Variable stiffness guide wire

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Abstract:

The mid-semester paper explores a number of options for the design and implementation of a guide wire for catheterization purposes. The device will be used to provide a route for a catheter which will access to the brain via the circulatory system. The intended use of the catheter is to release specific chemicals into localized regions of the brain. Currently, the surgeon must place the flexible part of the guide wire into the vessel far enough that it doesn't slip out when the catheter is introduced. But, they also need to keep it far enough out of the vessel that stiffer part of the guide wire doesn't drag the more flexible section back out of the vessel. These designs attempt to provide the surgeon with some greater margin of error by making the 15-20 cm nearest the tip variably flexible.

Introduction:

Catheter Background

Catheters have been improved over many years. Catheters are designed to deliver a sensor, chemicals, or other instruments to a specific target within the circulatory system. One of the most important breakthroughs was the introduction of a guide wire over which the catheter slides. The guide wire is an easily guided, flexible metal wire. It is constructed in a coiled configuration with a central strand and a single winding around it. By decreasing the thickness of the coiling wire near the tip, the wire becomes more flexible. Catheters are most commonly introduced with the Seldinger process. This involves inserting a needle into the desired vessel, passing a guide-wire through the needle, advancing it, and then removing the needle (Cook). The catheter is then slid over the guide-wire and the two are advanced with the guide-wire leading and being used to direct the catheter's path. Once a surgeon has inserted the guide wire to the desired location, they slide the catheter over it to its final destination.

Problem Specifics

Our client is attempting to release chemicals into a blood vessel near the brain. These chemicals then travel with the blood flow and are dispersed. Images are taken of these concentrations. To get the chemicals into this vessel, the catheter must follow a sharp bend which conventional guide wires are not strong enough to maintain their position while the catheter slides over. The client has been able to insert existing guide wires to follow the required path and hold their position, but it frequently takes multiple attempts to get the correct distance. As this distance varies with each individual, it is difficult to gauge precisely how far the guide wire needs to be inserted. Our task is to design a guide wire that is flexible enough to be easily inserted into the vessel. Once in place, the surgeon must be able to linearly increase the stiffness to facilitate the placement of the catheter. The surgeon then needs to be able to decrease the stiffness and extract the guide wire.

Design Requirements:

Physical Requirements

The device must be 150 cm long and no wider that .97 mm. It must be coated with a hydrophilic sheath to allow minimum friction with its surroundings as it is threaded through the circulatory system. The 15 to 20 cm nearest the tip need to be variably flexible (Haughton). The device must be able to be inserted through a 100 to 140 degree bend in the vessel and then be rigid enough for the catheter to be slipped over the guide wire into the required vessel (Haughton). While the device must be limited to a single insertion into the body, it must be constructed using a reversible stiffening mechanism(Guidant). For more extensive physical and other specifications, please refer to the attached PDS.

Possible Designs:

Mechanical Bead

The mechanical bead device is based upon the idea that a number of interlocking beads are connected by a central strand, and when tension is applied to the strand, the beads are held together in their current configuration. It is a key feature of this design that before tension is applied, the beads are free to slide over each other as the guide wire flexes and rotates through the blood vessels. Once the wire is positioned properly, the operator applies a force along the central strand pulling the beads together. This increases the friction between each bead and its neighbor. Consequently, the entire structure becomes more rigid.

Envisioned is a set of beads that are flared cup-shaped and interlocking as demonstrated in Figure 1. The top of each bead is covered with bumps in a regular pattern. The bottom of each bead is covered with indentations, also in this regular pattern. Before compression, the beads slide over or under the adjacent beads, allowing the guide wire to be directed through the sharp bends of the circulatory system. After compression, the beads are pulled tightly together. The sets of bumps and indentations that cover adjacent surfaces would resist the natural tendency of the beads to straighten out. It is believed that this system would allow the guide wire to maintain its shape and have a decreased overall flexibility.

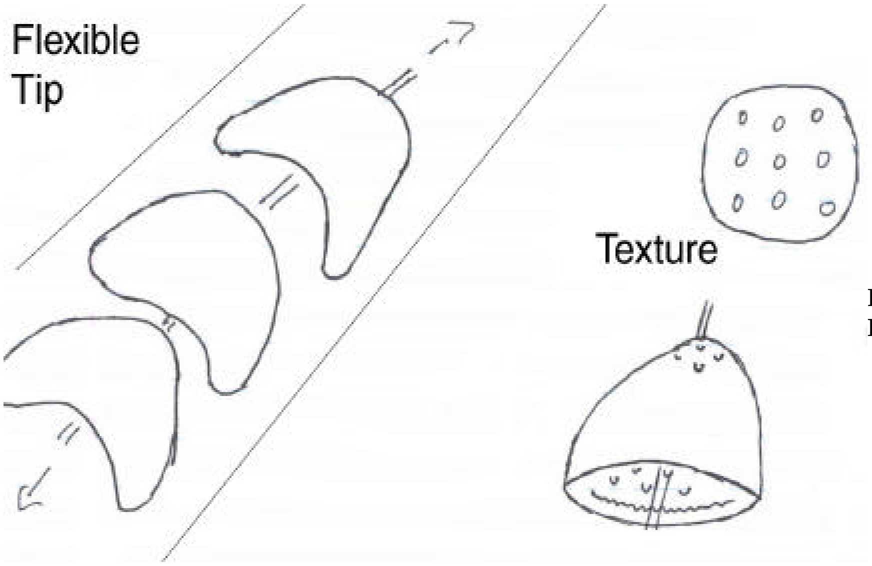

Figure 1: Mechanical Bead Design

Ferrofluid

Another potential method for varying the stiffness of a guide wire is to fill the hollow space between the outer coil and the inner strand with a ferrofluid. Ferrofluids are a relatively new development in fluid technologies. They consist of a higher density fluid, like an oil of some type, with particles of magnetite less then 100 Angstroms in diameter suspended within. This combination produces a colloidal (liquid with suspended particles that don't separate easily, like milk) mixture with the ability to act as a solid when influenced by a magnet.

To actually implement this device, one would have to ensure that the outer coil loops are insulated from each other and arranged in such a manner as to form a circuit. With the fluid in the center of what is essentially a long, thin solenoid, all that remains is to apply a current. It is believed that the application of such a current would cause the desired stiffening of the guide wire. Figure 2 is a diagram of this implementation when it is unaligned.

One foreseeable problem with this method of implementation is that any other magnets being used in the operation will have an effect upon the fluid. Furthermore, the solenoid itself may interfere with certain types of scans that may be needed simultaneously.

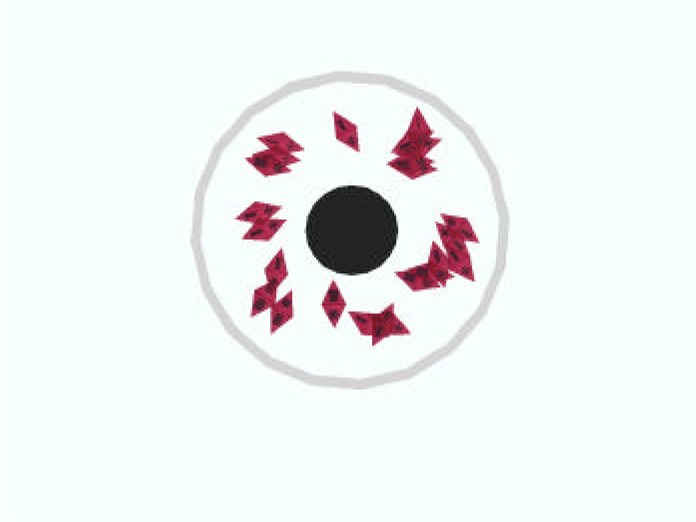

Figure 2: Unaligned Ferro-fluid

Rotational-catch

Another intriguing possibility of a mechanism for varying the stiffness of the wire is to manufacture small catches in the wire. The way this would work is to have a two-piece guide wire, with an inner core and an outer sheath. The inner face of the sheath and outer face of the core would have spaced catches on them in a configuration such that when the two pieces are rotated relative to each other, the catches alternately stick and release. This would provide stiffness to the wire when the catches are stuck together and flexibility when they are allowed to move freely past each other, as seen in Figure 3.

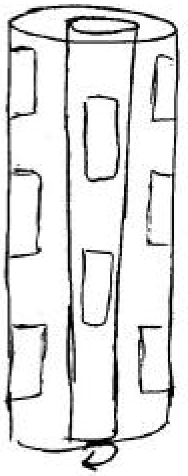

Figure 3: Rotational Catch Design

Polymer options

Under this category there are many potential options. They have all been lumped together because of the similarities among all the methods proposed. All options are based on the premise that polymers can vary their characteristics depending on their environment. All proposals have some sort of polymer enclosed within an extremely flexible piece of tubing acting as the variable stiffness segment of the guidewire.

One proposal is to have a bundle of thin metallic fibers within the polymer. The polymer would be able to fit between each fiber, so that when the polymer is stiff, the fibers cannot move past each other, and thus the wire is stiff. However, many polymers have the ability to soften when heated (e.g. rubber). By applying a heat source to the fibers outside of the patient's body, the polymer would soften enough to allow the fibers to move freely past one another, providing the flexibility needed. Removing the heat source would allow the device to cool past it's critical temperature and the device would re-stiffen (Dagani). For this method the tubing would most likely need to be an insulator.

Another possibility is to use a photopolymer, or light-sensitive polymer. These materials are capable of hardening upon exposure to light. A simple method to provide the necessary light to the tip of the guide wire is to replace the current metallic core of the wire with an optic fiber or a bundle of fibers. The key to making this idea work is to find a method of softening the polymer once it has been hardened. One idea is to find an enzyme that attacks the bonds that polymerization forms; equilibrium could be established between bond breaking and bond making leading to true variable stiffness depending on the intensity of light (Electron). In addition, it is possible that once stiffened the guide wire could be re-softened by heat. Even if this destroyed the polymer entirely, if another stiffening was needed the physician could simply remove the old guide wire and replace it with a new one.

A third option involving polymers is to have a polymer that swells and retracts lock the wire into a shape. Polymers that swell in response to their environment are called hydrogels. Certain hydrogels will swell when subjected to an electric field as evidenced in Figure 4. We propose that the outer tube and inner sheath act as a capacitor, so that to stiffen the wire the physician need only apply a voltage externally. If protrusions were present on the outer sheath and the hydrogel was anchored to the inner core, this method could provide a great deal of stiffening that would be fully reversible.

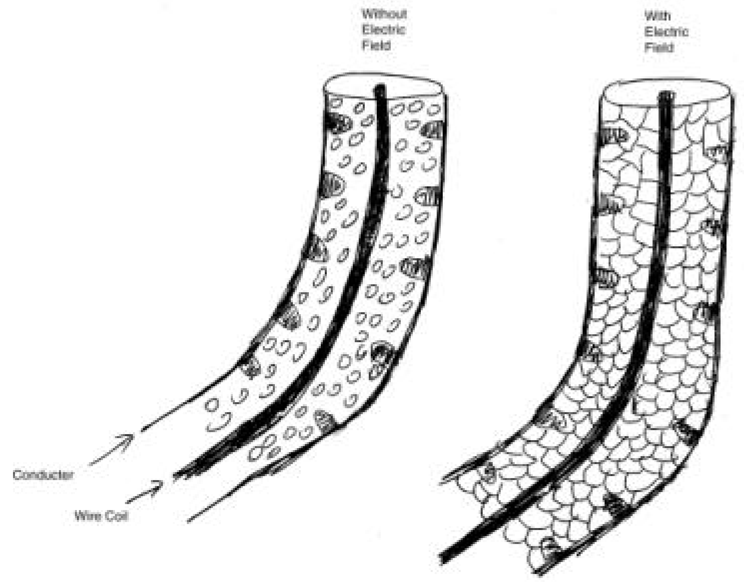

Figure 4: Electrically alterable Hydrogel

It is important to realize that because of the wide range of polymers available, there are many ways to combine these ideas, or to come up with other ideas. Without more research on polymers in general, it is difficult to know which ideas are feasible.

Conclusion:

Although all of the designs for the variable stiffness guide wire have the potential to satisfy the client's specifications, they rely on the usage of technology that is very difficult for students in our position to research accurately. Materials properties change when scaled down to the size needed so building large scale models may not accurately reflect what the device will really do. Exotic materials like environment-sensitive polymers and ferrofluids are expensive to obtain and work with. However, we used our limited knowledge and the research we were able to perform to form the basis for the evaluation seen in figure 5.

Consequently at this time, we feel our best course of action for the next several weeks is to contact various specialists in these fields and get their opinions of the ideas. It is hoped that their knowledge will replace quantitative tests or at least minimize oversights due to our inability to properly evaluate the designs. Hopefully this method of research will enable us to make precise evaluations and determine which design or combination of design characteristics will best serve Dr. Haughton's needs.

	Contains harmful substances	Brain-compatible	Reliable	Simple	Construction Difficulty	Feasible
Mechanical Beads	+	+	+	-	-	+
Rotational Catches	+	+	-	-	-	-
Ferrofluids	-	-	+	+	+	-
Polymers	-	+	+	+	+	+

"+" means good attribute
"-" means bad attribute

Figure 5: Evaluation table

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