The Effect of Distal Core Flattening and Heat Treatment on 304 Stainless Steel Guide Wires

A Senior Project presented to the Faculty of the Materials Engineering Department, California Polytechnic State University, San Luis Obispo

In Partial Fulfillment of the Requirements for the Degree Bachelor of Science

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Abstract

The mechanical response of 304 stainless steel guide wires due to different temper conditions and amounts of flattening is to be explored in this project. For this specific project, there is no public literature on the mechanical properties of guide wires with the above conditions through tensile testing or Turns to Failure Testing. To address this, the project with Abbott Vascular will measure the mechanical properties of guide wires using the aforementioned factors. Due to a lack of previous literature on this research topic, there are no quantitative goals for the project, however, any new research compiled in this area will be beneficial. As a result of the COVID-19 pandemic, current limitations to lab access prevent new data from being collected on guide wires, so this report will mainly focus on existing data from wire manufacturers. Available tensile properties of 304 stainless steel at varying cold work levels will be taken into account to better understand guide wire behavior and allow us to suggest the next steps in order to progress this project in the future.

Keywords: 304 Stainless Steel, Guide Wires, Biomedical Engineering, Heat Treatment, Tensile Test, Single Spring, Triple Spring, Ductile Fracture, Materials Engineering, Abbott Vascular, Flattening, Plastic Deformation, Turns to Failure, TTF

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Introduction

Problem Statement

The mechanical response of 304 stainless steel guide wires due to different temper conditions and amounts of flattening is not fully explored. To address this problem, this project with Abbott Vascular will measure the mechanical properties of guide wires comparing “Single” and “Triple” spring temper conditions in addition to four different amounts of flattening: the product specification, greater than the product specification, less than the product specification, and no flattening. A total of 160 guide wires will be tensile tested following heat treatment, grinding, and flattening. Tensile testing and failure analysis such as SEM will be done at Cal Poly SLO while the Turns to Failure Testing (TTF) and guide wire processing will be done at Abbott Vascular in Temecula. For this project, there is no public literature on the mechanical properties of guide wires for the combined processing conditions or mechanical data on turns to failure testing. Due to this reason, there are no quantitative goals for the project, however, any new data gathered will be beneficial for Abbott Vascular.

Abbott Vascular Inc.

Abbott Vascular Inc., the cardiovascular division of parent company Abbott, is a world leader in the medical device industry, having been established for over 130 years and currently distributing to over 160 countries. Their main objective is to advance the field of minimally invasive procedures and develop medical technologies that restore people’s health and allow them to return to living their best lives, faster. They focus on technologies that improve treatment for vascular diseases, heart arrhythmias, and diseases of the heart valves. Some of their products include heart valve repair and replacement technologies, heart failure and cardiac rhythm management devices, vascular stents, catheters, and guide wires.[1]

Abbott Vascular Inc. is located in Temecula, CA, and is one of six subdivisions of Abbott, which also develops products for diabetes, diagnostics, neuromodulation, nutrition, and pharmaceuticals. In 2016, Abbott Vascular Inc. acquired St. Jude Medical Inc., allowing them to compete in nearly every area of the cardiovascular device market. St. Jude's leading products in heart failure devices, atrial defibrillation, and cardiac rhythm complement Abbott's already existing line coronary intervention and transcatheter mitral repair products.[2] This acquisition also led to the development of the entirely new neuromodulation division which includes technologies to manage chronic pain, which now represents one-third of Abbott's total business.

Medical Guide Wires

Medical guide wires are small-diameter, flexible wires inserted into the body in order to guide larger instruments such as a catheter or feeding tube. The use of guide wires on humans was first developed by German physician Dr. Werner Forssmann in 1929 for cardiac catheterization.[3] Since then, guide wires have become smaller, more complex, and made with a variety of materials in order to handle a range of medical operations.

The basic building blocks of the guide wire include the core diameter, core material, core taper and grind, tip design, and coatings (Figure 1). When selecting the core diameter of the guide wire, the most common sizes are 0.014, 0.018, and 0.035 inches. Larger diameters are stronger and have improved torque which can be utilized to straighten vessels. Smaller diameters, on the other hand, have the advantage of increased flexibility and trackability through the vessel. The core material influences the flexibility, support, steering, and tracking of the guide wire. Two of the most utilized materials are stainless steel (easier to torque and more rigid providing better support) and nitinol (more flexible and kink resistant). Hybrid wires have also been developed that include high tensile strength stainless steel shafts with nitinol tips to achieve high torquability with kink-resistant tips. Adjusting the core taper influences the durability and pushability of the wire in the vessel. Longer, more gradual tapers offer access to smaller vessels and improve tracking around bends. More abrupt, shorter tapers provide better support in shorter distances, but tend to fold in on itself and become weak. Guide wire tip designs affect shaping, durability, and pushability. Wires whose core extends to the tip have increased pushability and are more durable and steerable but are also more likely to inadvertently injure blood vessels. When the core does not extend to the tip, it is flexible and easier to shape, but results in less control and stability. Additionally, coils can be added to the tip to increase support, trackability, shaping, and radiopacity.[4] The coating of the wire can be either hydrophobic or hydrophilic, and is usually chosen based on the physician's preference. Hydrophobic coatings form a smooth surface and repel water, reducing friction. Hydrophilic coatings, on the other hand, attract water to produce a slippery, gel-like surface.[5]

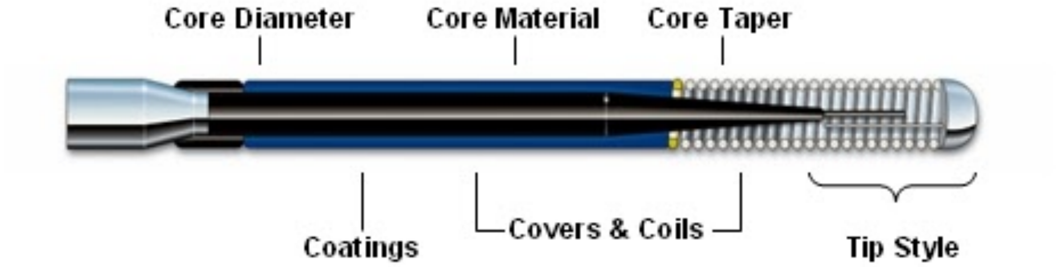


Figure 1 - Basic components of medical guide wires shown in the figure influence its properties and performance in non-invasive procedures.[4]

Other properties of guide wires such as radiopaque coils that affect their performance include radiopacity and wire length. Visibility of the wire is directly related to the core material's density, which makes guide wires difficult to see in fluoroscopic imaging due to the low density of stainless steel. To remedy this, radiopaque markers made of gold or platinum are implemented to improve visibility in the vessels.[6] Longer wires allow for easier device delivery without losing position of the target site; however, there is a loss of torque response as the wire gets farther from the point of entry. Torque control is also affected by curved segments. Adding secondary bends such as a "J" tip provide a better angle for navigating curved areas and are at lower risk of perforating the vessel.[4]

One of the most common procedures in which guide wires are used is angioplasty. This is an operation that involves the mechanical dilation of a narrowed vessel that may become blocked over time due to smoking, high cholesterol, high blood pressure, or obesity (Figure 2).[7] Guide wires navigate the vessels to the target site and are followed by a balloon catheter that gently inflates to expand the area. A small mesh tube called a stent is then inserted over the guide wire and acts as a permanent scaffolding to support the vessel and keep it open.

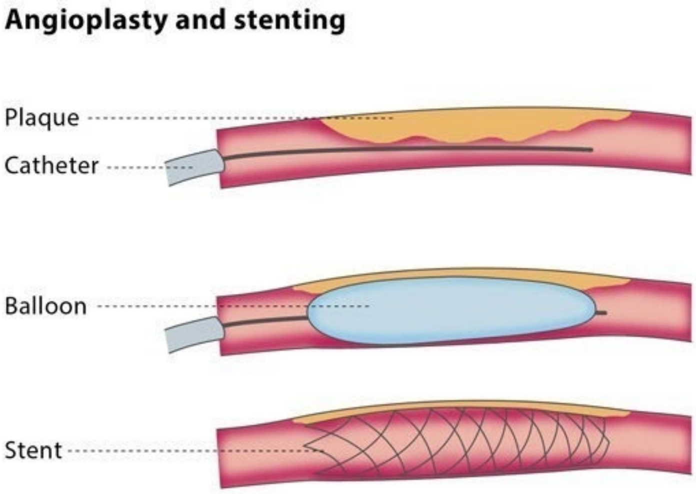


Figure 2 - Guide wires are often used in balloon angioplasty and stenting procedures to deliver devices to target locations in the body.[7]

Guide Wire Processing

The general processing of guide wires involves heat treatment, cold rolling, and cold drawing. Wire drawing reduces the wire's diameter by pulling it through a die. The geometry of the die determines the dimensions, cross sectional area, and reduction in area. The preparation for cold drawing includes heat treatment to make the wire ductile enough and surface preparation such as cleaning.[8] An important aspect of wire drawing is that the pulling force or drawing stress cannot be greater than the strength of the wire or fracture occurs. The most common processing technique is an area reduction of 20.7% per pass. In order to produce the desired diameter, many drawing passes are typically necessary. In a carbide die, the wire makes contact in the drawing cone along the approach angle and becomes reduced to the dimensions of the exit drawing cone (Figure 3).[8] The bearing area involves no further reduction and allows the die to be refinished. The back-relief region (Figure 3) reduces the amount of abrasion in the event that drawing process stops or the die is out of alignment. Lubricant is inserted at the bell region (Figure 3) and is pulled into the die-wire interface by the moving wire.[8]

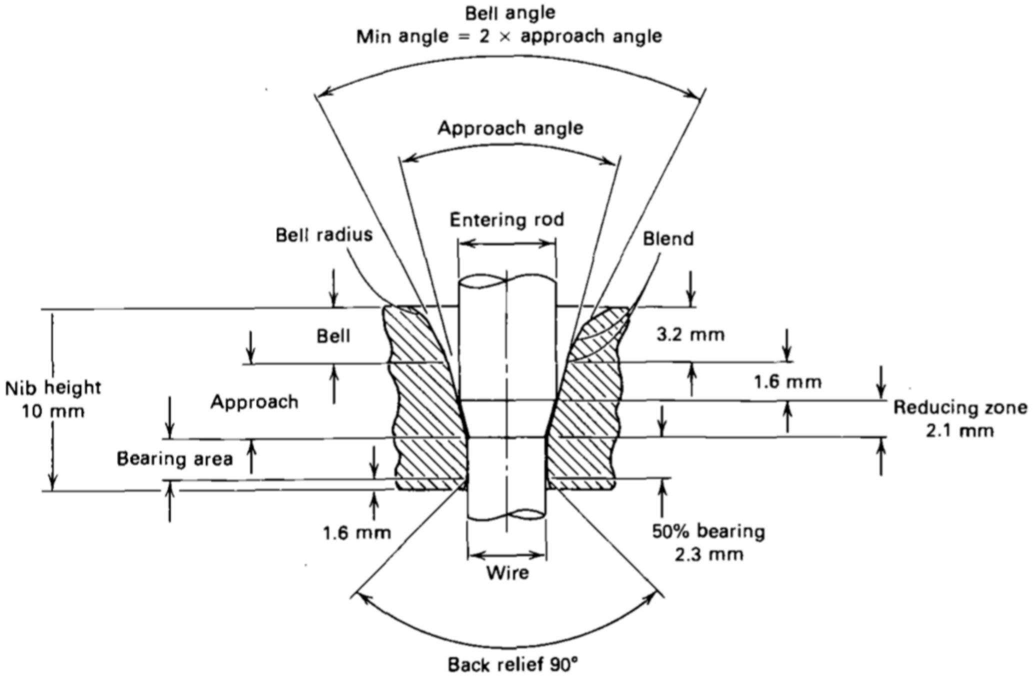


Figure 3 - Cross sectional image of wire dies for drawing. Multiple passes are required to reach certain diameter.[8]

In the post processing of guide wires, grinding is used to form shapes such as tapers, angles, and arcs. Centerless grinding is the most commonly used method and utilizes a control wheel that rotates the workpiece while the grinding wheel cuts into it (Figure 4). This method produces more accurate wires at faster rates than traditional methods.[3]

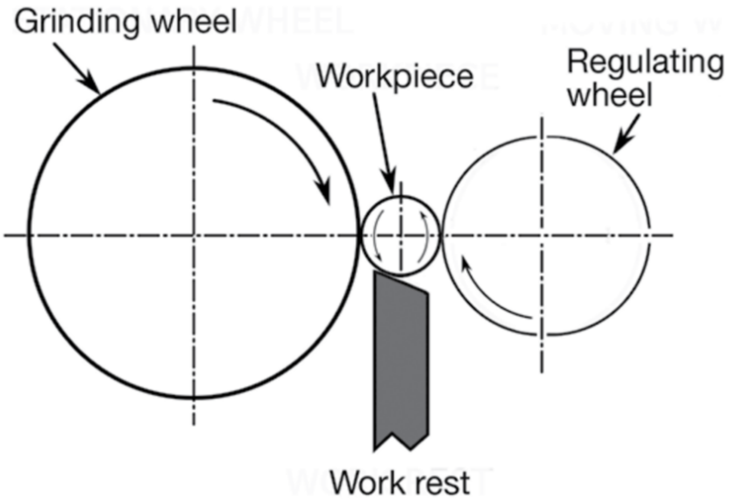
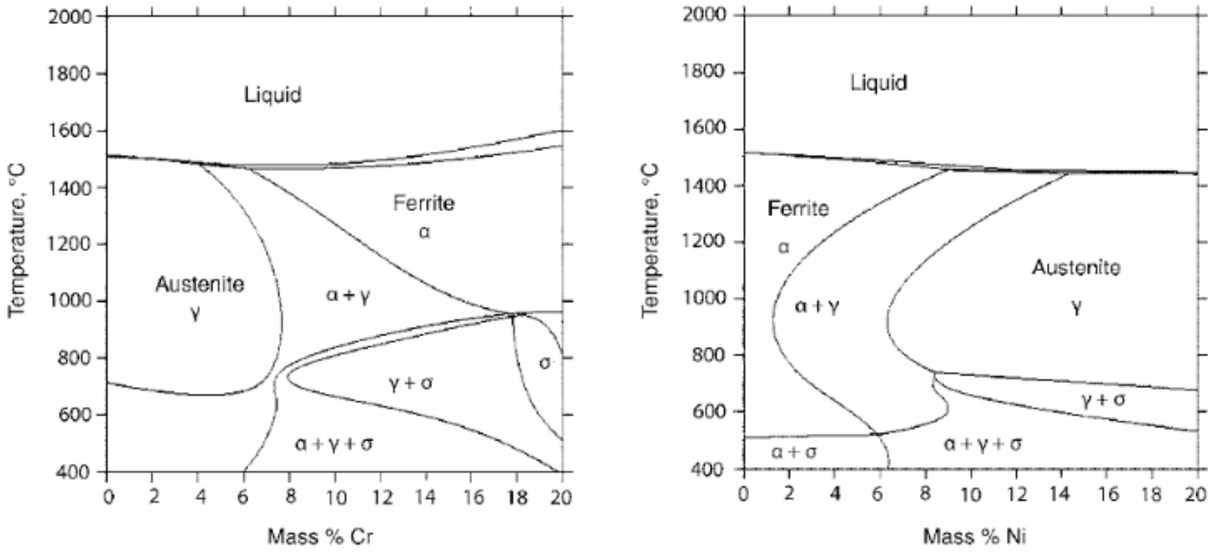


Figure 4 - Centerless Grinding diagram. The grinding wheel pushes the workpiece into the regulating wheel.[9]

Abbott Vascular receives core guide wires with a desired heat treatment and drawn diameter from an external vendor. The wire is then coated with Teflon (PTFE) through reel to reel coating and straightening. An alternative to the coating process is straightening then spray coating. Wire straightening involves the wire being fed into a rotary device where the wire is plastically deformed at a high rate. Following straightening and coating, the wires go through a burn-in step which relieves internal stresses in the material. They are then cut to the desired length, ground, and flattened to the desired amount. A coil is then soldered onto the wire and the guide wires are post processed for packaging and distribution. Depending on the wire family, additional coating may be applied.

304 Stainless Steel

Stainless steels (SS) are iron-based alloys that contain a minimum of approximately 12% Chromium. The most common type of SS is austenitic stainless steel, which contains nickel to help stabilize the austenitic structure (FCC, face-centered cubic). At room temperature, 304 SS contains a majority austenite with some ferrite and sigma phase (Figure 5).[10]



(a) (b)

Figure 5 - (a) Phase diagram of stainless steel relative to Cr composition (b) Phase diagram of stainless steel relative to Ni composition.[10]

304 SS is a general-purpose austenitic SS; the number designation and composition are specified by A313/A313M − 18 (Table I).[11] Typical mechanical properties of annealed 304 SS show a tensile strength of 515 MPa (75 ksi), a yield strength of 205 MPa (30 ksi), and 40 percent elongation in 2 inches.[12]

Table I: Chemical Composition For 304 Stainless Steel in Weight Percent[11]

UNS Designation	C	M	P	S	Si	Cr	Ni	N
S 30400	0.08	2.00	0.045	0.03	1.00	18-20	8-10.5	0.1

This mechanical data matches the expected trend of cold working; increase in yield strength and decrease in ductility. These wires are electric arc melted and additionally vacuum arc re-melted (denoted by "V") to refine the metal, yielding more uniform chemistry and minimum contaminants.[12] In wire form, 304V SS will gain tensile strength when stress relieved from 350-427°C and will fully anneal at 1010-1121°C in minutes.[12]

Table II: 304V SS with Varying % Cold Work[12]

% Cold Work	Yield Strength (ksi)	Tensile Strength (ksi)	% Elongation (10" gauge length)
0%	50	107	41%
20%	70	140	14%
37%	90	184	4%
50%	140	208	3%
60%	160	229	2.6%
68%	180	247	2.7%
75%	200	265	2.6%
80%	215	272	2.9%
84%	230	289	2.5%
90%	245	306	2.6%
93%	250	316	2.7%
95%	280	334	2.6%

304 Austenitic stainless steels are advantageous for various metallurgical reasons. They are soft enough to be easily machined but can be made extremely strong through cold working. The FCC structure is tough at low temperatures and does not lose strength at elevated temperatures as quickly as ferritic stainless steels.[10] There is excellent corrosion resistance to a wide range of environments and good oxidation resistance up to 870°C.[13] Additionally,

austenitic stainless steels are beneficial because of their excellent formability, low cost, high yield strength, and ease of cleaning. In particular, the ability to be formed easily into shapes makes 304 SS a common and well-known material for guide wire cores.[14]

Heat Treating 304 SS

Austenitic stainless steels, such as 304 SS, have little structural changes upon heating, thus are only hardened by cold working. As a result, there are only a two methods of heat treatment: annealing and stress relieving. The most important heat treatment of 304 SS guide wires is annealing. As a result of the production methods, guide wires are heavily cold worked. The resulting guide wire is stronger but also less ductile. The main functions of annealing are to remove cold work and put alloying elements into solid solution. Annealing removes the effects of cold working by recovery, recrystallization, and grain growth. The internal stresses are relieved by the diffusion of atoms into a more thermodynamically favorable state. Annealing brings the metal into a solid solution and dissolves chromium carbides, which precipitate at around 425 to 900°C. Chromium carbides greatly decrease the resistance to intergranular corrosion; therefore, 304 SS should be annealed above 1040°C and then rapidly cooled to prevent carbides from precipitating.[15]

The different amounts of annealing performed after cold working are referred to as the "temper" conditions and are often defined in terms of minimum hardness or tensile strength corresponding to a specific percent of cold working following a full anneal. Tensile strength and yield strength increase with more tempering, while % elongation decreases (Table III).[16] The main "temper" conditions are listed below:

- "Dead soft" - Fully annealed.
- "Full hard" - A temper corresponding approximately to a cold worked state beyond which the material can no longer be formed by bending.
- "Spring" - A temper corresponding approximately to a cold worked state ⅔ of the way from full hard and extra spring.

- "Extra spring" - A temper corresponding approximately to a cold worked state beyond which further cold work will not measurably increase the strength and hardness.[17]

Table III: Mechanical Properties of Various 304 Stainless Steel Temper Conditions[16]

Temper	Tensile Strength Minimum (ksi)	Yield Strength Minimum (ksi)	% Elongation in 2" Minimum
Annealed	75	30	40%
1/4 Hard	125	75	10%
1/2 Hard	150	110	6%
Full Hard	185	140	3%

Plastic Deformation of 304 SS

Due to the metastable austenitic phase of 304 SS, plastic deformation will induce a phase transformation in 304 stainless steel. Deformation Induced Martensite (DIM) is separated into two types: Stress Assisted Martensite (SAM) and Strain Induced Martensite (SIM).[18] The plastic deformation of 304 SS includes three phases: γ-austenite (FCC), ε-martensite (HCP, Hexagonal Closed Packed), and α′-martensite (BCT, Body Centered Tetragonal).[19] SIM changes from γ-austenite to α′-martensite while SAM transforms from γ-austenite, ε-martensite, and finally to α′-martensite.[18]

There are two stages to the plastic deformation region when the temperature is below room temperature. The initial stage of rapidly decreasing strain hardening rate occurs with the formation of ε-martensite, while in the second stage, the increasing strain hardening rate corresponds to the formation of α′-martensite. The formation of the ε-martensite relaxes the stress of austenitic grains while the formation of α′-martensite can accommodate a large amount of strain and dissipates local stress concentrations, promoting uniform tensile deformation.[18] The plastic deformation of 304 SS is characterized by the dissociation of perfect dislocations in Shockley partial dislocations and the formation of wide stacking faults.[20] Strain induced ε-martensite is formed because of randomly spaced overlapping stacking faults.[19] The α′-martensite phase is formed because of dislocation pile ups. α′ phase increases the work hardening capacity and ductility of steels.[19]

In the microstructure of plastically deformed 304 stainless steel, strain induced ε-martensite appears as parallel shear bands (Figure 6). Shear bands are defined as planar defects formed as a result of overlapping stacking faults on austenite {111} planes during deformation.[20] α′-martensite in the microstructure can be seen as irregular, rough edged, and at the intersection of the shear bands (Figure 6).[20]

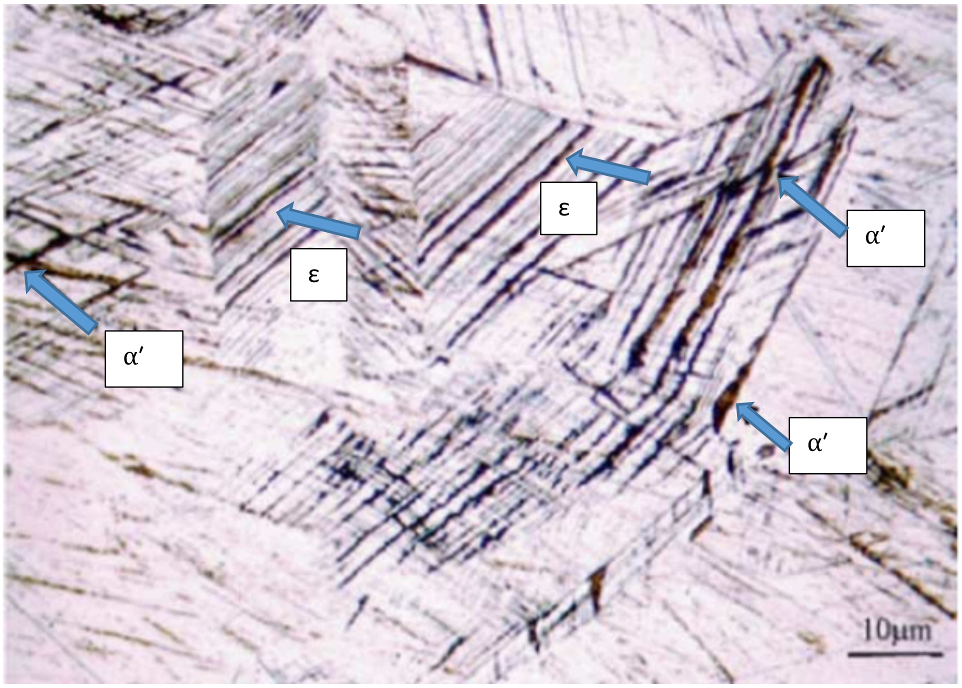


Figure 6 - 304 stainless steel plastically deformed. Blue arrows point to α′ phase and ε phase.[20]

Experimental Procedures

The goal of this project is to investigate the effects of flattening and temper condition on the mechanical properties of 304 SS guide wires. To study these effects, tensile testing of various guide wires will be performed using the Mini Instron 55 located in the Materials Engineering Dept. at Cal Poly, San Luis Obispo. Abbott will supply 8 different groups of 20 guide wires, 4 groups of single spring temper condition and 4 groups of triple spring temper condition. Each temper condition will have a different group for the different amounts of flattening associated with a typical guide wire product. These flattening amounts and associated diameters/thicknesses are as follows: no flattening (0.0033 in), below specification (>0.0024 in), at specification (0.0020-0.0024 in), and above specification (<0.0020 in). Each guide wire with flattening will be flattened the entire length of the wire, 30 cm, to ensure uniform tensile testing. In addition to the 160 guide wires sent to Cal Poly, Abbott Vascular will manufacture 160 guide wires with the exact same processing conditions above and conduct Turns to Failure (TTF) testing at their facility. TTF testing involves twisting the proximal end of a guide wire until failure while the distal end of the guide wire remains fixed. The guide wires used for TTF testing will be flattened to accurately represent guide wires used in industry.

Safety

This project involves the tensile testing of thin biomedical guide wires using the Mini Instron 55. Closed toed shoes, long pants, and safety glasses are required during testing. Additionally, tensile testing must be conducted with at least one other person in the lab in case of an emergency.

Tensile Testing

To operate the Mini Instron 55 (Figure 7), turn on the computer and Mini Instron machine. Select the “Blue Hill 3” icon on the desktop to open the Mini Instron 55 software. Select “Test Method”, click “Yes” and then click “No”. Remove the bottom grips from the Mini Instron, select the “Load Cell” icon and perform the calibration, then reinstall the Bollard grips and wire adapters (Figure 8). Locate and pull the red button on the Mini Instron, select the “Tensile/Frame” icon and enable the frame. Load the guide wires into the Bollard grips, wrapping the wire around the grips at least 2 times, keeping the wires as taut as possible. After the wire is loaded, select “Test”, “Method”, “Next”, and enter the file name. Then select “Next” and input the pertinent dimensional and strain rate information. For the purpose of this project, a crosshead displacement rate of 0.2 in/min will be used. Next, select “Zero Extension”, “Balance Load”, and then “Run”.

Figure 7 - Mini Instron 55 is used for smaller tensile specimens.

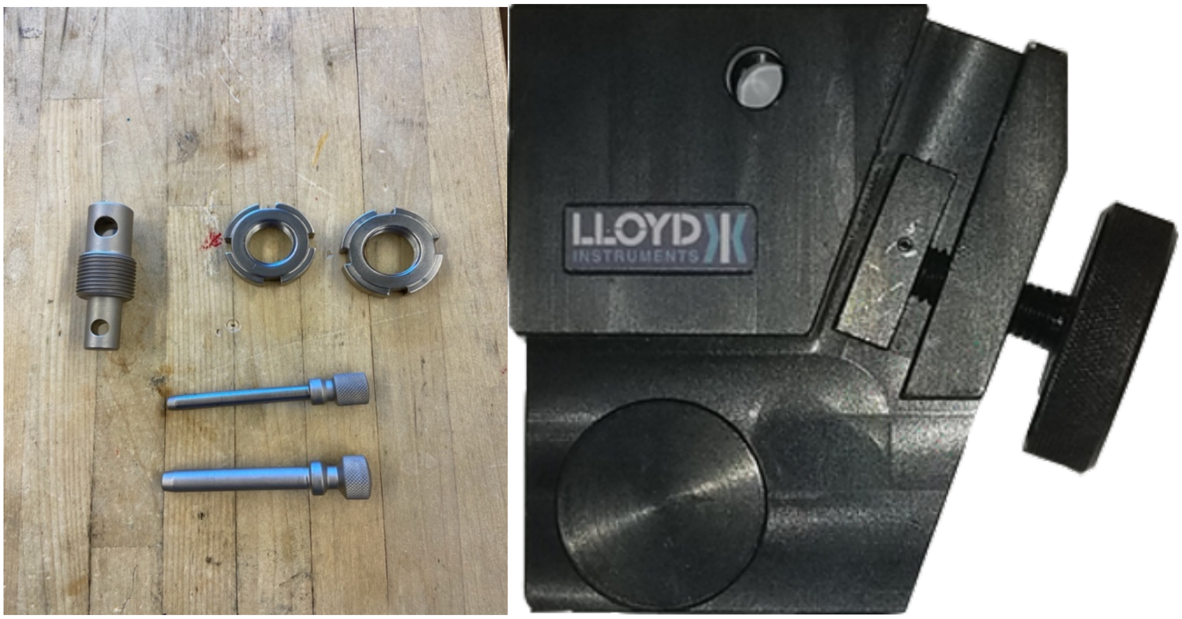


Figure 8 - Adapters (left) to connect Mini Instron 55 to Bollard wire grips (right). Wire ends are fastened and secured in place then wrapped around the spool to ensure the testing section is taut.

Preliminary Data

Before receiving the guide wire samples, Abbott Vascular sent experimental guide wires to practice using the Mini Instron 55. A total of two samples were tested with their load versus displacement curves (Figure 9), each color representing a different sample. It is important to note that these guide wires have extremely small diameters, making them appear brittle in the curve, however, if the curve was zoomed in, there would be some necking and ductility seen. Additionally, the curves have different starting points in the displacement axis because of different amounts of slack in the guide wires when they are loaded.

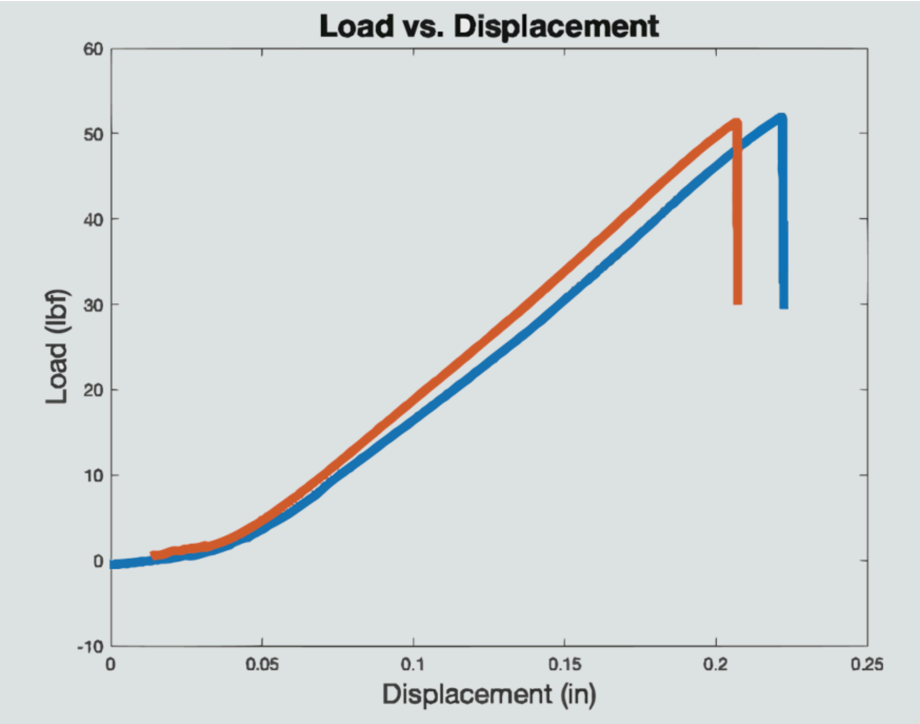


Figure 9 - Load vs. displacement curves of practice samples. Colors indicate two different samples.

Future Work and Recommendations

After finishing the extended literature review and minor testing, some future work remains to be completed. First, all tensile testing should be completed and the load versus displacement graphs should be adjusted to eliminate the offset caused by the slack in the guide wires during loading. Next, the specific processing steps for single and triple spring heat treatment should be researched in order to gain a better understanding of how each temper should behave mechanically. After compiling all TTF and tensile data, statistical analysis should be performed to find trends in the data and understand the mechanical properties.

After completion of all future work, some recommendations were made to better understand the various 304 SS guide wires. Due to the nature of the application, it would be interesting to research the corrosion resistance of these 304 SS guide wires. Additionally, SEM imaging of the fracture surfaces could possibly reveal additional information about the fracture mechanisms.

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