Variable Stiffness Guidewire

Kristi Hinner and Erik Birkeneder

BME 200/300

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Client: Dr. Victor Haughton

Advisor: Kreg Gruben

Problem Statement:

To design a guide wire of variable stiffness to be used in a catheterization procedure where the conventional guide wires fail. The wire must be of correct stiffness in order to reach the correct point in the vessel, but also provide enough force for the catheter to follow into the vessel.

Abstract

An important part of catheterization is the guidewire that is first inserted and then used to aid in the placement of the catheter. However, a guidewire that is too stiff will not allow for maneuverability around vessel turns, and one that is too limp will cause difficulty when catheter is followed over it and into the vessel. Therefore, a guidewire which is able to vary in stiffness depending on its point in the procedure would be ideal. After comparing several different possible solutions, we decided on a phase-varying material to be placed inside the wire which would allow for heating of the material and varying degrees of stiffness.

Introduction

Catheterization is required for numerous surgical procedures as well as for monitoring such things as invasive blood pressure and cardiac output following surgery or during general patient monitoring. The patient is usually awake or under a mild sedation. Local anaesthetic is applied to the groins, elbow or the neck. The catheters are inserted through sheaths into the arteries and veins of the body (2). The physician uses a needle to enter the blood vessel. A guide wire is passed through the needle and the needle is removed. Next, a small plastic tube (catheter) is threaded over the wire and guided through the vessel and into the chambers of the heart (1). Many of the procedures requiring catheterization are heart surgeries, such as angioplasty or valve replacement. However, catheters are also used cerebrally. Cerebral catheterization and angiography is a discipline that involves the invasive study of the vessels that constitute the blood supply and drainage of the nervous system. In general, the techniques involve the percutaneous introduction of catheters into the arterial or venous systems, most commonly via the femoral approach, with selective or supraselective catheterization of specific neurovascular structures under fluoroscopic guidance. This is followed by the injection of a contrast agent into the vessels concurrently with the acquisition of radiographic images (3). This procedure, being invasive and requiring great skill on the part of the physician, is one which has seen many improvements over the past 20 years. One of the biggest difficulties is the maneuverability of the catheter around the blood vessels, especially those in the heart. The guidewire is very helpful, as it is much easier to guide than the catheter alone. It does, however, have several drawbacks. When a turn in a vessel is encountered, a more flexible wire is easiest to maneuver. However, when the catheter needs to pass over the wire, it would be most helpful if it were stiffer. Most guidewires now incorporate a flexible tip and decreasing flexibility further down the wire. Ideally, though, would be a wire that could vary in its degrees of flexibility and be adjusted as needed by the physician during insertion.

Alternative Solutions

Each of our alternative solutions follow our client's guidelines of a wire which has a flexible tip, 10-20 cm of a method of variable stiffness, and a stiff remaining portion of wire. The tip and stiff sections will be identical to that of existing guidewires. Our designs are for the 10-20 cm of variable stiffness only.

1. *Air-filled tubing*

   This design solution incorporates a section of flexible plastic tubing between the flexible tip and stiff portion of the wire. This section of the wire would be limp without extra pressure (no air) on the inside. The air compressor would be used to pump air into the tubing portion of the wire and increase the air pressure, thereby increasing the stiffness of the limp section of the guidewire.

2. *Hydraulic*

   The concept for this idea is similar to the air-filled guidewire except hydraulic pressure is utilized instead of air. In this design the pressure would be varied with a mechanically manipulated piston attached to the end of the guidewire. The identical section of limp guidewire would also be implemented. When water is forced into the tubing, this section becomes stiffer.

3. *Bead idea*

   This design would use an exoskeleton of wires that would have beads strung along them. These beads would fit together snuggly when the wires are pulled taut, creating a stiffer section of the wire. An external handle from the end of the guidewire would be used to pull the stringing wires.

4. *Charged magnets*

   This concept would incorporate the same basic idea of the beads, except every other bead would be an electromagnet, and the others would be metal. When a small voltage would be applied to the inner wire running to the electromagnets, the magnets would attract to each other, stiffening the wire.

Chosen Design

This design, Figure (1), incorporates a thermal regulation system that could change the phase of a material inside the guidewire. This material, located inside the variable portion of the wire, would be solid at room temperature and have a relatively low melting point. A heating coil would be located inside this material and the entire section would be insulated. Upon heating, material will melt and the wire will become more flexible.

Varying temperatures will allow for varying degrees of flexibility. The material we chose was Paraffin, which has a melting point of 44-60°C (4).

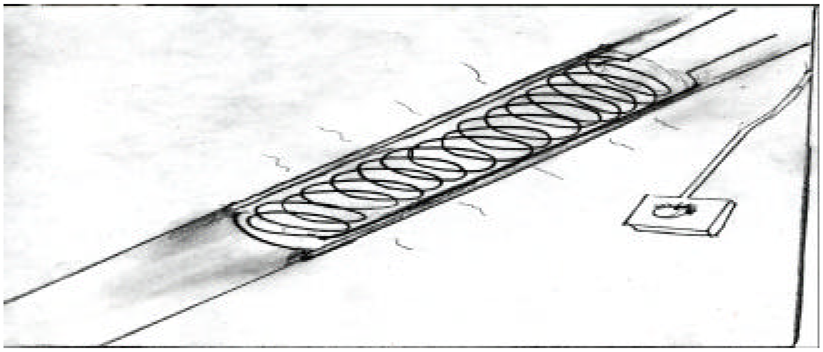

Figure 1 - Thermally-Varying Material Design.

Evaluation of Designs

A design matrix can be found in Figure (2) below. One of the major advantages of the chosen design is that no foreign substances need to be introduced into the body. Both the air-filled tubing and hydraulic methods would require that something be forced into the tubing, and therefore the body. This poses many risks, and was the main reason we did not choose either of those designs. Both of these alternatives would also cause additional pressure to be put on the tubing, which may cause a variety of difficulties, such as expansion within the vessel and possibility of rupturing of this portion of the wire. Another advantage to the temperature variation on a material idea is the concept of varying degrees of stiffness. Neither the bead nor electromagnetic methods allow for any variation: either the wire is limp or it is stiff. Although this would be a bit more helpful than existing guidewires, is does not fully serve the needs of variable stiffness. A final strength of our chosen design is that paraffin, a wax, has a relatively low melting point. This would require that the heating coil be heated to only a low power.

One of the weaknesses of our design is the increase of temperarure. Heating the material may cause an increase the temperature of the blood, which could disturb body conditions (especially if a patient is in surgery and thermally compromised already). However, if the wire is over-insulated, it will not be able to cool back down and return to its solid state. Although it does have the ability of numerous degrees of stiffness, gauging these may be very difficult and would require a great deal of research to determine temperatures which correlate to the different phases in stiffness of the paraffin. A third weakness is the tedious manufacturing that would be required for this design. A very tiny heating coil and power source would need to be incorporated into a wire diameter of about 0.97 mm.

Criteria	Air Pressure	Hydraulic	Heat	Bead	Electromag
Ease of Use	-	-	?	+	?
Variability of Stiffness	+	+	?	-	-
Saftey	-	-	?	+	?
Cost	-	?	?	?	-
Ease of Manufacturing	?	-	?	-	-
Mobility	-	?	+	+	+
Rate of Stiffness Change	+	+	?	+	+
Precise increments of Stiffness	+	+	+	-	-
Score	-1	0	2	1	-2

Figure 2 - Design Matrix.

Future Work

If this design is the one chosen by our eight-person team, there are several steps which much be taken. The first is testing of the different viscosities of paraffin and various temperatures. These studies will have to be careful, precise studies in order to correctly determine the variations in phase. Choosing a polymer for this section of the wire and making a choice about insulation will also have to be done. As discussed in the evaluation section, the insulator choice is a crucial part of the design. Finally, implementing the heating mechanism will require some research time. Factors such as wiring and power choices will need to be researched.

References

1. American Academy of Neurology: Guidelines for Credentialing in Neuroimaging; http://www.asnweb.org/practice/niguidelines.htm

2. Biomaterials Properties Database, University of Michigan http://www.lib.umich.edu/libhome/Dentistry.lib/Dental_tables/Melttemps.html

3. Cardiac Catheterization Laboratory; St. Vincent's Hospital; http://www.angelfire.com/ab/cardiosv/cath.html#cath

4. Cardiac Catheterization: The Procedure; University of Iowa Department of Internal Medicine; http://www.vh.org/Patients/IHB/IntMed/Cardio/Cath/Procedure.html

Appendix A: Product Design Specification

Preliminary Design Specifications

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.
      - Conform to existing guidewire 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
      - Physician-friendly.

   h. *Size*:
      - Total length of 150 cm.

- Tip length of 3 cm.
- 10-20 cm of variable stiffness.

i. *Weight*:
- Cannot alter normal functions.

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*: none

c. *Patient-related concerns*: none

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