BME 400
Capstone Design

Steerable Core Biopsy Needle

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Abstract

Core biopsies are performed regularly by radiologists to obtain tissue samples using a spring loaded, rigid needle. However, occasionally the needle is misguided and ends up adjacent to the target tissue. No current method for re-directing the needle exists except to completely retract the needle and begin the procedure over. For this reason, a steerable core biopsy needle is needed. Research was conducted to gather information on core biopsy procedures, the current devices used, and competitive devices on the market. Using the design constraints specified by the client, a co-axial, passively steerable core biopsy needle was designed. Two large scale prototypes were constructed and preliminary testing was conducted using gelatin as the tissue-like medium. Future work includes finalizing material selection, building a final actual sized prototype with the new materials, testing the device in a more biomimetic environment, perfecting the predictability and repeatability of the steering mechanism and modifying the device for use in the clinical setting.

Problem Statement

Our project is to design a core biopsy needle that can be steered into the correct location of tissue when the initial attempt fails. The current standards of tissue volume and integrity for core biopsy samples must be maintained. Operation of the needle must incorporate an external steering mechanism that is intuitive and predictable.

Introduction

Every day, radiologists across the U.S. are performing tissue biopsies. A biopsy is a medical procedure that involves retrieving cells of a target tissue for analysis and diagnosis. Tissue samples taken are analyzed to determine whether cells are abnormal. Biopsies are often used to diagnose different types of cancer or to determine the cause of an infection or inflammation. There are many different types of human tissue biopsied. A few of the major tissue types include liver, breast, kidney, abdomen, thyroid, lung and skin. The type of biopsy performed is dependent on what kind of tissue sample is being taken. Either a surgical or a needle biopsy is performed (Dr. Kelcz Interview).

Significance

Designing a steerable biopsy needle has the obvious advantage of minimizing patient discomfort. The ability to re-steer an inserted needle without completely removing it will prevent damage to more of the tissue surrounding, and leading up to, the lesion. In addition, successful steering of such a device can also contribute to the fields of localized drug delivery or treatment methods such as cryotherapy, as the needles can serve as therapy probes.

Background

A biopsy takes place when suspicion exists about abnormal growth or infection in tissue. The two prominent types of biopsies are core biopsy and fine needle aspiration. Core biopsy involves the removal of a 1-3 cm sample of tissue which is captured in a needle trough by a spring loaded device. The needles used for core biopsy range from 14 – 20 gauge (1.9 – 0.9 mm). During fine needle aspiration, usually at least three rounds of sampling take place with a 21-25 gauge (0.84 – 0. 53 mm) needle. The needle is moved through the targeted mass 10-15 times per sample, with suction taking place to remove the surrounding cells (Berg, 2004).

Seven studies completed over a period of ten years show a 92-100% success rate in successfully diagnosing cancer using core biopsy with a 14 gauge needle. In approximately 11% of cases, more than one biopsy was needed due to an atypical lesion and only 0.5% of the time the lesion was completely missed. For palpable breast masses, one study showed that fine needle aspiration was able to correctly identify 90% of cancerous lesions while core biopsy could detect 95%. Core biopsy is preferred for both palpable and non-palpable masses and is also able to show better distinction between malignant and benign tissues within a lesion (Berg, 2004).

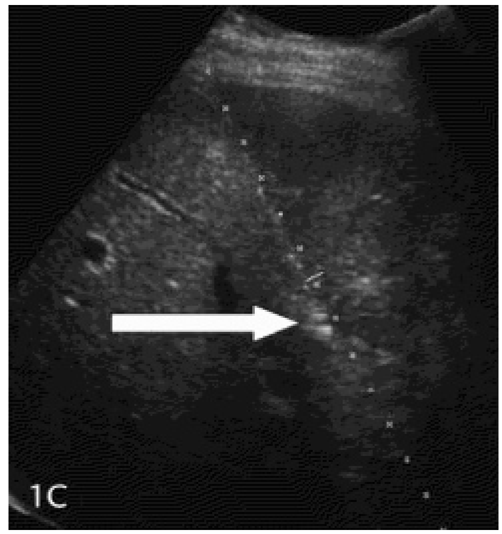

Figure 1. A dotted line created by an ultra-sound device identifies the needle pathway to the targeted mass.

During a biopsy, an ultrasound machine may be placed directly on the skin surface of a patient to aid in the location of the needle target (**Figure 1**). Ultrasound-guided biopsies are most typically performed on thyroid nodules, abdominal masses and liver masses; but they can be safely done on nearly any neck, thoracic, abdominal or pelvic mass. Computed tomography (CT) is another option for image-guided biopsies. However, because it does not have real time capabilities, it is only used in cases where the mass cannot be seen using ultrasound. While using ultrasound, performing a biopsy successfully can be difficult because of obstacles such as ribs or gas bubbles in the abdomen (Samani, et al., 2003).

Core biopsies should be performed in the liver following the discovery of certain types of masses including hepatocellular carcinoma, benign liver neoplasms, metastases from unknown sources, and metastases that remain undiagnosed after prior attempts at fine-needle aspiration cytology. Before a liver biopsy procedure, at least 5 mL of 1-2% lidocaine anesthetic should be delivered to the expected course the needle. Patient positioning is important to achieve the greatest access to the target while reducing the potential for damage to the nearby gallbladder and diaphragm (Samani, et al., 2003).

Figure 2. Two lines surrounding the targeted biopsy area in the liver to diagnose hepatitis.

Random core liver biopsies take place when a single mass is not targeted, but a tissue sample is needed to diagnose hepatitis or an infection. In this case, either lobe of the liver can be sampled and it is not necessary to penetrate more than a 1-2 cm beyond the liver surface (Samani, et al., 2003). The targeted area can be identified on an ultrasound screen by setting the area between two lines (**Figure 2**).

Current Devices

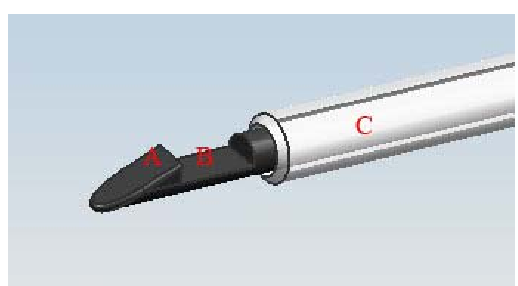

Figure 3. Shown are A – Beveled tip, B- Trough which are part of the inner needle, C- Outer Sheath

The current core biopsy needles all function using a similar mechanism. The needles are rigid, coaxial and externally controlled. The rigid inner needle has a beveled tip located at the end of the needle distal to an open trough. The outer sheath of the needle is a cylindrical tube of the same rigid material (**Figure 3**). The firing mechanism of the device is spring loaded. Both the inner and outer components of the needle are pulled back and locked. The needle is inserted, directed toward the target tissue, and fired. The firing mechanism first shoots the inner needle, which is quickly followed by the outer needle that cuts and captures the tissue in the trough (**Figure 4**). This same type of needle is used for most core biopsies on all different types of tissue. Needles are available in different lengths depending on the type of tissue sample being taken. Longer needles are used for abdominal biopsies, while shorter needles are used for biopsies when the target tissue is located close to the skin, such as a thyroid. They are designed as single use devices to avoid cross-contamination.

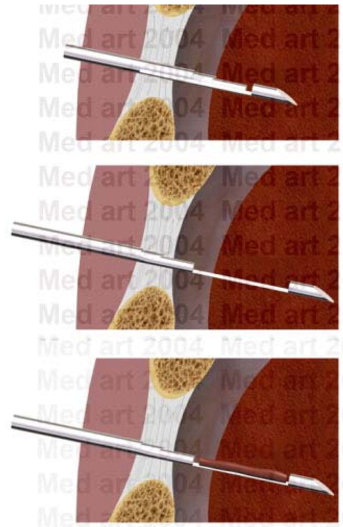

Figure 4. Depiction of the tissue capturing mechanism of a core biopsy needle.

PneumRx (www.pneumrx.com) currently manufactures a product called the Seeker Steerable Biopsy Needle for fine needle aspiration biopsies. The needle consists of a coaxial design. The outside of the needle is semi-rigid. There are two inner needles that can be inserted into this sheath creating a cannula (**Figure 5**). One needle is stiff, which

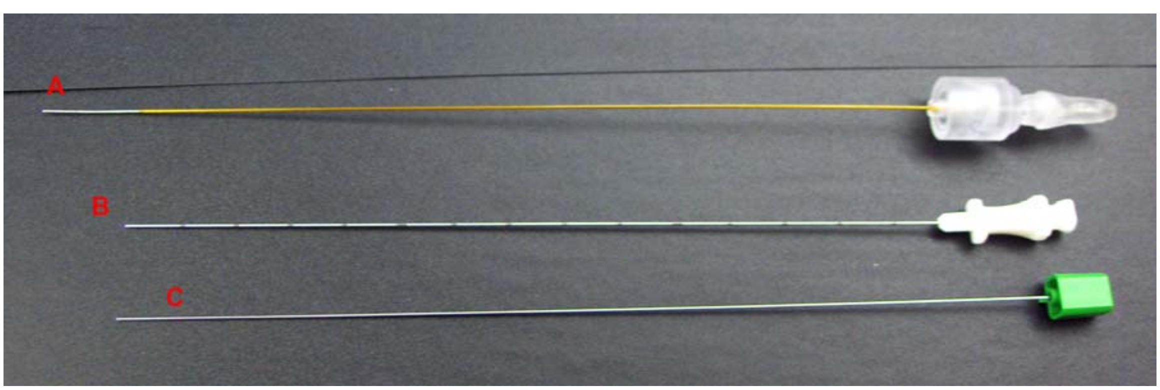

Figure 5. A picture of the Seeker Steerable Biopsy needle by PneumRx and its three components A – inner steerable needle with joystick operation, B – Ouster sheath, C – Rigid inner needle

allows the device to be inserted straight into the tissue. If the needle must be repositioned, this rigid inner needle is replaced by its semi-rigid counterpart that is controlled by a joystick. The joystick allows the tip to rotate 360 degrees about the long axis of the needle toward the target of interest. When the needle has been steered to the correct location, the inner needle is removed and is replaced by a syringe used to extract cells from the desired region. This design allows for increased accuracy and decreases the number of needle passes required to get a large enough tissue sample. Although the PneumRx steering method is sufficient for fine needle aspiration, the desired device must incorporate a core biopsy tissue capture mechanism.

Design Requirements

The motivation for the design of a steerable biopsy needle is to make the biopsy procedure less painful and less time consuming. When a biopsy is performed and the target tissue site is missed with the first attempt, a full withdrawal of the needle is required to redirect the needle to the desired position.

Our design focuses on trying to keep as many aspects of current core biopsy needles the same. Current core biopsy needles are 14 gauge or smaller. The core sample should be as big as the inner diameter of the needle and 1 - 3 cm long. The needle must also be visible on both ultrasound and CT imaging systems. Therefore the needle must be made out of a material that has a different permeability constant than skin or soft tissues or some other enhancement on the outer sheath increase contrast in the image. The current retail price range of core biopsy is $100 - $500 (Dr. Kelcz Interview). The cost of the device should be within this range. The needle must be disposable.

The fact that the needle will be steerable adds several more requirements beyond the normal core biopsy needle's basic functions. Generally the target tissue is only missed by a few centimeters so only the distal 2-3 cm of the needle need to be steered within a limited range of motion. This means if the target mass is missed by 2 cm and the distal 3 cm of the needle are steerable, a bend of only 38 degrees is needed.

The steering mechanism must be intuitive to the user. This can be accomplished by having clearly marked instructions as to how to steer the needle in the desired direction. The steering must be easy to perform with one hand. Inherent to steering motion of the needle is the chance for more damage to the surrounding tissue due to the lateral motion of the needle without actually cutting the tissue. This will cause an unwanted strain on surrounding tissue that could cause unwanted damage. We want to minimize this, via having the steering occur in conjunction with a forward motion. The spring-loaded cutting mechanism should function in the same way to take a core sample when the needle is in the bent position.

Design Considerations

Coaxial Vs. Articulation

The two main categories for possible solution for steering the needle are deforming the needle or incorporation of a joint. By adding a joint, the needle would be able to pivot about the joint which would be placed at a certain distance away from the tip to allow for the adequate range to reach any missed target. Deforming the needle would require a coaxial needle where the inner needle could be replaced if the user wants the needle to deform or stay rigid.

To put an articulation in the length of the needle, a portion of the needle must be bendable to a variable degree beyond the joint. The drawback in this method is that the path of tissue between the initial insertion line and the desired insertion line will be damaged (**Figure 6**).

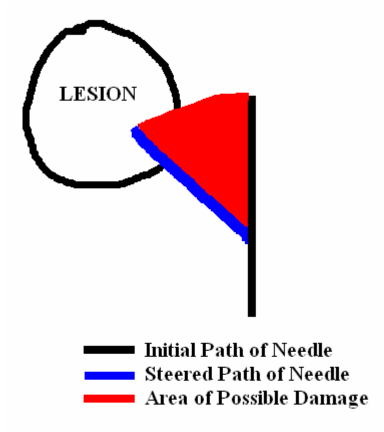

Figure 6. Area of possible damage if needle is pushed laterally from its axis.

Other problems with using a joint include steering the joint externally and firing the core sampling mechanism. A proposed external control would incorporate four long wires down the length of the needle (**Figure 7**). The wires in the left and right positions (blue) would be fixed, while the top and bottom wires (green) could move. If no steering was required, the configuration (**Figure 7a**) would be used to capture the tissue. If steering was needed, one wire would be pushed in causing the needle to bend accordingly (**Figure 7b).** Besides damaging the tissue in the steered path, different forces would be required to bend the needle the same

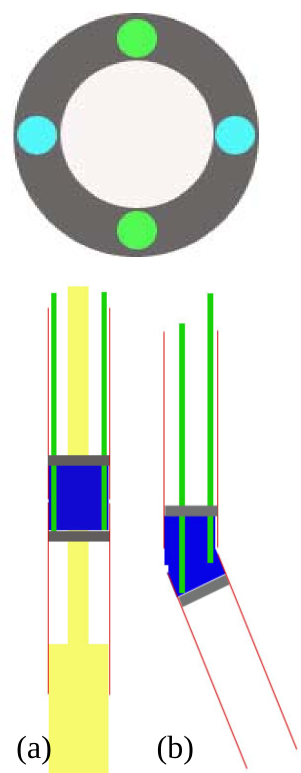

Figure 7. A design consideration incorporating wires as a steering mechanism

amount if used in different tissue environments. This makes it difficult to make this steering method predictable. Taking a core biopsy sample while the joint is in the bent conformation, fitting the spring loaded core tissue capturing mechanism into the small needle was too complicated and unfeasible to incorporate into our design.

The design for a deformable coaxial needle works on the same premise as the PneumRx fine aspiration needle. The coaxial technique uses a steering technique, described below, that will minimize injury to surrounding tissue. When the needle is brought back (**Figure 8b)** after missing the target (**Figure 8a)**, the needle will deform on an angle (**Figure 8c**) to steer the needle into the desired area (**Figure 8d**). Because of this advantage, the coaxial design was chosen over using an articulation. One draw back of this design is the unrepeatable bending. Since, the forces applied to the needle are different in different tissue environments. Harder tissues will cause more bending of the needle compared to softer tissues.

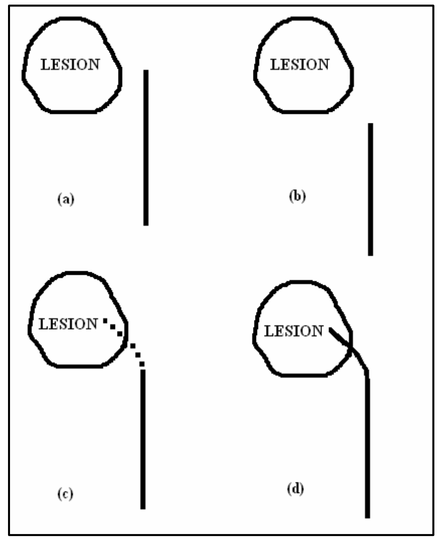

Figure 8. Mechanism by which the PneumRx steers toward a lesion.

Beveled Tip

A beveled tip needle is already used in currently marketed core biopsy needle designs. The beveled tip aids in the tissue capturing mechanism. As the inner needle with the beveled tip is advanced in front of the outer sheath the needle bends away from the beveled tip. When the spring-loaded outer sheath is then fired over the extended and bent inner needle, the inner needle is forced to straighten out (**Figure 9** -- note that angle of bending is exaggerated to show property). As the inner needle straightens out, it is moved upward forcing tissue into the trough as the outer sheath cuts the sample off.

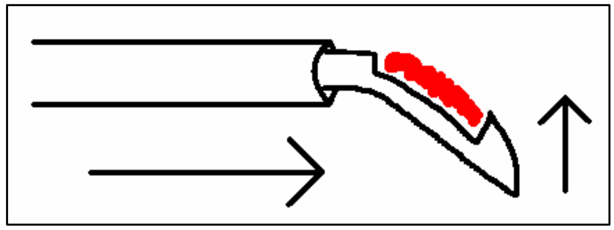

Figure 9. The outer sheath is able to fire over the bent needle tip to straighten it and capture tissue.

Steering

There are two options for steering the needle, one being externally controlled by the user and the other would utilize the forces applied to the beveled tip to deform the needle in the desired direction. Controlling the needle externally would require a joystick similar to the PneumRx steering design. This design is optimal because it rotates in all directions and gives predictable movement. Utilizing this mechanism, however, will be hard to incorporate and still have the needle take a core sample. The PneumRx uses a 25 gauge needle that does not have a relatively high stiffness. Implementing the joystick approach at the 14-18 gauge range changes the material properties that make it simple for the PneumRx to freely rotate.

The simplest approach would allow the forces already exerted on the needle by the surrounding tissue to deform the needle (**Figure 10**). The forces acting on the needle everywhere except the tip force the needle to go straight. This happens because the surrounding tissue resists any lateral motion. However, the forces acting on the tip are unequal. By having the inner needle and outer sheath made of material which is deformable, these forces can be utilized as a steering mechanism but still be strong enough to cut tissue. Since the tip is beveled, this creates a large area on one side of the needle, which creates a larger force distribution compared to the un-beveled side. In addition the beveled tip creates a force that is perpendicular to the long axis of the needle that can force the tip of the needle towards the un-beveled side. The amount the needle curves is dependent on how far the needle is retraced back before insertion. The distance retracted determines the amount of the needle that can bend because the rest of the needle is stabilized by the surrounding tissue and can resist bending. The further the needle is retracted the more the needle will bend.

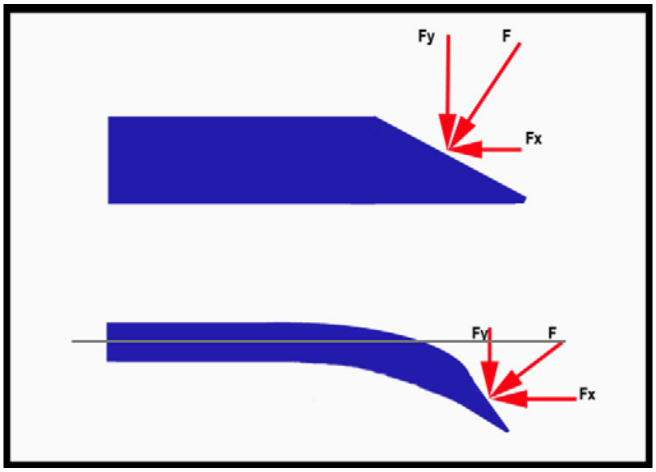

Figure 10. Forces that act on the beveled tip and cause bending in the needle.

Tissue Capturing

Acquiring a tissue sample with the device will be done much in the same way that the current models of core biopsy needles do. Therefore, for simplicity, the mechanism will stay the same. The tissue capturing will work if the needle is straight or bent. The outer sheath is drawn back to compress a spring. The full needle is inserted into the body with the rigid inner needle inside the sheath. If the ultrasound feedback is positive, the inner needle is then advanced forward into the target tissue and the same mechanism described in **Figure 8**. In the case that the initial attempt fails, the full needle will be drawn back slightly depending on the amount of curvature needed. The rigid inner needle will then be removed and replaced with its semi-rigid counterpart. This inner needle will be extended forward on a curvature. However, unlike the previous type, the outer sheath does not straighten out the tip. It fires over the tip to capture the tissue sample.

Materials Selection

The selection of materials is a crucial part of the creation of a successful steerable biopsy needle. The materials chosen for the first generation prototype may not be suitable for a scaled down version of the device depending on the changes in material properties when the components are shorter and narrower. When materials for the actual needle are chosen, two factors must be considered. First, they must be able to withstand sterilization. If the properties are changed as the device is sterilized, it could break while in use, which would be detrimental to both the patient and the sample. Second, the materials need to be biocompatible so that they will not cause a significant immune response from the patient.

For the alpha prototype, aluminum was chosen for the handle because it is stable, stiff, relatively lightweight, and easy to machine. If the handle weights too much it could become burdensome for the physician to hold and may tug on the skin surrounding the puncture site. The outer sheath was made of clear vinyl tubing because it is able to bend due to the forces of surrounding tissues but will not compress or lose integrity *in vivo*. Aluminum was chosen for the rigid inner needle because it has a high strength to weight ratio and will not bend from tissues in the body. Therefore it is able to approach the targeted area in a straight line. The inner semi-rigid needle was made of polyurethane due to its ability to bend easily in response to the forces on its beveled tip.

The total cost to make this prototype (**Table 1)** is much less than the cost to make an actual device, which will need specially molded pieces and will have to undergo sterilization.

Part	Size	Price
Aluminum Box	3.1" x 1.3" x 1.0"	N/A
Aluminum Sheet	3.3" x 0.1" x 0.25"	N/A
Rubber Ring	1/2" OD, 5/16" ID, 3/32" thick	$0.20
Spring	3/8" x 3/4" x 0.032"	$0.36
Clear Vinyl Tubing	1/4" OD, 3/8" ID, 2" long	$0.04
Clear Vinyl Tubing	7/16" OD, 5/16" ID, 6" long	$0.12
Aluminum Rod	1/4" dia, 7" long	$0.41
Polyurethane Rod	1/4" dia, 7" long	$5.37
Total		**$6.50**

Table 1. Components of alpha prototype with costs.

Future Work

There are many opportunities to advance this design further. The material selection for the beta prototype must be finalized. As mentioned in the previous section, material selection has been quite a challenge for this project. Since many material properties are based on the size of the material used, the materials used for the current scaled up prototype will most likely not be suitable for the actual sized device. Materials that could be considered include titanium or different grades of stainless steel.

After determining the final materials, a new, to-scale prototype will be made. Testing will need to be done on this model using materials that more accurately mimic the real biological environment. Preliminary testing was conducted using the first generation prototype and gelatin. However, differing stiffnesses of the gelatin altered the testing. If the gelatin was too stiff, penetration of the surface by the needle caused the gelatin to rip. If the gelatin was not stiff enough, it did not produce enough resistance to the needle. A more biomimetic environment can be produced in several ways. There are various recipes available that use both collagen gelatin and agar to produce a material with the same consistency as abdominal tissues. Including olives or grapes in the material will provide a target area to try to steer the needle toward. After this is accomplished, the needle can be tested in raw chicken meat, which also has similar mechanical properties to natural human tissue. In testing the prototype, the steering mechanism will need to be perfected to ensure that the device is both predictable and motion is repeatable.

Finally, the device must be improved for use in the clinical setting. In order to be a popular, marketable device, it must appeal to users. This will be accomplished through modifying the handle, the spring loaded trigger and the ends of the inner needle components so that they are ergonomic. The handle must be sized correctly to feel comfortable to physicians. Also, the spring loaded trigger must engage intuitively with ease and safety. Both the semi-rigid and rigid inner needle components must be easy to remove and insert safely from the device while it is inserted in the patient.

Conclusion

Given the needs and requirements of the client, a co-axial, steerable biopsy needle has been designed. Significant progress was made in constructing large scaled prototypes to test the design concept. Future work will be done to create an actual sized prototype of different materials that can be tested and perfected for use in the clinical setting. Success of this project will greatly aid radiologists in performing biopsies more accurately, preventing unnecessary pain for the patient and may also contribute to research done using biopsy needles as therapeutic probes for treatment.

References

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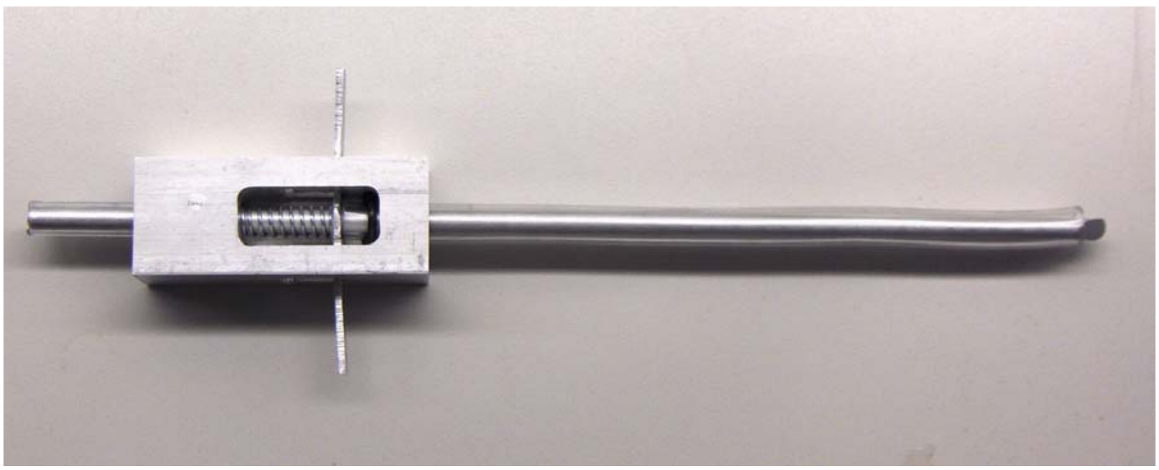
Samani, A., Bishop, J., Luginbuhl, C., Plewes, D. (2003). Measuring the elastic modulus of *ex vivo* small tissue samples. *Physics in Medicine and Biology, 48,* 2183-2198.

Interview with Dr. Frederick Kelcz, UW-Hospital, September 15, 2006.

Appendix A: Prototype Photographs



Appendix B: Product Design Specfications

Steerable Biopsy Needle

Product Design Specifications

October 24, 2006

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Function : Design a biopsy needle that can be steered into the correct place when the desired location is missed while keeping current standards for core biopsy relatively the same. The operation of the needle must be intuitive to the user.

Client requirements : Our client requirements are as follows:

- Must be less than a 14 gauge needle
- Externally controlled
- Compatible with Ultrasound and Computed Tomography
- Core biopsy sample acquired from needle of quality close to current methods
- Ability to steer must not corrupt the tissue sample
- Realignment of needle must not require complete retraction of needle out of body
- Must not cause more damage than current biopsy needles
- Biopsies must be repeatable and predictable

Design requirements :

1. Physical and Operational Characteristics

a. *Performance requirements:* Must withstand internal body conditions and be strong enough not to break when inserted into the patient. However, it must be able to puncture soft tissue. Core biopsy standards similar to current non-steerable needles.

b. *Safety:* Needle user must have complete control of the mechanism and sterilized.

c. *Accuracy and Reliability:* Biopsy taken using this steerable needle must be easily taken. The steerable portion of the needle must react, in the same environment, the same every time.

d. *Life in Service:* Disposable.

e. *Operating Environment:* Our device will be exposed to normal hospital conditions. Needle will be used inside the body, so it must be able to be sterilized.

f. *Ergonomics:* Must be easy to use and the movement of the needle must be intuitive (turn left to make the needle go left)

g. *Size:* Must not exceed the size of a typical 14 gauge needle.

h. *Weight:* The weight will not be factored into our design, as it will be limited by the size of the unit, but must still be within reasonable standards.
i. *Materials:* All material used in this design, metal and polymers, must be compatible with environment of the human body and still me our design standards. .

2. Product Characteristics

a. *Quantity:* Only one unit will be necessary to meet the requirements of a successful design. This design should be reproducible, however.
b. *Target Product Cost:* Current needles cost approximately $150, so for our steerable needle will cost between $200 to $250

3. Miscellaneous

a. *Competition:* A group at the University of British Columbia is developing a steerable biopsy needle but it has not gone into clinical testing yet. Also, PneumRx have developed a steerable FNA needle that they are currently testing and marketing.