

Intravascular Ultrasonic Probe Imaging During Core Biopsy Procedures

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Abstract

Core biopsy procedures are currently subject to high specificity due to inaccurate imaging of small tumors around the biopsy needle. Design alternatives to improve MRI guided core biopsy yield using optical fluorescence and ultrasonic imaging were explored. Optical fluorescence techniques using fiber optics are currently being researched Dr. Nimmi Ramanujam. These techniques differentiate between cancerous tissue and normal tissue by comparing the concentrations of specific fluorophores. As these techniques were being explored by another research group, this design was not chosen. Ultrasonic imaging can differentiate between tissue types by the differences in echogenic calcifications. The basics of IVUS probes were used to develop two ultrasonic methods: an integrated ultrasonic probe and a catheter based IVUS probe technique. The integrated design involves the redesign of an IVUS probe to attach it to the core biopsy procedure. This technique provides effective 360 degree imaging, however the cost associated with the redesign makes it impractical. The chosen design involves the insertion of a catheter based IVUS probe, once the needle is in place. This technique should provide accurate imaging and is extremely practical to implement. However, this techniques will require experimentation to evaluate its ability to image within the needle in the presence of a strong magnetic field.

§1. Problem Statement

During stereotactic biopsy procedures, needle placement is difficult to verify. In cases of small tumors or calcifications, the needle itself can actually prevent imaging of the suspicious area; therefore, many stereotactic procedures lead to false negatives. The goal of this project is to improve biopsy yield via local imaging around the needle.

§2. Background Info

Before determining the method of imaging, it is crucial to understand the characteristics of cancerous breast tissue. As such, breast cancer and biopsy procedures were extensively researched.

§2.1 Breast Cancer

Core biopsy procedures are often required to diagnosis breast cancer. Breast cancer affects over 200,000 people per year, and early detection has been a continued requirement for successful treatment. Many simple forms detection exist, including self breast exams and mammography, however they often produce inconclusive results. [11]

Mammography provides the early detection of breast cancer with higher certainty than self breast exams. It is recommended that women over the age of 40 receive one every year. A mammogram lets the doctors view the breast from a film box with a small x-ray dose. It detects 80-90% of all breast cancers, even small, non-palpable cancerous lesions which cannot be found self exams. Suspicious lesions in mammography lead to further examination using ultrasound and biopsies. [9]

One possible finding on a mammogram is a calcification. As their name suggests, calcifications are small build-ups of calcium and minerals in the breast tissue. This is a common

sign of aging; generally most calcifications are benign. To decide whether or not further testing is necessary, size, shape, and distribution of the calcifications are analyzed. [13] In one study, 17% of biopsies taken after suspicious calcifications turned out to be invasive cancers. [10] In these cases, early detection is a matter of life or death.

If tumors are found, doctors will classify the type and stage of breast cancer into four categories, stages 0-4. The stage is dependent on the tumor's size and ability to metastasize. Stage 0 consists of lobular carcinoma *in situ* and ductal carcinoma *in situ*. In this stage, abnormal cells stay within the lining of the lobule or ducts and have not invaded any other nearby cells. Stage 4 is the highest level of cancer as the cancer has spread throughout the body. [2] Even after successful treatment, there is always a chance that the cancer will come back. Early detection improves the chances that secondary treatment will not be needed.

§2.2 Core Biopsy Procedures

Biopsy is often required to correctly diagnose suspicious breast tissues discovered during a regular mammogram. Radiologists depend heavily on pathological analysis of excised tissue, as it is the most accurate method for cancer diagnosis. Several options are available, including fine needle aspiration, stereotactic biopsy, excisional biopsy, and core biopsy. Core biopsy is a popular option and is very accurate in diagnosing most tumors and calcifications.

Core biopsy is a method by which small sections of suspicious breast tissue are removed with a specialized needle, which is hollow with a short cutting edge near its end (Figure 1). Needles are typically 11 or 14 gauge with an internal diameter of 3-4 mm. When the lump is palpable, the needle is simply hand-guided by the physician. In other cases, the procedure is generally guided by ultrasound or magnetic resonance imaging (MRI). [4]

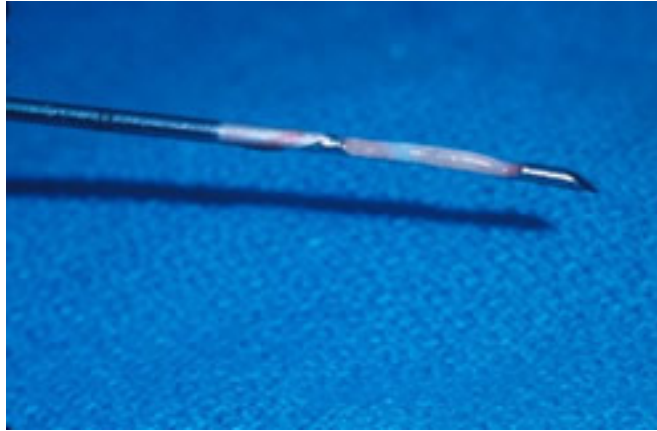


Figure 1. Core biopsy needle including excised tissue sample. [1]

MRI has extremely high spatial resolution, and as such, it is an ideal method to provide accurate imaging feedback during needle insertion. After suspicious tissue is observed in a mammogram, the patient returns for a second appointment during which the biopsy actually occurs. An MR image is taken while the breast is immobilized under light compression. A small incision is made under local anesthesia, and a small plastic clip with a trailing wire is inserted at the abnormal site. A second MR image then verifies correct placement of the clip, after which the core needle is guided by the protruding wire to the biopsy site. A grid system is placed beside the breast and used to guide the needle to a preset depth, also aligning it according to the second MR image. An electric motor is attached to the end of the needle to provide torque, spinning the cutting edge to remove a small cylindrical bore of tissue. Three to six tissue samples are taken to ensure an accurate diagnosis; each sample is approximately 2.0 cm long and 0.16 cm in diameter. Each sample is then sent to the lab, where chemical analysis can be. The entire biopsy procedure lasts 15 minutes, and results are available within a few days. [3]

The benefit of core biopsy is that it allows histological analysis by the pathologist. This means that comparisons between abnormal and normal tissues can be made, as samples are often

large enough to contain both species. In techniques such as fine needle aspiration, only a few suspicious cells are removed; as a result histological comparison is not possible. However, in both cases only samples of the suspicious area are removed, so the possibility remains for cancerous sections to be missed by biopsy. Furthermore, very small tumors and calcifications may be covered up by the core needle itself. If a lesion has approximately the same cross-sectional area as the needle itself, the needle can block sight of the abnormality. From ultrasound and MRI images, the physician is unable to distinguish whether the tip of the needle is above, below, or exactly at the correct biopsy site. Should a negative diagnosis be returned, the physician cannot be sure if the lump is truly benign, or whether normal tissue was removed instead (Figure 2).

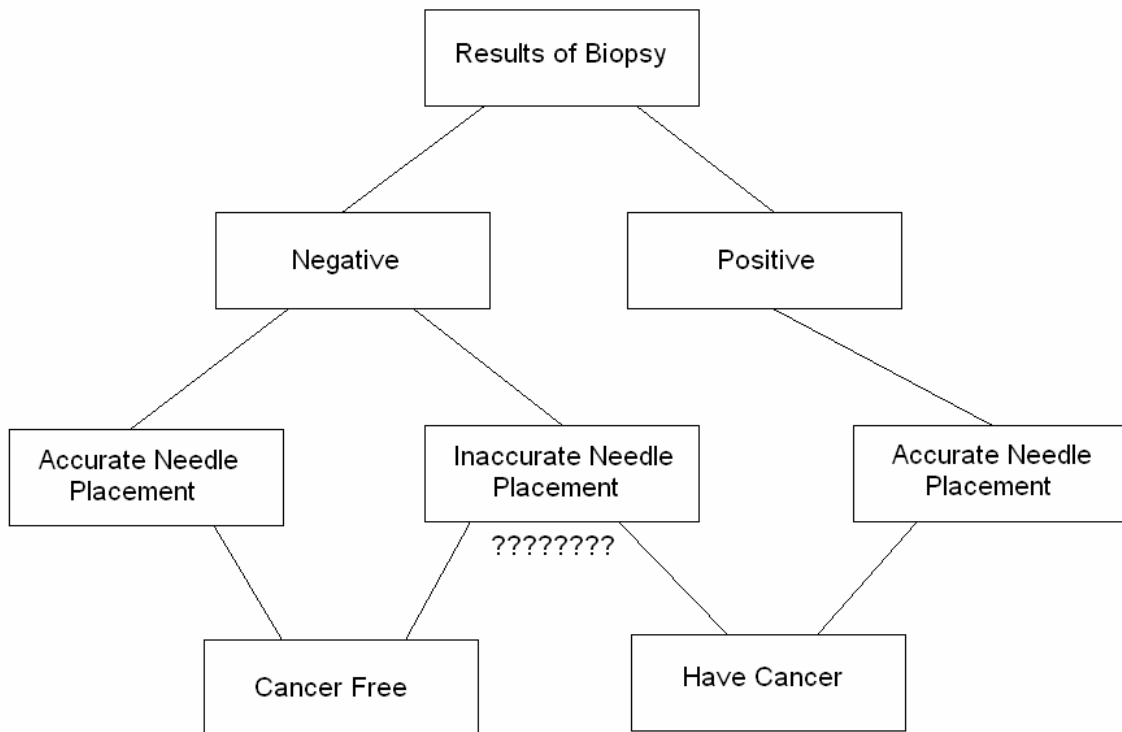


Figure 2. Possible biopsy diagnosis results. No conclusion can be made if inaccurate needle placement occurs.

§3. Literature Search

While the idea of placing an intravascular ultrasonic probe within a core biopsy needle for the purpose of aiding in the precision of its positioning is a novel one, there have been a number of U.S. patents issued related to the topic.

One method outlined in U.S. patent number 6,669,643 describes the use of catheters in combination with biopsy devices in order to provide “accuracy, economy, and efficiency in internal examination, diagnosis, biopsy and surgical removal of lesions.” The device was designed primarily for use in female vaginal and uterine chambers, and consists of a “tubular catheter and any of a wide variety of biopsy devices adapted for disposition on or within the catheter.” Additionally, the patent outlines a method for using “sonographic or fluoroscopic imaging in combination with the apparatus” for the function of guiding biopsy procedures. [5]

Although the idea behind this device is quite similar to that being proposed, there are many differences with regards to the actual design. A main structural difference in our proposed design is that the imaging probe would be placed inside the core needle, where as in Dubinsky’s device the biopsy instrument is placed inside a catheter, and an imaging probe is used simultaneously but externally. Regardless, given the anatomical differences between breast tissue and the vaginal chamber, the patented method is not appropriate for our application.

U.S. patent number 6,421,454 also relates to the accurate identification of small calcifications in the breast. It describes a method for imaging breast calcifications by “correlating an ultrasonographic data set with a radiographic image.” However, this method refers specifically to the identification of the position of the calcification before a biopsy is performed, and does not insure the placement of the biopsy needle once inside the breast tissue. [7]

Although the fore mentioned U.S. patents relate to the use of ultrasonic probes in biopsy, other online literature searches were performed in order to uncover the most recent developments related to this topic. Dr. Stephen Smith of Duke University is currently developing two-dimensional array transducers to be used simultaneously with the ultrasound procedure. These transducers will generate a three-dimensional ultrasound image of the biopsy site. The primary focus of his research is the development of “improved medical ultrasound image quality for applications in cardiology, radiology, and obstetrics” The rationale behind Smith’s research is similar that of this project; however, his focus is directed at designing new transducers, rather than pursuing new medical applications of such devices. [12]

§4. Design Constraints

The device will be used in conjunction with either current ultrasound systems or MRI systems. A long list of standards is associated with MRI systems to ensure the safety of both patients and healthcare professionals. An instruments used within the MRI suite must be made of non-ferrous materials, and the electronics involved must operate unaffected in the presence of a strong magnetic field. Magnetic components are allowed in the MRI control room, where proper shielding exists, and controls, displays, and other components may be wired to components within the room. Sterilization of the probe between patients is a necessity; or it must be disposable. It should not hinder or greatly prolong the biopsy procedure and should be user friendly. A spatial resolution of 1-2 mm and depth perception of 3-5 mm are desired. The probe must work with 11 and 14 gauge core biopsy needles.

§5. Design Alternatives

Various methods of improving biopsy yield were investigated. Optical fluorescence and ultrasound are two possible imaging methods for distinguishing malignant and normal breast

tissues. Two variations of the IVUS probes were considered, an integrated IVUS-core needle system and a catheter based IVUS system.

§5.1 Design Alternative 1: Fiber Optic Fluorescence Transducer

Optical fluorescence is currently being developed by Dr. Nimmi Ramanujam, an assistant professor in the Biomedical Engineering department at the University of Wisconsin-Madison. Though in principle the imaging modality is very different, the mechanism of interaction between the optical probe and core needle is very similar to that of the IVUS probe system. A fiber optic probe is fed into the bore of the core biopsy needle until it reaches the cutaway portion (Figure 3). This device was developed based on the characteristic way in which molecules in cancerous cells respond to the fluorescence from the optical fiber. Specific wavelengths of light, mostly in the near infrared region, are transmitted into the tissue by the optical fibers, exciting specific biological fluorophores. These include flavin adenine dinucleotide (FAD), nicotinamide adenine dinucleotide (NADH), and collagen, among others. Each fluorophore responds to excitation light by emitting photons with a particular shifted wavelength as each returns to its own unique ground state. The various concentrations of each compound in a sample can be determined by analyzing the fluorescent response of the tissue as a whole. Because the concentrations of these compounds differ across certain types of tissue, a characteristic response exists for both cancerous and normal tissues. Compounds such as FAD and NADH are involved in glycolysis and cellular respiration, and thus are found in greater quantities in tissues containing actively dividing and growing cells. In addition, collagen is essential in developing the extracellular matrix and is concentrated in tumors. The technique has been successful in diagnosing cervical cancer, but has yet to undergo clinical testing for the diagnosis of breast cancers. [8]

With this method, viewing is limited to the size of the cutaway portion of the biopsy needle, but 360° imaging is possible if the needle can be rotated. The device is relatively simple to set up and use, and is fully MRI compatible.

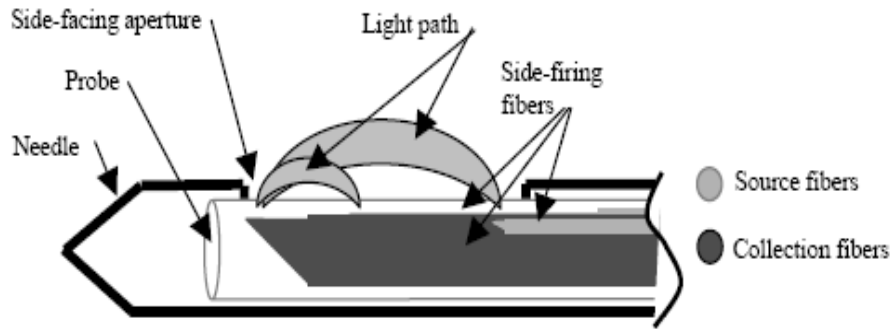


Figure 3. Schematic for fiberoptic probe [8].

§5.2 Design Alternatives 2&3: Intravascular Probes

Ultrasonic imaging is a well founded means of imaging, and is commonly used in almost all hospitals as a safe and effective imaging technique. Typical ultrasonic imaging units consist of two main elements, a pizo-electric based transducer and an electronic control system. The transducers convert ultrasonic waves into electrical signals and vice versa. Waveform generation and perception is done by an electronic control system. This system usually applies a set ultrasonic sequencing pattern specific to the transducer setup. In conventional imaging, waveforms are emitted from the transducer and the reflections are read by the same transducer at a frequency and intensity governed by the echogenicity of the material. In biological imaging, different tissues have different acoustic impedances, and hence have different reflection frequency responses. In 3D and 2D systems, arrays of transducers are aligned such that a reflection from a single point is received at multiple transducers with each signal slightly different phase due to unequal traveling distances. The distances between the transducers in the

array are known such that an image can be formed through a triangulation method. It is highly dependent on sequencing parameters which ultimately determine the depth of imaging. [6]

Ultrasonic imaging has been modified to allow imaging of veins and arteries in an invasive technique utilizing an intravascular ultrasonic (IVUS) probe. This probe consists of a piezoelectric ultrasonic probe within a catheter that can be inserted into veins and arteries. A typical catheter used for this procedure is 100-130 cm long and 8-14 F in diameter. Two fundamentally different IVUS probes exist: rotational and multi-transducer. The first uses a motor that spins a single rotating transducer at 1800 rpm, providing a cross sectional image at roughly 30 frames/sec. The second contains a radial array of transducers which sweep the position of the acoustic beam in radial patterns. A precisely timed transmission/receiving sequence for the radial array effectively mimics rotational motion. Both methods have a fixed focal radius, which allow for imaging depth 1-2 cm around the probe. Both systems also use high frequency ultrasound (20-30 Hz) as compared to normal ultrasound (3-5 Hz), achieving higher temporal resolution at a cost of reduced imaging depth. 2D image reconstruction is real time, however spatial resolution is poor. 3D imaging has been achieved using similar probes by stacking cross sections with the positions and orientations determined by a catheter tracking system; however these systems are subject to streak artifact. [14]

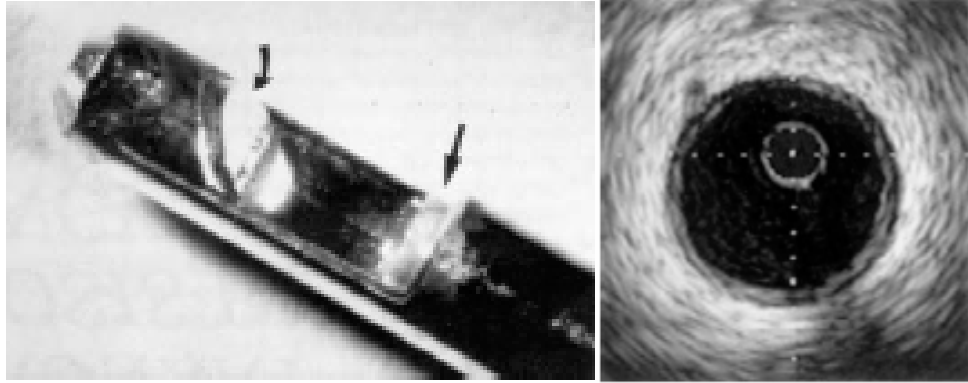


Figure 4. Cross-section of artery using rotating IVUS probe (right). The smallest circle is the probe itself.

§5.2 Design Alternative 2: Integrated IVUS-Core Needle System

An 11 gauge core biopsy needle will be constructed with a built-in ultrasonic probe similar to non-rotational IVUS probes (Figure 5). Placement of the probe just beyond the cutaway section will allow for imaging of the area slightly ahead of the needle opening. With this placement, the probe will image a full 360 degrees around the needle, but will require the use of a multi-transducer array to obtain the cross section. The multi transducer array is subject to streak artifacts between the transducers and has lower spatial resolution than rotational probes. However, since the probe will be held in a relatively stable position, motion artifact will be greatly reduced. Since the transducer will not be contained inside the needle, needle reflection artifact will be negligible. An array of 20 to 40 Hz ultrasonic transducers spaced 10-20 degrees apart along the needle's outer surface should allow for accurate image reconstruction, and provide a high signal to noise ratio (SNR). The effective viewing depth is expected to be 2 cm for a 20 Hz probe and has been experimentally shown to be 5 mm for a 40 Hz probe.

Construction of the integrated probe design may prove to be inhibitive difficult. The redesign of an ultrasonic probe requires advanced knowledge of piezoelectric components and requires micro-constructive techniques. As such, the cost of outsourcing probe design and

construction is rather high, especially for the budget constraints of this project (Appendix A). Future industry support may be possible, but not until the effectiveness and marketable use for the system are proven.

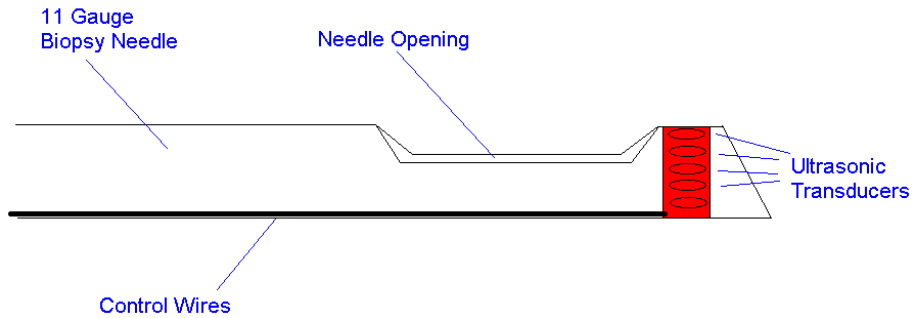


Figure 5. Schematic for integrated needle-IVUS system.

§5.3 Design Alternative 3: Catheter Based IVUS Probe

An insertable IVUS probe is temporarily placed within an 11 gauge core biopsy needle just before biopsy. With this method, the rotational probe or multi-transducer array can be used. While the rotational probes have higher spatial resolution and are generally better for intravascular imaging, the rotation of the probe may increase the noise created by reflection within the needle. Both probes are capable of 360 degree viewing; however, because the transducer is located inside the bore of the needle, its effective viewing angle is limited by the size of the cutaway portion, similar to the fiberoptic probe. With a multi transducer IVUS probe, it may be possible to turn off transmission of the transducers that are viewing the highly echogenic walls of the needle. Therefore, the multi-transducer array may be better suited for this specific purpose, but further testing is needed to explore its actual imaging properties. Also, the motor required for the rotational probe may make it unsuitable for MRI.

The viewing depth of the catheter-based system is identical to that of the integrated system (2 cm for 20 Hz, 5 mm for 40 Hz). Assuming MRI compatibility, it is a very practical

solution, as IVUS probes are widely available, currently used by many cardiologists in assessing vascular disease. Figure 6, outlines the basic biopsy procedure that will be followed using the catheter based IVUS probe. The main addition to the procedure is after the third MR image. The IVUS probe provides fine tuning of the needle placement. Accurate placement of needle is determined by the imaging presence of calcifications.

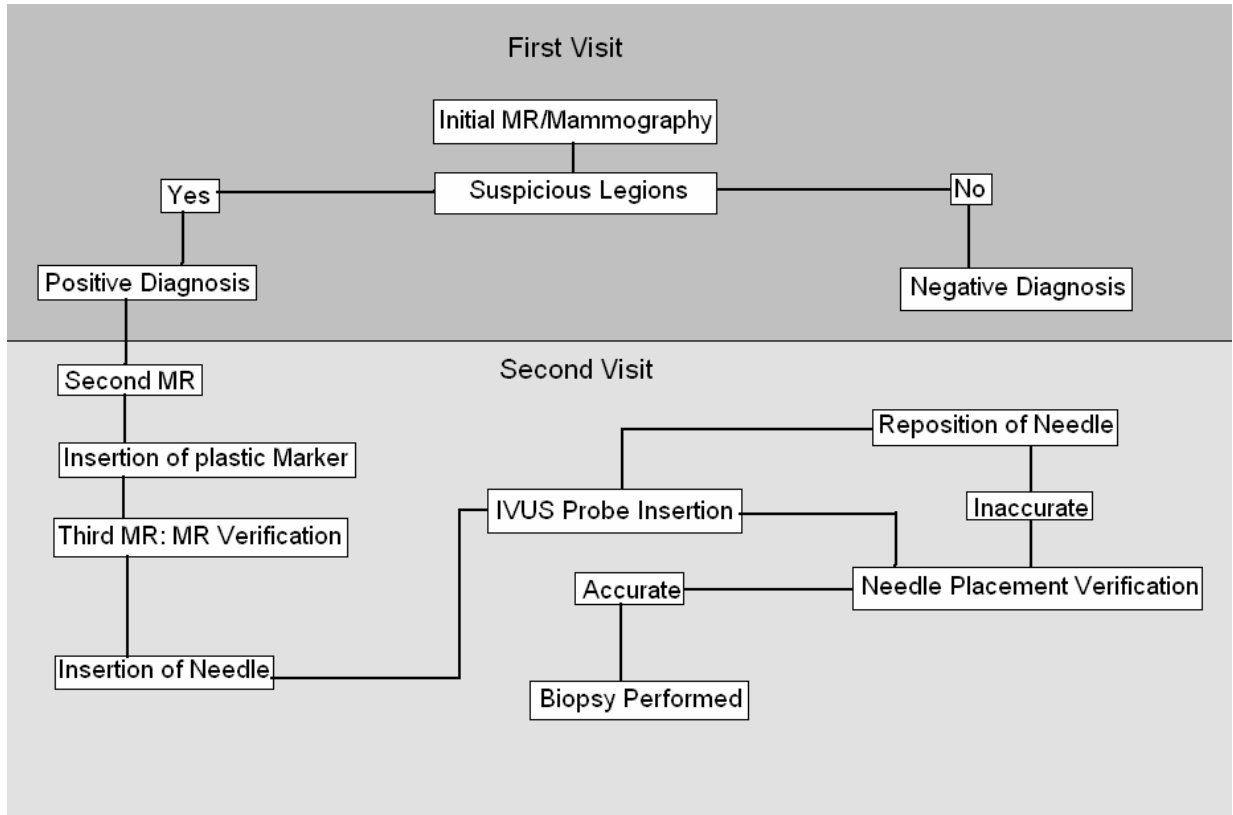


Figure 6. A flow chart modeling the revised biopsy procedure.

§6. Final Design

A design matrix was employed to compare the fiberoptic probe, integrated system, and catheter based system, using five selection criteria with a zero (worst) to 10 (best) scale (Figure 6). The fiberoptic probe is already being pursued by Dr. Ramanujam's team, and the integrated IVUS system requires a significant probe redesign before testing can begin. For these reasons, we propose to use a catheter based IVUS probe in conjunction with the core biopsy needle. This

design features low cost and is relatively easy to use. Its accuracy and precision are not yet determined, but significant testing will assess its ability to generate viable images. A 40 Hz commercial IVUS probe, available through the Medical Physics Department at UW-Madison, is currently under loan for use in initial testing (Figure 7).

	<u>Fiberoptic</u>	<u>Integrated IVUS</u>	<u>Catheter IVUS</u>
Price	2	0	10
Measurement	8	10	5
MRI Compatibility	10	7	7
Ease of Use	7	10	7
Ethics of use	2	9	9
Total	29	36	38

Figure 6. Design comparison matrix, using zero (worst) to 10 (best) scale. The catheter IVUS device received highest rating.

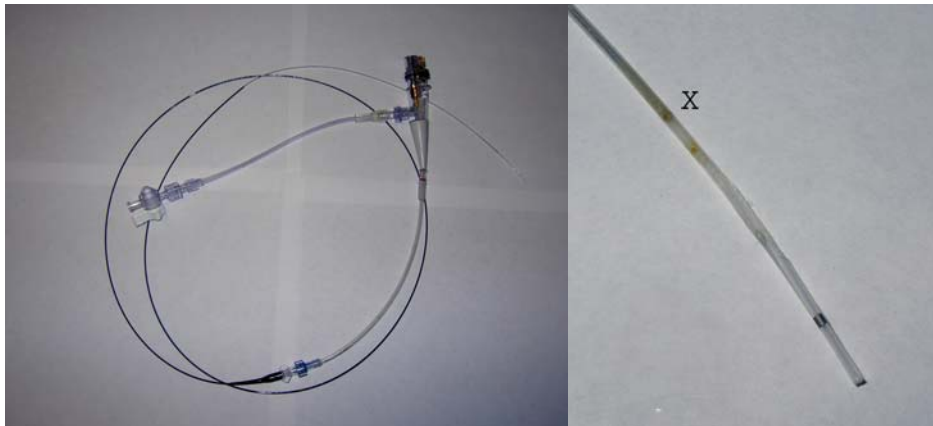


Figure 7. Catheter based 40 Hz IVUS probe used for initial testing (left). Close-up view of transducer, located at X (right).

§7. Future Work – Potential Problems

There is an extensive amount of future work needed to validate and develop the catheter based IVUS probe system as well as to develop an alternative method. Cancerous tissues of the breast have yet to be characterized by ultrasonic probes operating at 20 to 40 Hz, especially in the presence of a metallic biopsy needle. Significant testing is required to demonstrate the catheter based system's ability to distinguish abnormal from normal tissues, including both calcifications, an indication of *in situ* cancer, and small breast lesions.

Imaging is currently being conducted on an ultrasound machine located at the Medical Physics Department at UW-Madison (Figure 8). Preliminary investigations were conducted in a 100 mL beaker using microspheres of varying diameter (0.5-1.5 mm) in solution. This test demonstrated the most basic functionality of the isolated IVUS probe, as well as established its effective viewing depth. For the 40 Hz IVUS probe, we recorded a maximum depth of 5 mm, with signal attenuation occurring beyond 2.5 mm. This means the circular image does not extend beyond a 5 mm radius around the center of the transducer. The final design will most likely use a probe with frequency closer to 20 Hz, so that the effective viewing depth is approximately 2 cm.



Figure 8. Ultrasound machine at Medical Physics Department on UW-Madison campus used for initial testing of IVUS probes with phantoms. Data will be recorded on VHS and digitally captured.

§7.1 Phantoms

Testing will begin with the isolated probe. The first phantom consists of a jello mold containing small calcium-containing bird seeds to simulate cancerous *in situ* breast tissue. This will evaluate the probe's ability to identify the position of small calcifications without interference of the biopsy needle. Similar phantoms with grapes or watermelons can be used as well. The sequence will be repeated with the probe inserted into the biopsy needle. This will assess the capability of the probe to function as an imaging tool inside the core biopsy needle. Of particular concern is the amount of artifact produced by reflection from the inner metallic needle surface. Once the catheter based IVUS probe has passed initial testing, studies will be conducted using real laboratory specimens obtained from UW-Hospital.

Testing will also be required to assess functionality of the IVUS probe in a magnetic field. To do this, a large laboratory static electromagnet will be placed in close proximity to a

phantom setup. Comparisons will be made of the images with and without the magnetic field. We expect to see minimal distortion in the presence of a strong magnetic field.

§7.2 Three-Dimensional Ultrasonic Arrays and Alternative Probes

Currently, research is being done to develop three-dimensional ultrasonic micro-arrays that could possibly be used in the core biopsy procedure. This allows for three-dimensional imaging, alleviates the need for rotational IVUS probes, and greatly increases the field of view. However, the practical application of these arrays has not been determined, and it is unknown if they would be able to operate in an MRI setting.

It is possible that the IVUS probe may prove incompatible with the MRI setting. While it is impractical to rebuild a probe for this projects application, there are many corporations with the ability to redesign a probe to fit the specific needs of a magnetic operating environment. If the probe needs redesign an integrated IVUS probe may be reconsidered.

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Appendix A

Project Design Specification

March 12, 2004

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Problem Statement: The goal of this project is to improve breast biopsy yield by local imaging during MRI and Ultrasound guided stereotatic biopsy procedures.

Client Requirements:

- Spatial resolution must be approximately 1-2mm
- Depth perception must be approximately 3-5mm
- Must be equal to or less than two hundred dollars
- Must be able to distinguish small tumors and calcifications from normal tissue
- Must be able to operate within core biopsy needle with minimal artifact
- Must be MRI compatible (non-magnetic)

Design Requirements:

1. Physical and Operational Characteristics

- Performance Requirements- The device must distinguish between small tumors/calcifications and normal breast tissue during core biopsy procedures.*
- Safety- The device must comply to standards for medical devices established by the FDA . The device also must not increase the risk of the operation procedure for the patient.*
- Accuracy and Reliability- Results must be repeatable. It must improve the accuracy of current biopsy procedures. It must have a spatial resolution of 1-2 mm, and a depth perception of 3-5 mm.*
- Shelf Life- Typically the type of probe that will be incorporated into our design is only used for one or two applications.*
- Operating Environment-Must operate in sterile operation conditions. For MRI probe, it must be able to operate in a magnetic field of approximately 1.5-3 T.*
- Ergonomics- The modifications must be non-obtrusive to the surgeon while they are performing the biopsy. The wires that connect the probe to the data interpretation equipment must not impair the surgeon's movements. Display must be clearly visible to user while in MRI suite.*
- Size and Shape- Must fit within the core biopsy needle. The needle has an internal diameter of 3-5mm; 7 and 14 gauge needles.*
- Weight- Must be able to be hand held for the duration of the biopsy procedure.*
- Materials- Must be non-magnetic or minimally magnetic in order to be used in the MRI suite. They must be able to be sterilized and biocompatible for use during the biopsy procedure.*
- Aesthetics – No constraints.*

2. Product Characteristics:

- Quantity – Only one device is needed.*
- Target Product Cost- The device should cost equal or less than two hundred dollars.*

3. Miscellaneous:

- a. *Standards and Specifications- The device should comply to the guidelines setup up by the FDA for medical instruments. Further information is available online at the FDA's website, but it too extensive to specifically list. The device is classified as a Class II medical instrument, and is subject to performance and safety standards without exemption.*
- b. *Customer- The device must be non-obtrusive to the surgeon while he/she is performing the biopsy. The wires that connect the probe to the data interpretation equipment must not impair the surgeon's movements. Additionally, the probe must provide a determinate image of the needle placement in relation to the lesion in question.*
- c. *Patient-related concerns- The use of this device should not prolong the overall biopsy procedure in any way, but rather enhance the accuracy of the breast biopsy procedure.*
- d. *Competition- U.S. patent number 6,669,643 describes the use of catheters in combination with biopsy devices, however this is primarily for use in female vaginal and uterine chambers, rather than the breast biopsy procedure. Optical fluorescence is currently being developed as a method in order to guide biopsy needles by Dr. Nimmi Ramanujam, an assistant professor in the Biomedical Engineering Department at UW-Madison. Her device was developed based on the characteristic way in which molecules in cancerous cells respond to the fluorescence from the optical fiber.*

Appendix B: Ethical Concerns

There are number of things to keep in mind while designing a new medical device or making modifications to existing technology. Currently stereotactic breast biopsy is being used to accurately assess abnormal breast tissue. The overall cost for a patient undergoing these preliminary procedures is lower than the cost for those who may miss an early diagnosis and undergo an extensive cancer treatment. The goal of this design is to make the biopsy process even more exact. Consequences that could potentially emerge include rising procedural costs and a longer time required to perform the procedure. Additionally, doctors will need to adjust their biopsy practice to include the use of this probe, requiring more time and training.

When assessing the overall impact of the implantation of this new medical device on the health care system, some potential consequences can result. While it may seem that the use of this device will lower patients' health costs in the long run, the procedure may actually lead to an increase in the cost of health care overall. If the procedure proves lengthier than expected, a potential consequence for the doctors would be that they would not be able to take as many patients in one working day. This could lead to an increase in the cost of the procedure to compensate for any lost profits from seeing fewer patients.

With any new device, training and familiarization with the technology is required. Until the doctors utilizing this technology are able to properly execute the procedure, a greater possibility of inaccurate results exists. In the future, if such a device is implemented into the breast biopsy procedure, an assessment of its benefits will need to be formed in order to conclusively determine its value.