BME 301 (Biomedical Engineering Design)
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Project #27: Manipulatable Intracoronary Wire

MID-SEMESTER REPORT

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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. In the future, the team seeks to address the potential problems identified and to continue to work on and develop the proposed solution.

Problem Motivation

Heart disease is the leading cause of death both globally and in the United States (USDHHS)[3]. 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)[4]. 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)[4]. The core is usually made of stainless steal. 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 comprise 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.

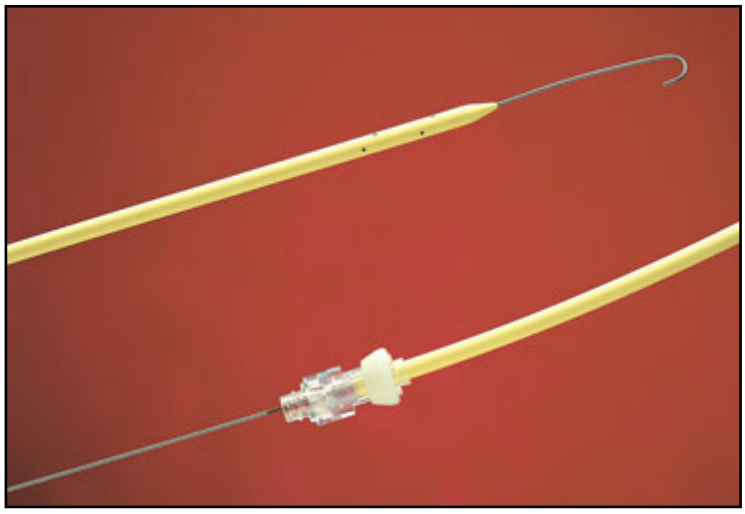

Figure 1: Depiction of current sheath method used in larger arteries. Obtained from https://lifeassistshop.life-assist.com/CatalogImages/FullSize/01_at2780a.jpg.

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.

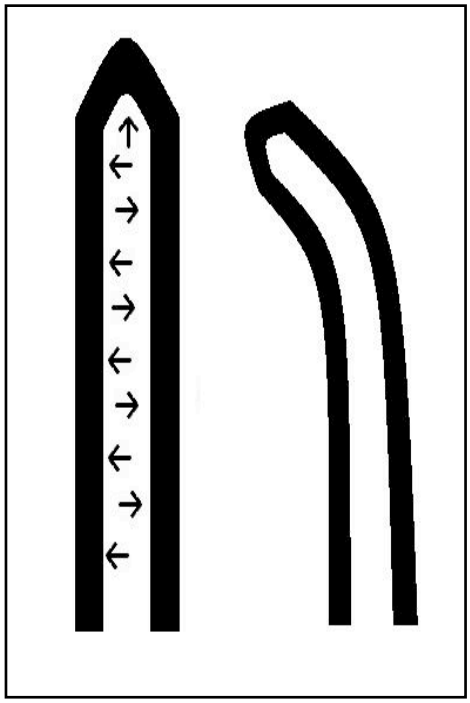

Figure 2: Pneumatic design. Normally, the wire is bent at the tip, but when the pressure of the air in the internal cavity is increased, the wire straightens.

MEMORY METAL

The third design utilizes a special type of alloy called nickel titanium (NiTi), or as it 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. 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 adhesive like epoxy or be connected via miniature clamps. Nitinol may not be welded as this permanently destroys its ability to change shape. The bound Nitinol will be in its deformed state, which means that when a current runs through it, the Nitinol

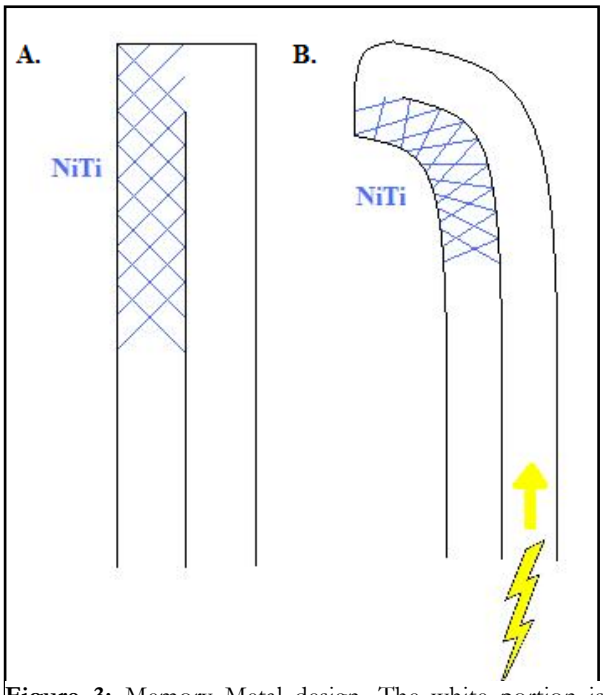

Figure 3: Memory Metal design. The white portion is stainless steel. Figure 3B is the same guidewire tip with a current passing through it. The Nitinol shortens and causes the guidewire to bend.

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 (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 preforming 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 fulfil 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.

Potential Difficulties

There are a few potential problems with the Memory Metal design. One problem lies with the mechanism to bind the Nitinol wire to the stainless steel wire. Currently, the team is considering using epoxy or some form of mini clamping system, although the effectiveness and feasibility of each option has yet to be evaluated. Should neither of these methods work, a different method will have to be developed. Another potential issue is the change of temperature occurring while the device is inside the patient's vasculature. Since the body is not suited for extreme temperature changes, the device will have to be well insulated to prevent any appreciable overall temperature change when the current is supplied.

Future Work

For the rest of the semester, the team must first determine the most suitable method for binding the Nitinol wire to stainless steel wire. Welding has already been ruled out, since this ruins Nitinol's shape memory properties. Epoxy and a mini clamping system have emerged as viable alternatives, and the team must further evaluate them to determine if they are appropriate. The next step would be to obtain Nitinol wire with the desired phase transformation temperature. Since Nitinol changes shape at this temperature, the phase transformation temperature of the particular Nitinol wire to be used should be above that of body temperature (37°C) to prevent it from changing its shape immediately upon insertion into the body. Once the appropriate materials have been obtained, a scaled-up version of the device will be constructed. The team will not attempt to construct a life-size prototype because that is a very difficult task given the limited resources (both ability and monetary). Finally, the team will carry out testing on the completed prototype.

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 will be pursued for the rest of the semester. To begin, the most suitable binding method will be determined and the appropriate materials will be obtained. Then, a largescale prototype will be built, tested, and modified as needed.

References

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APPENDIX: 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 steeriblity 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. As of this time, we do not have provided standard.

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- 450 μm. Length can range from 140 to 300cm.

i. **Weight:** Not Applicable.

j. **Materials:** Nitinol, stainless steel, and insulating material (exact material not yet determined).

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:** Unknown at this time. Similar products tend to cost around $100.

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.

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