Variable Stiffness Guidewire

Paper and Presentation by:

John Puccinelli and Hart Moss

Biomedical Engineering 200/300
University of Wisconsin, Madison
19 October 2001

Variable Stiffness Guidewire

Group Leader: Kristi Hinner
Communications: Jeremy O'Brien
BSAC: Tom Pearce
BWIG: Nick Vandehey

Biomedical Engineering 200/300
University of Wisconsin, Madison
19 October 2001

Client:

Dr. Victor Haughton, M.D., Ph.D., Radiology

Advisor:

Dr. Kreg G. Gruben, Ph.D., Biomedical Engineering

Writers and Creators of this Paper and its Ideas:

John Puccinelli and Hart Moss

Abstract:

This document explores a number of options for the design and implementation of a "variable stiffness" guidewire for catheterization. The guidewire will be used to provide easy steering through the circulator system as well as structural stability for catheter feeding. Current guidewires provide enough flexibility or stability but fail to do both when needed. The main focus of the new design is to create a guidewire whose flexibility can be manipulated by the physician performing the catheterization, so that after the flexible guidewire is maneuvered through sharp turns in the blood vessels, it can be hardened in place to allow the catheter to pass over it.

Table of Contents **Page Number**

Introduction:

Catheterization, a medical procedure revolutionized by Werner Forβmann, who successfully guided the first catheter to his own heart, has now become one of the most widely used procedures in cardiac analysis, and continues to advance in further areas, such as the brain. This procedure consists of guiding a thin tube (catheter), on the order of 1.5 mm to 2.5 mm in diameter, and 60 cm to 100 cm long [COOK], from the skin, through the sheaths of vessels in the brachial or femoral regions, to a desired location in the body such as the heart or the brain [Webster]. Catheterization is instrumental in a vast array of medical procedures, such as those used to diagnose heart conditions; measure cardiac pressures, flows, and oxygen saturations; or also corrective procedures. Minimally invasive techniques include the use of catheters to allow the controlled passage of urine through the urethra; in an angioplasty, which utilizes a balloon located at the tip of the catheter, that when inflated pushes plaque in a clogged blood vessel to the outside; or in a corrective procedure which supports deteriorating vessel walls with cage-like wire structures called stints. See figure 1 below for a basic look at three different shaped catheters.

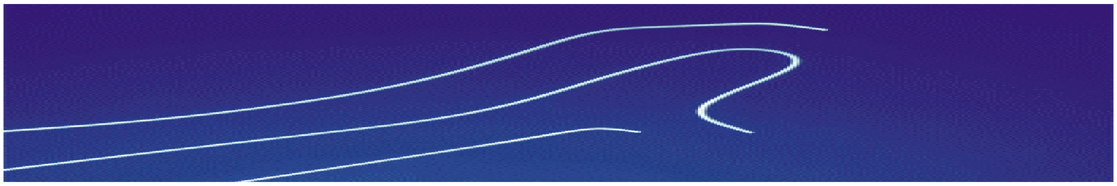

FIGURE 1: Basic catheter shape and design [COOK].

Difficulty in reaching the desired location arises in feeding the large, relatively stiff catheter through the network of vessels. To overcome the negative inherent guiding characteristics of the catheter, a solid wire, thinner (0.97 mm in diameter) and more flexible than the catheter, must first be inserted, maneuvered, and guided into place through the sharp turns in the circulatory system. Once this "guidewire" is in place, it must provide enough structural stability to maintain its position and allow passage of a catheter tube over it, at which point the guidewire must be removed and the actual procedure can be performed and completed.

The ideal guidewire possesses a balance between the flexibility needed to manipulate difficult turns and the rigidity necessary to stabilize the catheter's passage. While most products currently on the market provide flexibility or stiffness, they fail to do both efficiently at the same time. Doctors can purchase thicker, more stable guidewires that remain in place to facilitate the passage of the catheter, but these are not flexible enough to easily maneuver through turns. Thinner, more flexible guidewires are easier to steer, but they tend to slip back when the catheter is fed. Some "variable stiffness" guidewires already available are gradated, thinner at the tip, thereby providing a more stable base and a more flexible tip, but still fail to meet all the needs of the physicians because the stiffness of the guidewire cannot be manipulate. Most physicians today must use several gauges of guidewires for one procedure, making for an awkward procedure that costs time, money, and accuracy [Haughton].

The intent of this project, therefore, is to design the ideal guidewire that will allow physicians to easily and quickly maneuver a catheter into especially difficult areas where current guidewires fail. This ideal catheter would be of variable stiffness, adjustable by the physician during a procedure in a range from soft to stiff. Once designed, this guidewire will make the catheterization process more "doctor-friendly" and safer for the patient.

The client Dr. Victor Haughton, M.D., Ph.D. is interested in such a guidewire that will be used in a procedure directed at the brain's cerebral vessels. The client uses catheters to inject contrast and radiographic dies into the blood at a location near the brain, as the brain cannot be reached itself. These dies then travel through the blood to the desired location in the brain at which point pictures using CT, fluorescent detectors or other techniques are taken to study and investigate any occlusions or other problems. If such a problem is found, treatment may be necessary by locally injecting emboli or drugs, requiring that the catheter be guided directly up to the problem area. The guidewire necessary for this procedure must be of variable stiffness [Haughton].

Design Aspects:

The stiffness of the wire should change easily and quickly inside the body during a procedure in a range from soft to stiff. This guidewire must conform to the conventional standards of guidewires as far as size (0.97 mm in diameter) and biomaterials. (See appendix A, Product Design Specifications for more details.) The guidewire must not change shape during the transition from soft to rigid, but rather maintain the exact shape, size and location. The section of variability should be at least 10-20 cm long, starting 3 cm from the tip, with a total length of 150 cm. While soft, the guidewire must be able to maneuver around turns of an angle θ = 100-140 degree (See figure 2 below). The guidewire must not harm the patient in any way according to FDA standards [FDA].

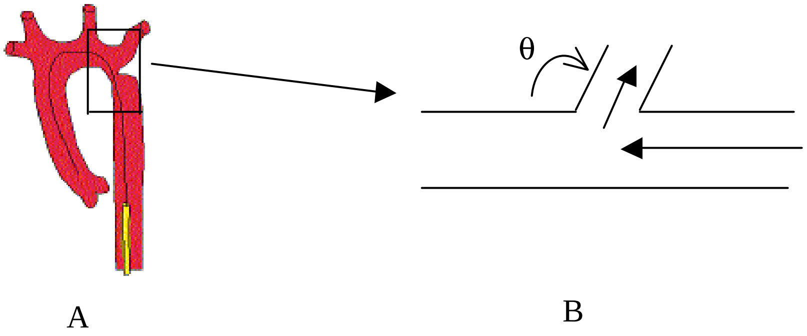

FIGURE 2: A- Depicts the artery with a guidewire fed and a catheter passing over. [COA] B- Shows the boxed area of A with a difficult turn of 100-140 degrees. Arrows represent direction of guiding. [Haugton]

Design Ideas and Alternatives:

Throughout the semester, thus far, a number of problems and solutions arose to satisfy the various parameters of this project. After scrutinizing each design, a number of pros and cons for each were established based on the design criteria. Some of the more promising ideas that had been perused with detail are presented below in order of least effective, to most effective. All of the following devices fulfill the PDS unless otherwise specified.

Hydraulics

The use of hydraulics operates under the basic principles of a fire hose. When water is pumped through an empty limp fire hose, the hose immediately stiffens and hardens. As the hose stiffens, however, it also straightens. On the smaller scale, if applied to a hose-like guidewire, this straightening effect would cause the wire to pull back through the vessel in order to obtain maximum straightness. This will not only defeat the purpose, but also cause pain to the patient. As a result of this danger, the idea of using any type of hydraulic device, no matter how modified, has been disregarded at this time.

Heat Activated Materials (Harden Inside Guidewire)

Deformable metals or plastics could also be used inside the guidewire. If these materials were chosen to have relatively low melting points, just above body temperature, heating them or passing a current through them would cause them to soften. In the softened state the guidewire would easily be maneuvered into place. At this time, removing the source of heat or current would solidify the wire in its current position without straightening, an improvement on the hydraulic principle. Problems arise in the time intrinsic to cooling under body temperature, and more importantly the risks involved in heating or passing current inside the body, especially near the brain, as current can interrupt neural mechanisms. Because of these problems, research was not pursued extensively in specific types of materials.

Sound Vibrated Sand

When sand or a particle-like sand material is placed under high pressure in a confined area, such as the core of a guidewire, the wire will become very rigid and stiff. When a strong vibration is applied to these particles they will vibrate and move around causing the wire to become limp or bendable. One such way to create this vibration would be to use sound waves. Ultrasound a medical procedure already in use utilizes high frequency sound waves to provide an image. If these sounds waves could be concentrated down the core of this guidewire on a central wire, then the sand particles would vibrate frantically [Webster]. The high frequency nature of the ultrasound, however, would presumably not affect the guide wire itself, meaning it would not vibrate noticeably, nor would it affect the guiding nature of the wire. This concept, however, is still uncertain and testing would have to be done to verify this possibility and all the effects it may have on the guiding procedure.

Stack of Books Theory

This idea is based upon the concept that when holding a stack of many books horizontally by applying pressure to both ends, the books stay together and do not fall, forming a rigid body. In essence, very small books or beads (0.9 mm) strung together with a central metal wire, can be placed inside a tube to allow for movement of the beads, and then coated with PTFE, FEP, Parylene or other coating [Starguide]. A force could then be applied to the loosely strung beads that will pull them together, forming a more rigid surface as with the books. The design and shape of the beads is a huge factor in properly designing this system. With square book shaped beads, curves will not hold the rigid properties needed, and may even tend to straighten upon applied force. A more effective design, much like a ball in socket joint will allow for curves. This design consists of concave and convex beads (See figure 3).

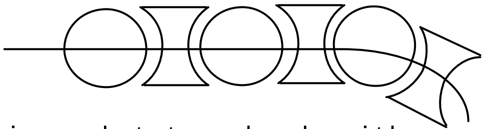

FIGURE 3: Shows ball in socket type beads with a central wire, dipicting the possiblilty of curvature.

Another more effective design would be the wedge shaped beads. The wedges would be able to rotate freely allowing turns, but also when pulled tight will have less of tendency to straighten out again. This is because with any of these bead designs when applying the force to the central wire, it will attempt to shape the beads so to achieve a minimal length rather than a maximum stiffness. With the wedge beads ideally shaped, no matter how they are turned the length of the central wire will remain the same after being pulled tight (See figure 4).

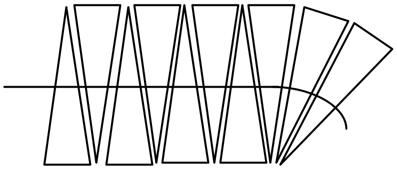

FIGURE 4: Section of the wedge forming a turn (not drawn to scale, elongated to show concept).

Ideally the central wire will pass through the center of the wedge always having an equal distance on both sides no matter how the wedge is turned as well as maintaining a smooth edge. Testing and calculations will have to done to find the exact shape that will fit these criteria, however, as the beads decrease in size and the number of beads increases the range for size variability increases, as does the freedom of the beads. The problem that arises with all these bead designs is creating the beads to be less than 0.97 centimeters. The wedges could be cut from a piece of solid tube and drilled out, or once a mold is made the beads could easily be formed from a polycarbonate material, or metal. The edge of contact of each bead could also be made rough, or could be coated with a sticky surface to increase the coefficient of friction when pulled tight thus increasing the stiffness.

Once the beads are designed and the guidewire is built, tension must be applied or released using the central wire. Fortunately, COOK already uses a deflecting tip guidewire that uses this same concept of pulling or pushing on the central wire. This device attaches to the end of the guide wire and acts much like a syringe (See figure 5). The central wire will be attached to the end of the beads, and the start of the beads will be fixed at the end of the stainless steel coil design of existing guidewires. This design fulfills the clients needs, and based upon the large-scale prototype that was created this design will hopefully be pursued further.

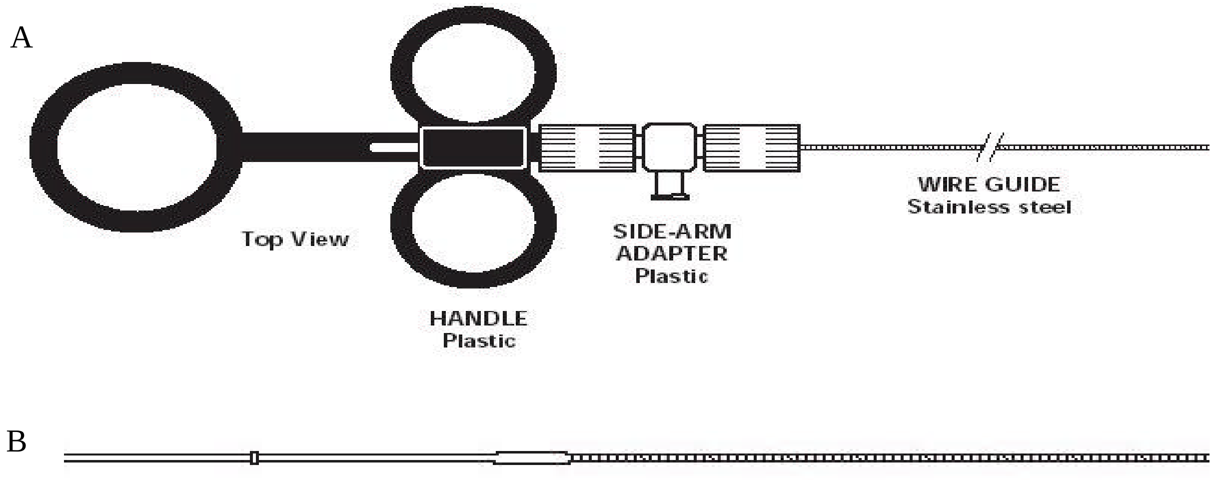

FIGURE 5: A- the plunger/syringe that adjusts the tension in the guide wire by pulling or compressing the far left ring. B– the guidewire itself that inserts into picture A as shown.

Summary Table of Designs:

Table 1: Summary of Designs with respect to the design criteria.

-Design-	Ease of Use	Presicison / accuracy	Cost	Sectional Stiffness (Turns)	Feasibility	Ergonomics
Hydraulics	+	–	–	–	–	–
Heated Metal/Pastics Materials	+	+	–	+	–	–
Sand Vibration	+	?	?	+	?	+
Ball in Socket Beads	+	+	+	+/–	+/–	+
Wedge Beads	+	+	+	+	+	+

Key: + means the design fulfills the requirnments
– means the design fails the requirnment and more work will be done to correct the flaws
+/- indicates that the feasibility is very simple if pursued
? means that this aspect of the design is yet unclear

Proposed Direction:

Based on the summary table above, the most feasible design is the wedge bead design. Therefore, a large-scale prototype was built from clay and is being analyzed. More extensive research and calculations will be performed on this design to determine if it will prove to be superior over the other designs presented here, and the designs of the other groups.

Conclusion:

For the remainder of the semester, the goals of the entire group are to implement these preliminary designs into one final design that will meet all of the design criteria and contain no visible flaws. Once this is accomplished, detailed drawings and plans will be formatted to lay the foundation for the construction of a more precise prototype. This new prototype will be built to scale of a real guidewire. To ensure all of the design aspects are fulfilled, the prototype will undergo numerous and extensive tests based on this scale factor. Based on the results of the tests, any and all problems encountered during construction and testing will be corrected to the best of the group's ability. Hopefully the work put forth during the semester will assist in better catheterization procedures, satisfying all of Dr. Haughton's needs.

References:

"Coarctation of the aorta (CoA)." http://www.rchc.rush.edu/rmawebfiles/chdforparentscoarc.htm

COOK Diagnostic and Interventional Products. http://www.cookincorporated.com/ (2000).

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

Starguide Precision Wire Technology. http://www.starguide.com/coating.html (1999).

U.S. Food and Drug Administration – Center for Devices and Radiological Health, "Is My Product Regulated by FDA's Center for Devices and Radiological Health?" http://www.fda.gov/ (1998).

"Werner Otto Theodor Forßmann." http://www.km-berlin.de/service/geschichte/forsmann.htm.

Webster, John. BME 310 Bioinstrumentation Text Chapters. http://courses.engr.wisc.edu/ecow/get/bme/310/beebe/bme310bioi/ (2001).

Appendix A

Product Design Specification

Variable Stiffness Guidewire

Last updated 9/28/01

Group Members: Kristi Hinner, Jeremy O'Brien, Brian Asti, Tom Pearce, Erik Birkeneder, Hart Moss, Nick Vandehey, John Puccinelli

Client: Dr. Victor Haughton, M.D., Ph.D.
Radiology Department- UW Hospital
PH#: 608-263-5306
email: vhaughton@mail.radiology.wisc.edu

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*:
        - 10-yr life expectancy.

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

    g. *Ergonomics*:
        - Patient friendly (FDA standards)
        - Physician-friendly.

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

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*:
    - Unknown

3. Miscellaneous

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

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