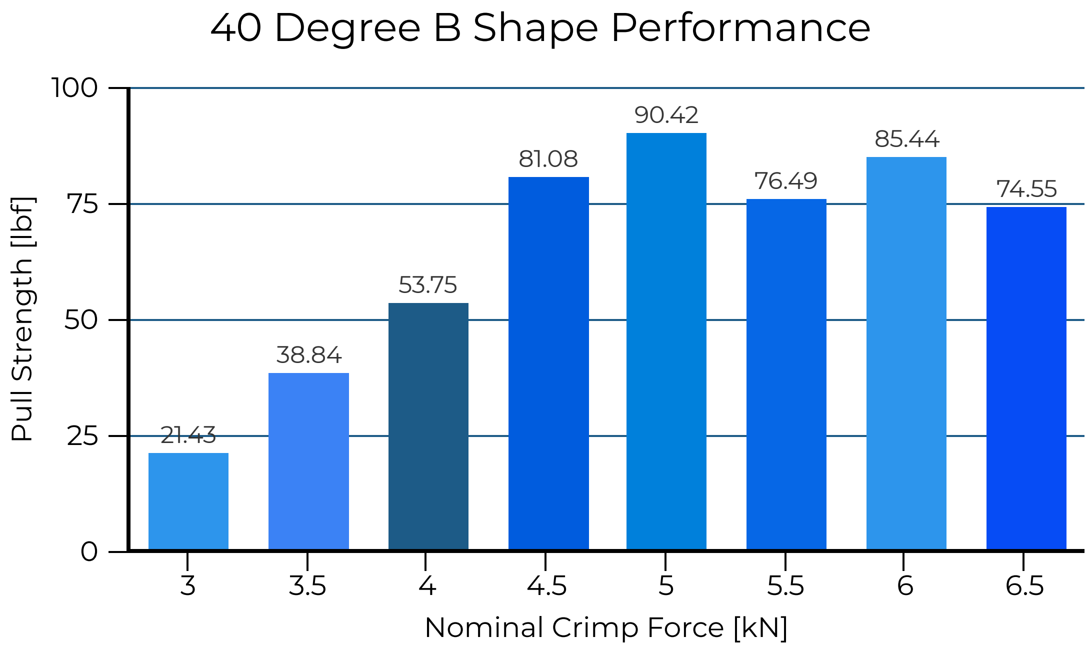
The team aimed to conduct further testing of the Nest and Indent Shape on forces between 5 and 6.5 kN, however testing was cut short due to the COVID 19 Pandemic.

B Die Shape Results

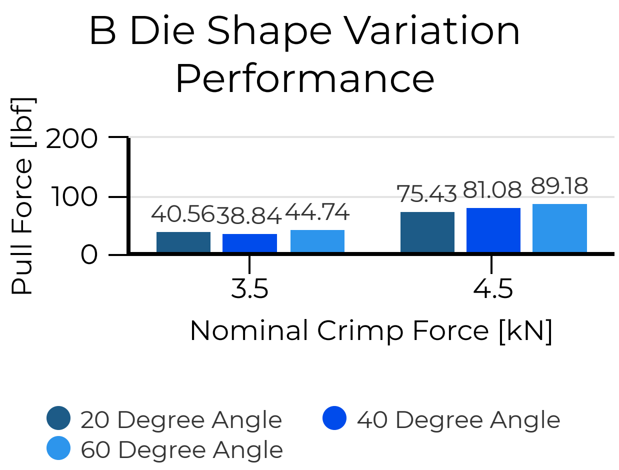
The B Die Shape produced successful crimps with crimp forces 4.5 kN and above. After comparative testing of the variations, the 60 degree angle paired with Tube 1 was the strongest combination.

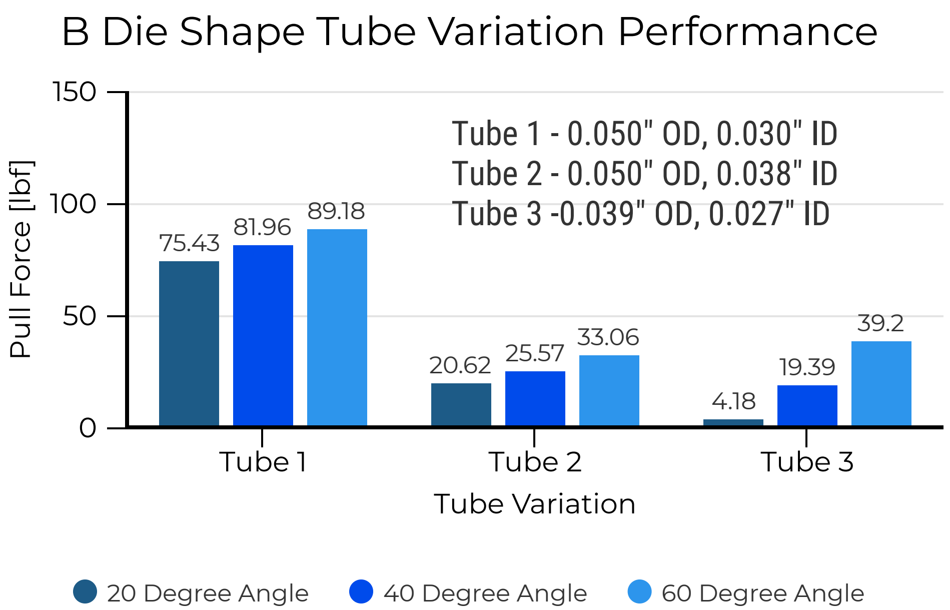
Tested crimps passed at 60+ lbf pull force to satisfy the device safety regulations.





The B shape was first tested at the 40 degree angle with no other variations applied yielding the results shown left.





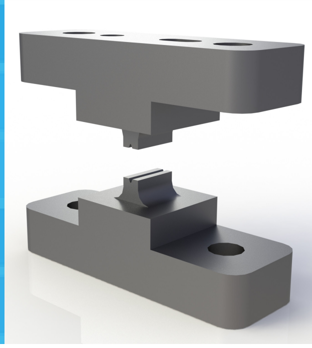
The team then tested each die shape variation at 3.5 kN and 4.5 kN, for this was the range the initial tested crimps began to pass the 60 lbf requirement.

The crimp force of 4.5 kN yielded passing crimps for each die angle variation so the 4.5 kN was chosen to test the tube dimensions. As shown above, the standard tube 1 was the only one to yield successful crimps, eliminating the need for further testing of tube 2 and tube 3.

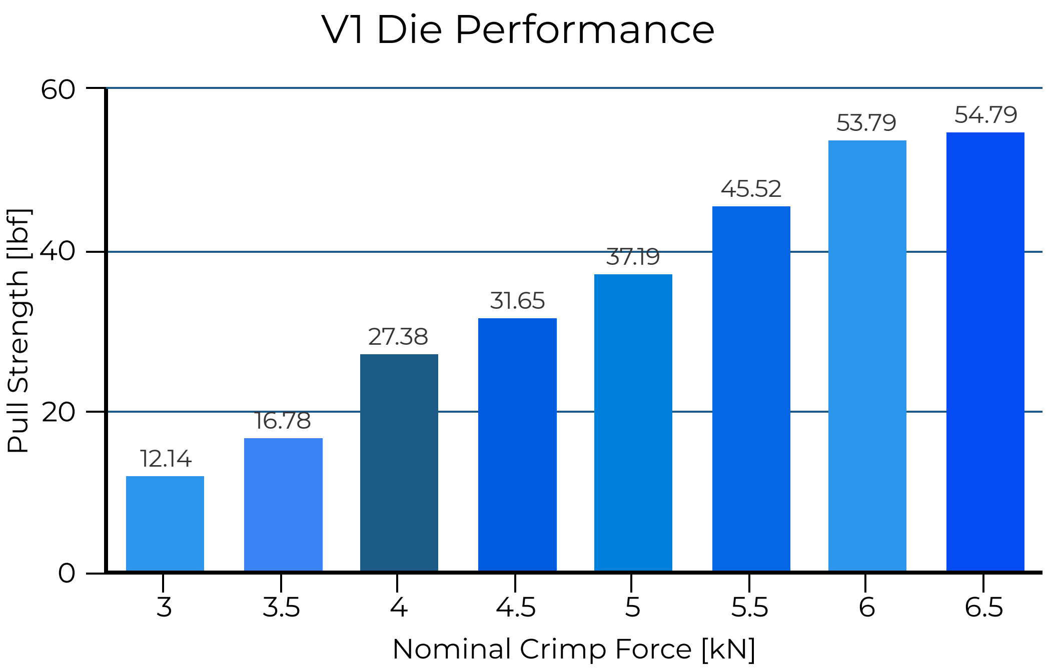
V Die Shape Results

The V Die Shape showed promise after the initial testing. At 6.5 kN, the two larger variations, V2 and V3, both surpassed the 60 lbf pull strength requirement. Further testing is needed to complete the V shape analysis.

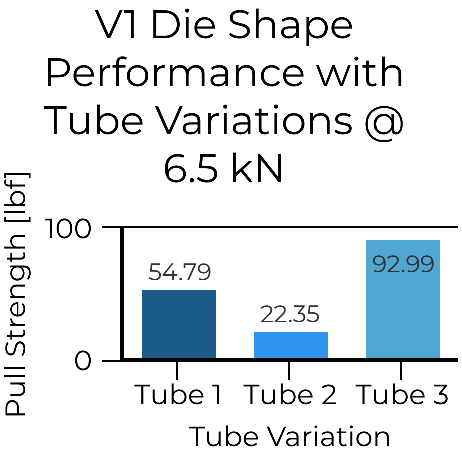
Tested crimps passed at 60+ lbf pull force to satisfy the device safety regulations.



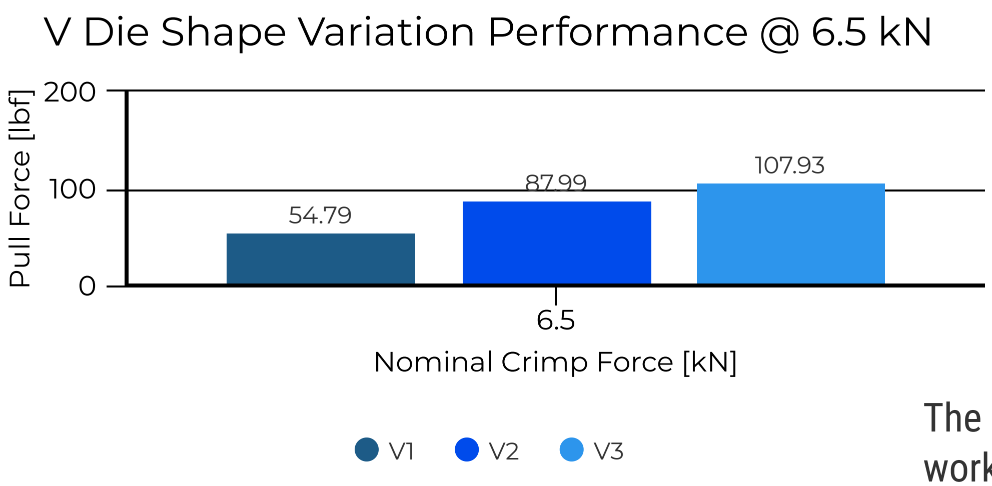
V Shape Variations
V1 - 0.025" clearance
V2 - 0.030" clearance
V3 - 0.035" clearance



The V shape was first tested at the smallest clearance with no other variations applied yielding the results shown left. As shown, higher crimp forces yielded results closest to the passing crimp force of 60 lbf.



Tube 1 - 0.050" OD, 0.030" ID
Tube 2 - 0.050" OD, 0.038" ID
Tube 3 - 0.039" OD, 0.027" ID



The tube variations showed Tube 3 to work best for all three V Shape variations. Tube 2 did not produce successful results, and the team concluded this occurred because the inner diameter of Tube 2 is larger than the clearances for each variation. Further testing could be used to confirm this theory.

We then tested each die shape variation at 3.5 kN, 5 kN, and 6.5 kN to provide overall performance data on each variation in clearance distance. The 6.5 kN showed passing crimps for V2 and V3 as evidenced in the graph above.

Project Conclusion and Next Steps

Conclusion

This project allowed the team to experience many aspects of being a professional engineer in the workforce. After receiving the project objectives, the team conducted in-depth research, made decisions and design iterations towards a final goal, fabricated components, and executed a test plan despite being halted by COVID-19. The opportunity to work face-to-face with an industry client as well-known and established as Medtronic was an added bonus.

The team would have liked to achieve more finalized conclusions with their testing results, but unfortunately the testing phase of the project was cut short. Ultimately, the team was able to eliminate one of the four die shapes designed and establish potential next steps for moving forward with the testing in the future based on the trends from the tested samples. Despite the abrupt conclusion of the project, the team eliminated the flat and nest and indent die shapes. For lower crimp forces with successful crimps, the B shape showed the most consistent results. To achieve the highest pull strength disregarding lower crimp forces, the V shape was the best performing die tested by the team.

Next Steps

The primary next step suggested by the team is to continue with the testing plan, moving forward into the in-depth and supplementary phases in order to analyze the trends for each variable on the remaining three die shapes. Based on the preliminary test results from the exploratory phase, the team brainstormed other possible options to pursue. One major idea was to interchange the die halves. Some of the die combinations could be swapped around, which could possibly fix issues that arose such as the tube slipping in the die. Durability tests could have been also implemented, since different die shapes are subject to different amounts of stress that could lead to breaking. Testing when the dies physically cut the cable/tube was also possible, since some dies such as the B shapes were prone to cutting the tube or the cable and causing it to fail. If this project could have been done for much longer, then the option of making new dies would have been on the table. Exploring different angles, widths, and shapes could all be beneficial. Guidance on these shapes could be gathered from the trends found from testing.

Recognitions and Acknowledgements

Team 11 would like to thank everyone involved in the success of our project throughout the past nine months. Each party involved was integral to the completion of the project.

The entire team would like to thank Medtronic for partnering with CU Boulder to give each of us the opportunity to experience working with one of the leaders in contributing to human welfare through innovative medical solutions.
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