BME 301 (Biomedical Engineering Design)
Spring 2009

Project #27: Manipulatable Intracoronary Wire

FINAL REPORT

May 7, 2009

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Abstract

The goal of this design project is to develop and construct a steerable guidewire that can be externally operated to change the direction of the tip of the guidewire in vivo. This would aid in coronary angioplasty procedures which require the guidewire to traverse tortuous vasculature. In accordance with the client's requirements, the team considered three design alternatives, and ultimately chose to pursue the Memory Metal design. After rigorous testing with different materials, the team successfully constructed a prototype using a Nitinol wire attached to two stainless steel wires and enclosed in heat shrinkable tubing. In the future, the team seeks to improve on the current prototype and carry out further testing in order to enhance its functionality.

Problem Motivation

Heart disease is the leading cause of death both globally and in the United States (USDHHS)[5]. Fatal heart attacks are caused primarily by the obstruction of the coronary arteries which supply blood and oxygen to the heart muscle. As people age, plaque tends to build up in their arteries, occluding the vessels. In a procedure known as coronary angioplasty, physicians use coronary guidewires to deliver stents to occluded arteries around the heart in order to reopen the arteries and return the supply of blood to the heart muscle (Ashley)[1]. The guidewire is inserted in a vein at the groin or upper arm and maneuvered to the aorta and then into the coronary arteries which branch off near the base of the aorta. From there, the coronaries branch further and become smaller (UV)[3]. Occasionally, the blockage or the relative number of twists and turns in the artery (tortuousness) necessitate a bend in the wire. This bend allows the physician to better manipulate the guidewire in difficult areas, but the wire must be completely removed from the body to bend or unbend the wire manually. Therefore, a guidewire with a variably curved and controllable tip would be useful in coronary angioplasty.

Background

Guidewires have two basic sections, the shaft, and the tip. The majority of the wire is the shaft which consists of only a thin metal wire coated with a hydrophilic or hydrophobic polymer to facilitate the interaction of the blood with the wire and insure biocompatibility. At the tip, the core portion of the wire tapers from being the wire's entire diameter to a point where the core is only about 10-15% of the entire 0.014 inch diameter. The rest of the wire is comprised of a platinum coil at the outer edge of the wire and a polymer which adheres to the platinum coil and to the core and makes up the majority of the tip's volume. The tip exists to reduce the risk of patient injury by making it more flexible. Unfortunately, the added flexibility reduces the operator's ability to steer the wire.

Guidewires come in a variety of lengths (150 to 350 cm), but most of the stents are designed to be loaded onto 0.014 inch diameter guidewires (Voda)[6]. The core is usually made of stainless steel. Stiffness along the length of the wire is important to transmit forces from the operator to the wire's tip. The wire must be torqueable, meaning that when the operator rotates the wire around its axis outside the body, so too is that rotation translated along the wire and observable at the distal end of the wire. The length of the flexible tip varies because the more flexible the tip, the less maneuverable it is and the less support it provides the stent. In general, the last 3 to 7 cm comprises the wire's tip.

In order to increase the wire's steerability, a mechanism for inducing a curve in the wire via external operation would be useful.

Client's Requirements & Design Constraints

For the new steerable guidewire to be a practical alternative to those currently on the market, it must be similar in size and stiffness, but have added functionality. Therefore, the diameter of the wire must be 0.014 inches, and the core should still be made of some kind of metal. Additionally, the wire should be around the same price range as those currently on the market, about $100. In order to provide improved functionality over current devices, the wire should be operated completely externally, and the operator should be able to bend and straighten the wire's tip without removing or relocating the wire in any way. Since the arteries in which the wire operates are quite narrow, the radius of curvature with which the tip bends needs to be at most 1 mm. This is in contrast to previously implemented steerable designs (such as Steer-It by Cordis) which had radii of curvature between 3 mm and 7 mm or more. Finally, the mechanism used to steer the wire must be safe and biocompatible. For example, the mechanism used to induce bending of the wire should not be forceful enough to tear the vessel's walls.

Design Alternatives

SHEATH

For this design, the wire used would be bent into a 'J' shape. When the sheath surrounding the wire is pushed over the tip of the wire, the tip would straighten out. As the sheath is pulled back, the wire would then retain its hooked shape. Currently, this concept is utilized in larger arteries, however, it has not been developed with a diameter less than 350 μm (see Figure 1). This method could also be implemented in the reverse. The wire would be set as straight and the sheath would curve the wire when pushed over the tip. This concept proves to be very simple and has minimal potential for mechanical failure. With this said, the device would still prove difficult to use while deep in the arteries due to the fact both moving parts would be tricky to manipulate using only fluoroscopy as a guide. It would take numerous amounts of practice and trial and error for the surgeon to get a feel for manipulating the sheath. Finally, the radius of curvature is set on the device, reducing the amount of lenience the surgeon has to turn down the tortuous vessels.

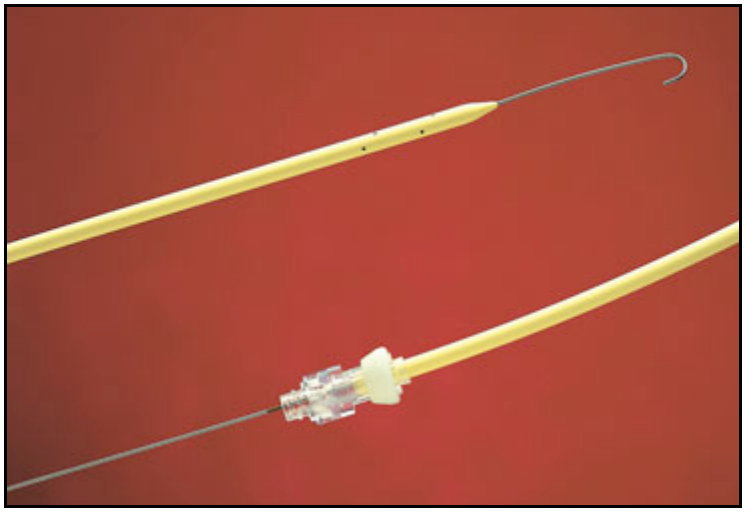


Figure 1: Depiction of current sheath method used in larger arteries. Obtained from https://lifeassistshop.life-assist.com/CatalogImages/FullSize/01_at2780a.jpg.

PNEUMATIC

In this design, the guidewire is normally curved, but air may be pumped into the wire, forcing it to straighten. By creating a hollow cavity at the tip of the wire and stressing the wire's tip to a curved state, the cavity functions as a pressure reservoir and allows the wire to straighten when the operator pumps air, or another fluid, into the chamber. This device takes advantage of existing guidewire designs. The outer portion of the tip remains unchanged (the outer coil, polymer and coating) while the core contains a hollow chamber running axial down the wire's center. Where the core tapers to a point in the wire's tip, the hollow interior bends with the bend of the wire. Since one side of the curved chamber is longer than the other, that half of the chamber's surface area is greater. Induced interior pressure, being constant throughout the fluid, imparts a greater force on the outer edge of the curved wire (Force = Pressure × Area). This causes the wire to straighten as the operator pumps air into it such that the force on each side of the chamber is equivalent (see Figure 2).

This design allows the operator substantial control and would cost about the same as a traditional guidewire, but would be very difficult to manufacture. Since the curvature of the wire is proportional to the pressure of the fluid inside the wire, which can be controlled by a machine, the wire's operator is at liberty to easily adjust the wire to a variety of positions. Also, since the basic elements of the wire are the same as in traditional guidewires, it is reasonable to assume they would cost about the same amount. Unfortunately, the guidewire's core is only about 50 μm wide at the tip. Producing a hollow wire this thin would be incredibly difficult. Additionally, since the wire is also very long and open only at one end, there are no manufacturing techniques available to adequately fabricate such a design.

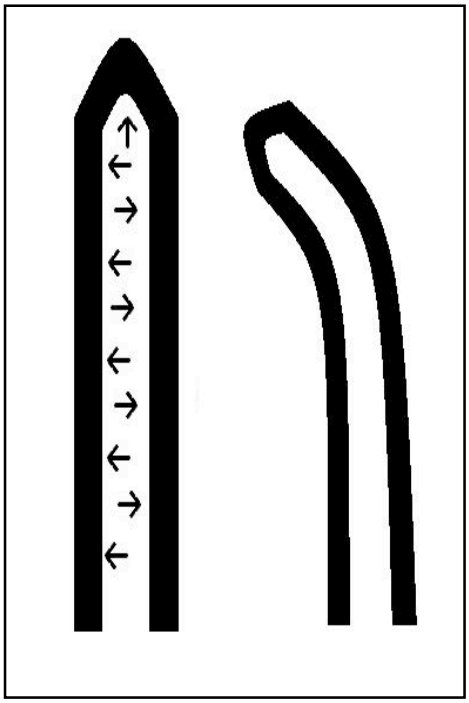


Figure 2: Pneumatic design. Normally, the wire is bent at the tip, but when the pressure [illegible]

MEMORY METAL

The third design utilizes a special type of alloy called nickel titanium (NiTi), or as it is more commonly known, Nitinol. The interesting property of this metal is that it has the ability to change shape when heated. Nitinol is defined by a crystalline structure which is capable of undergoing a change in shape from a perturbed conformation to a very rigid conformation. This process takes place once the alloy reaches a specific temperature, called the transformation temperature. By adjusting the relative amounts of nickel and titanium present in the material, the transformation temperature can be increased or decreased (UW)[4]. Running a current through the memory metal heats the metal and can cause it to reach this transformation temperature, thereby causing it to change shape.

This design utilizes the shape-changing properties of the memory metal. The tip of the guidewire will have a small portion of the Nitinol wire bound to stainless steel wire (see Figure 3). The Nitinol will either be adhered to the stainless steel via an

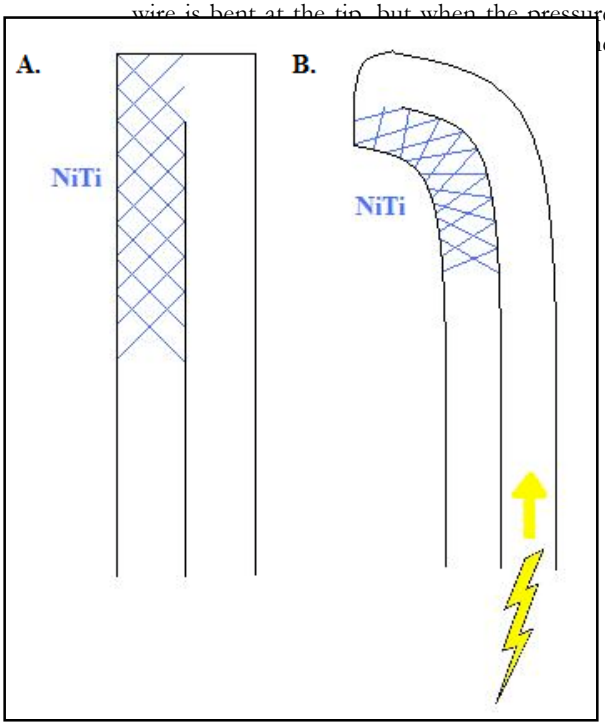


Figure 3: Memory Metal design. The white portion is stainless steel. Figure 3B is the same guidewire tip with a current passing through it. The Nitinol shortens and causes the guidewire to bend.

adhesive like epoxy or be connected via miniature clamps. Nitinol may not be welded as this permanently destroys its ability to change shape (UM)[2]. The bound Nitinol will be in its deformed state, which means that when a current runs through it, the Nitinol portion of the wire will shorten to its more rigid state and cause the tip of the guidewire to bend.

There are a couple of concerns that will have to be considered in the design process. For one, the transformation temperature of the Nitinol will have to be higher than the temperature of the environment in which it is entering: the human body. Bending of the wire wants to be controlled by the cardiologist performing the angioplasty. If the transformation temperature of the wire is lower than 37° C, the wire could bend once it enters the blood stream and would be useless as a maneuverable device. A second concern with this design is that an electric current will be in close contact with excitable cells of the heart. The wire will have to be well insulated so as not to induce any cellular damage or spontaneous contraction of the heart muscles.

Design Matrix

In order to evaluate the three design alternatives, a design matrix was created with several weighted criteria and the designs were ranked in each category (see Table 1).

The first criterion is ease of manufacturing. This deals with how easily the device can be fabricated and produced on a commercial scale. The Sheath design would be the easiest to manufacture, since it simply involves pre-forming a wire with a 'J'-shaped tip, then placing a sheath over it to straighten it out. The Memory Metal design is harder to manufacture, since it involves binding Nitinol wire to stainless steel wire, and a current source is also required. The Pneumatic design would be the most difficult to manufacture, since it is very difficult to construct a hollow wire that small (0.014 inch in diameter).

Another important factor in the design is the performance of the device. This measures how well the device carries out its intended purpose, which is to be able to be steered internally via external operation. The Memory Metal and Pneumatic designs are roughly equal in this aspect, since for both designs, the curvature of the tip of the wire can be altered to suit the operator's needs. This is simply done by changing the amount of current supplied or the amount of air pumped in. The Sheath design would yield a lower performance, since the curvature of the wire is preset. As a result, there might be some difficulties encountered when navigating certain branches in the coronary arteries.

Ease of use is a relatively less important component of the designs, but still is something that needs to be taken into consideration. It basically involves how easily operators can manipulate the device. Once again, the Memory Metal and Pneumatic designs are similar in this regard. Both designs are very easy and straightforward to use; the operator simply has to supply a current or pump air in to operate the devices. The Sheath design is harder to use because the operator has to manipulate the sheath while it is (at least partly) inside the body. There might be some complications regarding the ease with which this can be carried out.

Monetary cost is the last criterion used to decide among the design alternatives. The Sheath design is the cheapest to construct, since it only requires very few and simple materials. The Pneumatic design would be more expensive, since it requires a hollow wire and an air pumping system. The Memory Metal design would be the most expensive, since more materials are involved. Two different types of wires are needed (Nitinol and stainless steel), in addition to a mechanism to bind the wires together, as well as a source of electricity, all of which add to the expenses for construction.

CRITERIA	WEIGHT	SHEATH	PNEUMATIC	MEMORY METAL
Ease of Manufacturing	35	30	20	25
Performance	35	25	30	30
Ease of Use	20	16	20	20
Monetary Cost	10	9	8	7
TOTAL	**100**	**80**	**78**	**82**

Table 1: Design Matrix

Proposed Solution

When the numbers of the design matrix were added together, the Memory Metal design came out on top. This is the design that will be pursued for the rest of the semester. The manufacturing process for this design is definitely feasible, and the design would also be functional and fulfill the requirement of being able to be steered internally via external operation. Furthermore, a separate current source is used to deflect the guidewire tip, and this current source can easily be detached after use. This would allow other apparatus such as stents to be loaded onto the guidewire.

The Memory Metal design also takes into account human factors and ergonomics. By constructing the device based on this design, it would be safe due to its biocompatibility. The device would also be easy and straightforward to use. Its performance would be better than the current devices in use since it incorporates greater functionality. The proposed design also fulfils the Principles of Universal Design. The design is simple and intuitive, and can accommodate different operators as long as they are trained in guidewire insertion. The design also seeks to minimize potential dangers and hazards by incorporating insulation and biocompatibility. Finally, the design does not require any more effort than is currently required for guidewire insertion procedures since no additional specialized skills or knowledge are required for operation.

In sum, the Memory Metal design seems to be the most feasible and functional design out of the three alternatives.

Final Design

As the Memory Metal design scored the highest because of its potential to perform well according to the design specifications, it was deemed the best design to construct. The final design is comprised of several different components which are illustrated in Figure 4. The most important component of the design which ultimately allowed the tip of the guidewire to bend is the 2.5 cm long cut of 0.020 gauge Nitinol wire with a shepherd's staff shape. This unique shape of wire was prepared by using a jig such as the one shown in Figure 5. The wire was "trained" into this shape by first tightly winding the wire around the pegs. It was then placed in an oven and baked at 520° C for 20 min and allowed to cool for 2 hours. Once cooled, the wire was removed from the jig and deformed by pulling on the two ends. When heated to a

temperature above the transformation temperature of the wire, the Nitinol is then capable of reforming back into the "trained" shape; in the case with Figure 5 that shape spells out the word "ICE". For the guidewire design, a 2.5 cm portion of Nitinol wire "trained" in the shape of a shepherd's staff was cut. This wire was then deformed so that its shape was straight in its martensite phase. The tip of this straightened Nitinol wire was then soldered to the tips of two insulated stainless steel wires, one of which had the insulation removed from its tip to allow it to conduct electricity. The other end of the Nitinol wire was soldered to the same two stainless steel wires 2.5 cm from the tips. A portion of the stainless steel wire which had not previously been stripped of insulation was then stripped of its insulation at that area where the solder connected it to the Nitinol. The stripping of insulation was necessary so that the current could move from one stainless steel wire to the other via the Nitinol wire (see Figure 6).

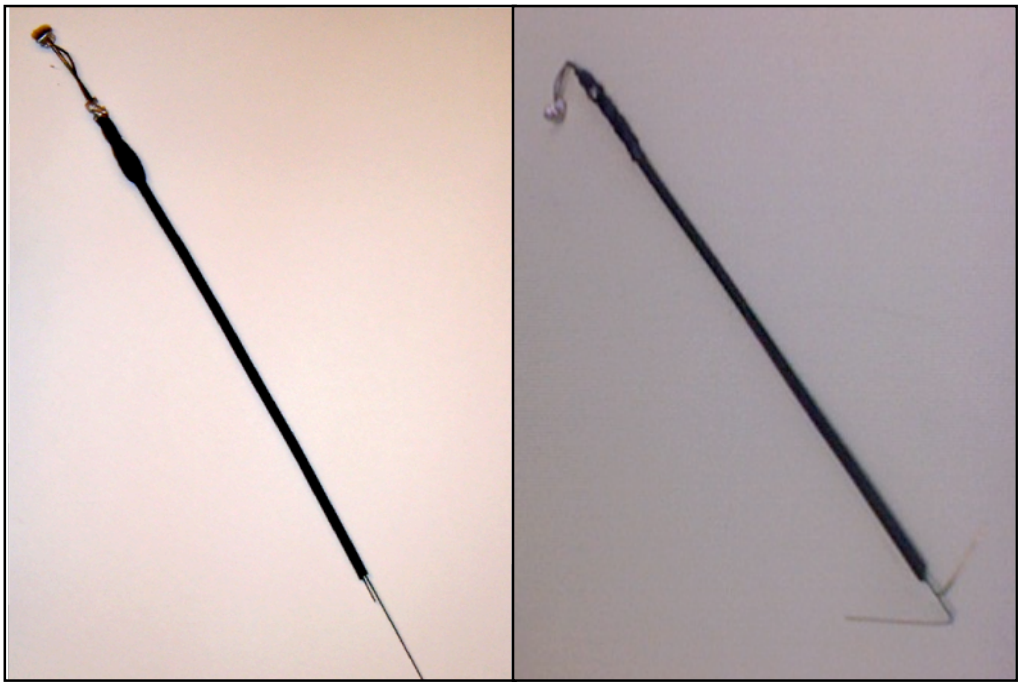
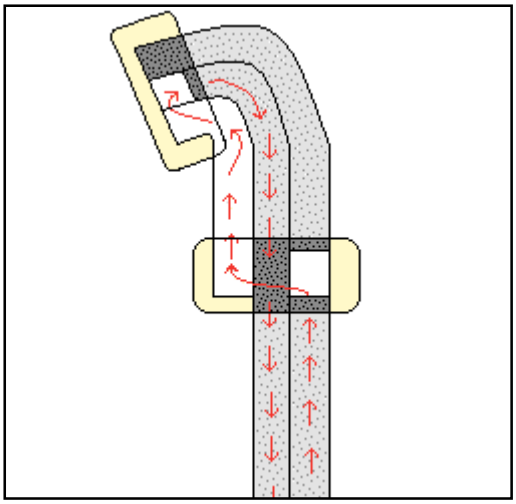


Figure 4: Final design. One Nitinol wire and two stainless steel wires are soldered together at two points. The wires are enclosed in heat shrinkable tubing for insulation. When no current is supplied (left), the tip is straight. When current is supplied (right), the tip curves.



The design ultimately works because, in the absence of a current, the tip of the guidewire is held straight by the two stainless steel wires. When a current is applied, the transformation temperature is surpassed and the Nitinol wire bends into its "trained", shepherd's staff shape, bending the two stainless steel wires with it. When the current is removed the Nitinol cools and the two stainless steel wires deform the Nitinol back into a straight configuration. When a cardiologist performing the angioplasty encounters a tortuous region, he/she can run current through the guidewire, inducing the bend at the tip, navigate the region, then remove the current to straighten out the tip, and continue on with the operation.

Figure 5: Nitinol jig. Stainless steel pegs protrude from a stainless steel platform. Nitinol is tightly wrapped around the pegs and "trained" to this shape while in its austenite phase in the oven. Obtained from http://mrsec.wisc.edu/Edetc/background/memmetal/index.html

The final design is safe for the patient. Because cardiomyocytes are excitable cells, running a current near them must be done with utmost care so as not to induce any arrhythmic heart contractions. Therefore, all three wires in the design are encased within heat shrinkable polymer tubing. As a result, any current running through the wires will be insulated from the outside environment. Any additional heat produced by the guidewire will also be quickly dissipated by the blood flowing through the vessels in the body.

Figure 6: Schematic of guidewire tip. The red arrows in the figure denote the direction that the current flows through the guidewire. The two gray wires represent the stainless steel wires which each have a small portion of insulation stripped from them (as seen in white). The white wire on the left is the Nitinol wire in its austenite phase. The tan boxes represent the areas of solder which conducts the current from wire to wire.

Testing

After deciding on using Nitinol as the driving force behind the bending mechanism but before coming up with a final design, testing was carried out to evaluate different methods of implementing the final design. Various methods of binding the wires together had been suggested, including soldering, clamping, and using epoxy. There were other options involved as well, such as whether to use two or three stainless steel wires, how to insulate the wires, and how much current or voltage was necessary to cause the wires to bend. The team examined all of these features and implemented a final design using only solder and two stainless steel wires but noting other realistic implementations as well.

In order to determine approximately how much current would be required, the team tested a piece of Nitinol wire with known length and diameter in the lab to determine its resistance. From there, the resistivity was calculated using $R = \rho \frac{l}{A}$. Knowing this, the team then created some Nitinol wire with preset bends to be used in the tip of the prototype. This was done in a lab in the UW-Madison Chemistry department using a jig with pegs around which the wire was stretched. Small portions of this wire were cut to function as the curving tip of the prototype. The stainless wires were to serve as support wires for the Nitinol. The team varied the number of stainless steel wires to determine the number of wires that would provide the best support (i.e., be able to bend with the Nitinol, yet be strong enough to pull the Nitinol back into a straight configuration when the current is removed), and found that using two stainless steel wires was the most effective.

Several methods were tried to insulate and connect the wires together. A spray on liquid insulating tape was first tested, but it was cumbersome and was not strong enough to hold the wires together when current was applied. Heat shrinkable polymer tubing was also tried but was too elastic to hold the wires together at the tip. Epoxy was difficult to handle, but it successfully held the wires together even after multiple cycles of bending and straightening the tip. Soldering the distal ends of the leads together was a necessary point of attachment to allow the current to pass through the functional Nitinol wire, and it also helped to prevent the wires from detaching from each other. In the final implementation, solder was also used to hold the wires together at about 1.5 cm from the tip to provide more stability. The wires were then

encased within heat shrinkable tubing to provide insulation and aesthetic appeal. From these measures, the team concluded that epoxy and soldering were good methods for adhering the wires together and that the heat shrinkable tubing, epoxy, and liquid insulating tape were effective methods of insulation.

Finally, the team tested the amount of voltage required to cause the Nitinol to bend. The number of 1.5 V batteries was varied to determine the optimum number of batteries required. The team concluded that the prototype worked best with four such batteries connected in series, giving a total voltage of 6 V.

Future Work

There are several aspects of the prototype that can still be improved on in the future. First, a better method for joining the tips of the wires together must be determined. Currently, the tips of the wires are soldered together. This method of joining is cumbersome, bulky, and not very durable. Some possible alternatives that can be looked into include brazing and welding. Second, the team must find a Nitinol wire that is more malleable in its cooled (martensite) state. This will allow the wire to be manipulated more easily so that less force has to be applied to straighten the tip. This in turn will make it easier to bind the wires together. To improve upon the design further, more guidewires should be tested to find one with the optimal flexibility and strength for attachment to the Nitinol wire. Ideally, the guidewire should have enough give to bend with the Nitinol wire when a current is supplied, as well as be able to pull the Nitinol back into a straight configuration once the current is stopped. Further testing can also be carried out to quantify and optimize the amount of current needed to activate the prototype. In addition, the durability of the prototype over several applications of current should also be tested to determine its limits of failure. Finally, the overall product needs to be scaled down to the size of current guidewires, which have a maximum diameter of 0.36 mm at the tip.

Conclusion

The goal of this project is to develop a steerable guidewire that can be externally controlled to change the direction of the guidewire tip in vivo, which will be used for coronary angioplasty procedures. After considering several designs including the Sheath design and Pneumatic design, the Memory Metal design was determined to be the best and was chosen as the final design. Per the client's requirements, the team successfully built a prototype that was able to bend at the tip when a current was supplied and return to a straight configuration when the current was removed. Testing was carried out to determine the most suitable materials to use and the best method of construction. In the future, the prototype needs to be scaled down and further testing must be carried out to optimize its functionality.

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APPENDIX I: PRODUCT DESIGN SPECIFICATIONS

PROJECT TITLE:

Manipulatable Intracoronary Wire
(Project Number: 27 / Project Code: intracoronary_wire)

INITIAL PROBLEM STATEMENT:

Guide wires are intended to facilitate the placement of interventional percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA) catheters, and other interventional devices including: intravascular stents, intravascular ultrasound devices and intravascular drug eluting stents. The purpose of the project would be to construct an intracoronary wire whose tip is adjustable and allows steerablity though tortuous vasculature.

REVISED PROBLEM STATEMENT:

Currently it is difficult to maneuver around tortuous vessels and largely occlusive clots during percutaneous transluminal coronary angioplasty (PTCA). Presently guidewires can be reshaped while outside the body but must be removed each time. The client requests a device to improve guidewire steerability by allowing for conformational changes in the guidewire's tip in vivo.

CLIENT REQUIREMENTS:

- Biocompatible (medically safe to use in patient)
- Percutaneous
- Steerable
- Trackable
- Torqueable

DESIGN REQUIREMENTS:

1. Physical & Operational Characteristics

a. **Performance Requirements:** Design must be able to be easily manipulated through tortuous vasculature.

b. **Safety:** Reduce risk of puncturing vessel wall in vivo. Will not elicit immune response.

c. **Accuracy & Reliability:** Durable enough to not break in vivo.

d. **Life in Service:** The device will only be used once in actual operation, thus the maximum usage time will be a few hours.

e. **Shelf Life:** Similar devices typically have a shelf life around one year.

f. **Operating Environment:** Tortuous vessels in the human body, specifically in the heart.

g. **Ergonomics:** Easy manipulated by a surgeon and mechanism for bending must be self-explanatory.

h. **Size:** Maximum outer radius of 250 to 450 μm. Length can range from 140 to 300 cm.

i. **Weight:** Similar to current guidewire standards.

j. **Materials:** Nitinol, two stainless steel guidewires, heat shrinkable polymer tubing, and current source.

k. **Aesthetics, Appearance & Finish:** Not applicable.

2. Production Characteristics

a. **Quantity:** Only one working prototype; could be mass produced based on demand and performance.

b. **Target Product Cost:** Around $100 which is similar to current products.

3. Miscellaneous

a. **Standards & Specifications:** FDA approval needed before actual implementation.

b. **Customers:** The client and potentially other physicians involved in coronary angioplasty.

c. **Patient-Related Concerns:** Must not cause interference when inserted into the vessels. Wire also cannot reach too high of a temperature so as to cause the blood to reach dangerous temperatures.

d. **Competition:** Currently, our only competition is non-steerable wires that are bent into place by a scalpel or a surgeon's fingers.

APPENDIX II: PROJECT EXPENDITURE

SOURCE	ITEM	QUANTITY	TOTAL COST (USD)
The Home Depot	Battery Holder with Leads Epoxy Liquid Insulating Tape AA Batteries (20-pack)	1 1 1 1	38.62
California Wire Company	0.0014" Nitinol Wire	1	44.18
BuyHeatShrink.com	Heat Shrink Tubing	2	65.89
		TOTAL:	**148.69**