Manipulatable Intracoronary Wire

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Abstract

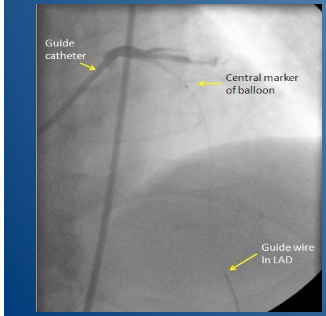
The goal of this design project is to develop and construct a steerable guidewire that can be externally operated to change the direction of the tip of the guidewire in vivo. This would aid in coronary angioplasty procedures which require the guidewire to traverse tortuous vasculature. In accordance with the client's requirements, the team considered three design alternatives, and ultimately chose to pursue the Memory Metal design. Using a Nitinol wire attached to two stainless steel wires and enclosed in a heat shrinkable sheath, we successfully constructed a prototype to meet our client's standards. In the future, the team seeks to address the potential problems identified and to continue to work on and develop the proposed solution.

Problem Statement

Motivation/Background

Heart disease is the leading cause of death both globally and in the United States. Coronary artery disease, a type of heart disease, is caused by the build-up of plaque, or thrombosis, within the walls of the arteries that supply the myocardium with blood. Myocardial infarction is a condition caused by coronary heart disease.

The current procedure to combat coronary artery thrombosis is called percutaneous transluminal coronary angioplasty. During this procedure, a physician delivers a stent via a coronary guidewire to the blocked artery. The guidewire is inserted into the vein at the groin or upper arm and maneuvered into the aorta and coronary arteries. These tiny arteries are often tortuous, spiraling and branching along the route leading to the stenosis. In order to navigate these vessels, it is often necessary to put a bend at the tip of the wire so that the physician can better manipulate the guidewire in difficult areas. However, there would be an increased level of in vivo steerablitiy if there is a mechanism for inducing a curve at the tip of the guidewire via external manipulation by the physician.



http://www.cardiophile.com/is-surgery-the-only-option-for-blocks-in-coronary-arteries

Picture of a coronary angioplasty surgery showing a guidewire and balloon stent.

Client Requirements

- Max. diameter < 0.36 mm
- Max. radius of curvature with which the tip bends < 1 mm
- The guidewire should cost no more than $100
- Device must be operated completely externally
- Operator should be able to bend and straighten the wire's tip without removing or relocating the wire in any way

Final Design

Three leads:

Two straight, stainless steel leads
One martensite phase curved Nitinol lead

Insulation of leads:

Stainless steel leads are insulated
Shrinkable polymer wraps around all leads
Leads are soldered together at tip

Operation:

Applied current causes Nitinol to bend
Without current, stainless steel straightens Nitinol
Current in Nitinol lead controls curvature

Safety:

Current insulated from body
Heat generated dissipates quickly in blood

Miscellaneous:

Comparable shelf life to current guidewires
Single use prevents subsequent failure of device

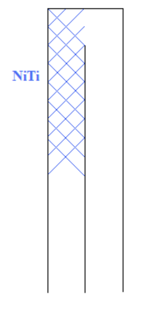


Diagram of the device in a straight position, no current is being applied.

Picture of the prototype tested.

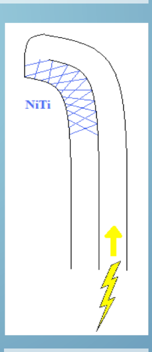


Diagram of the curved device as current is being applied. Varied current changes curvature.

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References

1. Ashley, Euan and Nibauer, Josef. (2004) "Coronary Artery Disease." Remedica: Cardiology Explained. http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=cardio&part=A196
2. University of Minnesota Medical Devices Center. (2009) "Nitinol Facts" http://www.mdc.umn.edu/nitinol_facts.pdf
3. US Dept. Health and Human Services. "Death – Leading Causes". National Center for Health Statistics. Sept. 2008. http://www.cdc.gov/nchs/FASTATS/lcod.htm
4. Voda, Jan. (1987) Angled Tip of the Steerable Guidewire and Its Usefulness in Percutaneous Transluminal Coronary Angioplasty. *Catheterization and Cardiovascular Diagnosis 13:204-210.*

Testing

The final design was determined by testing several different methods of wire attachment, wire types, and amount of current needed to bend prototype successfully. We performed the following testing:

- Tested various guidewires currently used in patients to find best support wire for the Nitinol wire so that our prototype has the ability to both bend and return to the starting position
- An assortment of insulating methods for the wires were tested including: insulating paint, heat shrinkable wrap, various tapes, and epoxy
- In order to determine the ideal amount of current needed for full functionality, we tested various amounts of voltage by varying the battery sources
- After insulating the wires, a myriad of connection methods were tried including soldering, taping, gluing (epoxy) and shrink-wrapping to find the most secure method

Future Work

- Determine if there is a better way to join the tips of the wires together (e.g., brazing, welding)
- Obtain Nitinol wire that is more malleable in the cooled state so that it is easier to manipulate
- Find a support wire that has optimal flexibility and strength
- Quantify the amount of current needed to produce shape change in Nitinol (or the temperature at which this occurs)
- Carry out more testing to see if device can undergo repeated applications of current (i.e., determine the failure limits of the device)
- Scale down construction to the size of normal guidewires (0.36 mm total diameter at the tip)

Cost Analysis

2 × Heat Shrink Tubing	$65.89
1 × Epoxy	$4.99
1 × Liquid Insulating Tape	$6.95
1 × Battery Holder with Leads	$10.10
1 × 0.0014" Nitinol Wire	$44.18
Total	**$132.11**