Variable Stiffness Guide Wire for Catheterization Procedure

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Abstract:

This document investigates a number of options for the design and implementation of a variable stiffness guide wire. The device will be used to direct a catheter into the cerebral branch of the aorta to inject contrast for CT imaging. There are currently variable stiffness guide wires on the market, but they do not hold their desired shape under the client specified circumstances. The main focus of the new design is create a guide wire that is versatile enough to be able to maneuver to the aorta, then to stiffen so that a catheter can be passed over the guide wire to the desired location and finally return to a flexible state for retraction.

Design Problem:

The goal of this project is to create a guide wire that will guide a catheter into the cerebral branch of the aorta. The client specified that the wire must be flexible enough to move through the catheter and a couple centimeters into the desired branch without altering the shape of the catheter. Then, the wire should stiffen and hold its shape and guide the catheter into the desired branch. After the catheter has moved over the wire, the wire should return to its original flexibility so it can be retracted from the body.

Background Information:

A particular part of the cerebrum needs to be accessed to inject contrast for CT procedures. This particular catheterization process starts by entering an artery in the groin. A guide wire is snaked up through the body and can be tracked by fluoroscopy methods. When the guide wire has reached the desired location below the aorta, a catheter is slipped over the guide wire and pushed past the end of the guide wire and up to the aorta. Then the first guide wire is retracted leaving the catheter in the aorta. From this point, the catheter cannot find its way into the correct branch on its own. A second guide wire is needed to guide the catheter up the correct branch. If this second wire is too stiff it will deform the catheter and will not hit the correct branch. If the wire is too flexible as the catheter is pushed over the guide wire, the catheter will move the wire and the target will not be reached. So, the goal of this project is to create a guide wire that enables the catheter to slide over the wire and into the target branch.

The wire should have a diameter of .038 inches with an overall length of 150cm. The first 15cm from the tip of the wire should be of variable stiffness, and the rest should act like a standard guide wire. The shelf life should be about 1 year with a maximum cost of about $50 per unit. The wire will be coated with the standard hydrophilic coating used with other guide wires. The biggest safety concern is that the wire will not break. If the wire were to break, broken parts will be sent directly to the brain, which could potentially kill the patient.

There are no products on the market now that meet these specifications, so there is no literature available on this topic. However Cook, Inc. and Boston Scientific (as well as others) make guide wires, so information is available on their websites. MedicalDesignOnline.com is another source of information that provided information about guide wires.

Hydraulics: The fire hose method

A spiral of small tubing makes up the internal portion of the guide wire. The guide is soft and flexible in its' initial configuration with empty tubing. By filling the tubing with saline (for safety purposes), the wall of the tubing will exert an outward force on the casing of the guide wire, which would cause the guide wire itself to become stiff. The catheter could then be passed over the guide wire and follow it down the correct branch of the artery.

Mechanical: The alternating method

The idea here is to use tiny alternating beads made of a material that has a relatively high coefficient of friction. During the initial state, the beads are separated resulting in a soft phase of the guide wire. Then by exerting some outside force on the beads, by simply pushing on a plunger that will push the beads into each other, they will come into contact and remain fixed due to the high coefficient of friction. It would then be due to the coefficient of friction that the guide wire would remain stiff and allow the catheter to pass over it without the guide wire failing.

Shape Memory Alloy:

This alternative utilizes a new kind of material, the shape memory alloy. The shape memory alloy can be trained to a certain initial configuration or shape. The alloy can then be deformed after cooling. As the internals of the guide wire, we would train the guide wire to the shape of the end of the catheter that is needed to negotiate branching in the arteries. The guide wire would be cooled so that it would be maneuverable as a normal guide wire. When the guide wire reached branches in the arteries, it could then be heated to make it snap back to its trained shape. The resulting shape would be more than sound to withstand the forces of the catheter being pushed over it. The catheter would follow the guide wire as desired, rather than straightening it out as it was passed over.

Dr. Haugton mentioned that one such alloy is Nitinol. This is a compound of Nickel and Titanium. There are many different grades of this metal that change at different temperatures. We have found that there is a certain grade that is in its flexible state below body temperature (37° C) then changes phase to a rigid state at body temperature. We can use this principle to change the flexibility as we change the temperature of the wire.

Proposed Solution:

~Design~	Cost	Ergonomics	Safety	Feasability
Hydraulics	+	+	+	?
Mechanical	+	+	+	?
Shape Memory Alloy	0	?	+	+

After analyzing all of the different factors that go into the different design alternatives, we decided to propose the shape memory alloy design as our favored design. Although the other designs seemed to have better cost and ergonomic values, in the end we were uncertain as to whether they could actually produce the result that we were looking for. On the other hand, the shape memory alloy design is experimentally proven to return to a trained shape after a change in temperature. Since it is a metal alloy, we are confident that it will be stiff enough to resist straightening out due to the catheter following over it.

Potential problems:

There are two main potential problems that a shape memory alloy will present. First of all, the phase change will require a change in temperature. If this changing of temperatures affects the temperature of the blood, the patient will either shiver or sweat. Neither of these situations are acceptable. The second problem is that the bend must be trained to be in a certain point on the wire before it enters the body. This means that the wire must be very close to the correct point in the blood vessel before changing to the stiff phase. If a stiff bend forms in the wrong position it could damage the blood vessel or just not be effective.

Appendix A:

REFERNCES:

Cardima. http://www.cardima.com/

Guidant Consumer Home Page. http://www.guidant.com/products/optima.shtml

Haughton, Dr. Victor, University of Wisconsin: Department of Radiology, (Madison: 25 September 2001), In-person interview.

Lake Region Manufacturing. http://www.lakergn.com/

Lakes, Dr. Rod, University of Wisconsin: Department of Biomedical Engineering, (Madison: 4 October 2001), In-person interview.

Star Guide. http://www.starguide.com/

Vadnais Technologies Corporation. http://www.vadtec.com/capabilities/guidewire_catheter_coils/default.htm

Appendix B:

Variable Stiffness Guidewire - PDS

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Function: A catheter guidewire of variable stiffness to be used in a cerebral catheterization procedure and in situations where the conventional guidewires fail. The wire must be flexible enough to reach the correct point in the vessel, but stiff enough to provide stability for the catheter to follow into the vessel.

Client Requirements:

- 10-20 cm of variable stiffness between flexible tip and stiff remaining wire.
- Wire diameter of 0.97 mm.
- Guide around turns angles of 100-140° in vessels.

Design requirements:

1. **Physical and Operational Characteristics**
   a. *Performance requirements*:
      - Single-use.
      - Change rigidity from flexible to stiff and back to flexible.
      - Conform to existing guide wire standards.

   b. *Safety*:
      - Non-hazardous biomaterials.
      - Cannot change the environment of its surroundings (e.g. temperature, size).

   c. *Accuracy and Reliability*:
      - Must maneuver through desired vessel turns effectively.
      - Withstand internal conditions of human body.

   d. *Life in Service*:
      - Withstand one catheterization.

   e. *Shelf Life*:
      - 1-year shelf life.

   f. *Operating Environment*:
      - Blood vessels of human body.

g. *Ergonomics*:
- 0.97 mm in diameter
- Easy for a physician to use.

h. *Size*:
- Total length of 150 cm.
- Tip length of 3 cm.
- 10-20 cm of variable stiffness.

i. *Weight*:
- Cannot alter normal functions of any body part.

j. *Materials*:
- Stainless steel or similar material for inner portion of wire.
- Hypoallergenic, hydrophilic coating.

k. *Aesthetics, Appearance, and Finish*:
- Similar to existing guidewires.

2. Production Characteristics

a. *Quantity*:
- One.

b. *Target Product Cost*:
- Projected cost of $40-50 at the most.

3. Miscellaneous

a. *Standards and Specifications*:
- Must be FDA approved.

b. *Customer*:

c. *Patient-related concerns*:

d. *Competition*:
- One such guide wire currently undergoing research at Cook, Inc.