

Intravascular Ultrasonic Probe Imaging During Core Biopsy Procedures

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Abstract

MRI and mammography guided core biopsy procedures are currently subject to high specificity due to inaccurate imaging of small tumors around the biopsy needle. The implementation of an intravascular ultrasonic probe to image the area around the opening of the needle was explored. Ultrasonic imaging has been proven to differentiate abnormal tissue types by the differences in echogenic calcification concentrations. To allow for the use of the IVUS probe within the core biopsy needle a plastic insert was developed to correctly position the needle and reduce needle reflection. Phantoms were performed on orange slices, ultrasonic gel, and turkey using ground cuttle bone to simulate calcifications. With orange slices, the echogenic background prevented differentiation; however, the orange slice was considered a poor model of breast tissue. In ultrasonic gel it was easy to differentiate between surrounding gel and simulated calcifications. Imaging within the turkey breast, the most representative phantom, showed promising ability to differentiate tissue types, but required the use of the insert. Imaging within the needle without the insert had prohibitively high amounts of reflection artifact. Currently the IVUS probe system is not MRI compatible due to the magnetic components, but simple modifications could be made to achieve Zone III compatibility. To bring this system to market, further work is planned to explore probe redesign, imaging of actual excised tissue, and imaging dependence on probe frequency.

§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 yields via local imaging around the needle with an intravascular ultrasonic probe (IVUS).

§2. Background Info

To evaluate the diagnostic power of an IVUS based imaging system both breast cancer and the core biopsy procedure were evaluated.

§2.1 Breast Cancer

Core biopsy procedures are used to diagnose breast cancer, a disease in which early detection is crucial for successful treatment [8]. Annual mammograms detect 80-90% of breast cancers, including small non-palpable cancerous lesions, which cannot be found by self-exams. Nevertheless, a positive mammogram is only a sign of breast cancer and further testing using ultrasound and biopsies is often required [7].

Calcifications are small build-ups of calcium and minerals in the breast tissue, and are indicative of *in situ* breast cancers. Their frequency increases with age, but in general most are benign. Further testing is conducted if they constitute a certain size, shape, and distribution [10]. Fortunately, they are particularly visible using X-ray, MRI, or ultrasound.

§2.2 Core Biopsy Procedures

There are many procedures available for excising tissue 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. Small sections of suspicious breast tissue are removed with a specialized 11-14 gauge needle, which is hollow with a short cutting edge near its end (Figure 1). For palpable tumors, the needle is simply hand guided; non-palpable tumors often require image guidance using ultrasound or MRI [4].



Figure 1. A Sonos Surgical vacuum assisted 8 gauge MRI compatible core biopsy needle. The tubes lead to a pneumatic pump unit which provides cutting power for cutting and sets up a vacuum.

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. Three to six tissue samples are taken, with the entire procedure lasting 15 minutes [3].

The benefit of core biopsy is that it allows histological analysis by the pathologist. Comparison between abnormal and normal tissues is then possible, as samples are often large enough to contain both species. However, only samples of the suspicious area are removed, so the possibility remains for cancerous sections to be missed. Furthermore, very small tumors and calcifications may be covered up by the core needle itself. The radiologist is therefore 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, one cannot be sure if the lump is truly benign, or whether normal tissue was removed instead.

§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” [5]. 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” [5]. A main structural difference in our proposed design is that the imaging probe would be placed inside the core biopsy needle, whereas in the aforementioned patent an imaging

probe is used simultaneously but externally. 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 describes a method for imaging breast calcifications by “correlating an ultrasonographic data set with a radiographic image.” However, this method refers specifically to identifying the position of the calcification before biopsy, and does not insure placement of the biopsy needle once inside the breast tissue [1].

§4. Design Constraints

The device must adhere to FDA medical device standards, especially the ability to be sterilized and the requirements for accuracy. The device will be used in conjunction with either current ultrasound systems or MRI systems. As such, the device should be compatible with either of the systems. The numerous restrictions for MRI systems must be accounted for in the design process. Performance-wise, the system must have a spatial resolution of 0.5-1.0 mm in order to image small calcifications. Also, the device should be able to image the area 1.0-2.0 cm from the opening of a 9 to 11 gauge core biopsy needle. The workings of the device should not affect the biopsy procedure, and its use should not significantly increase the procedure time. An extended list of design constraints is available in Appendix A.

§5. Final Design

Before deciding on an IVUS system, various methods of improving biopsy yield were investigated, including an optical fluorescence system, an integrated IVUS system, and a catheter based system. After an extensive analysis of each of design, a catheter-based IVUS system was determined to be the most effective solution.

§5.1 Intravascular Probes

Ultrasound is a well-founded means of imaging, and is commonly used in almost all hospitals as a safe and effective 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 2-D and 3-D systems, arrays of transducers are aligned such that a reflection from a single point is received at multiple transducers. The received signals are out of phase. An image can be formed through a triangulation method using the known distances between the transducers. 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 (Figure 2). This probe consists of a pizo-electric ultrasonic transducer within a catheter that can be inserted into veins and arteries. A typical transducer used for this procedure is 100-130 cm long and 8-14 F in diameter. They are generally single-use probes, and currently cost approximately \$1000 each. 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 allows for an imaging depth of 1-2 cm around the probe. Both systems also use high frequency ultrasound (20-40 MHz) as compared to normal ultrasound (3-5 MHz), thus achieving higher temporal resolution at a cost of reducing imaging depth. 2-D image reconstruction is real time; however, spatial resolution is poor. 3-D imaging has been achieved using similar probes by stacking cross sections with the positions and orientations determined by a catheter tracking system. Unfortunately these systems are subject to streak artifact. [11]

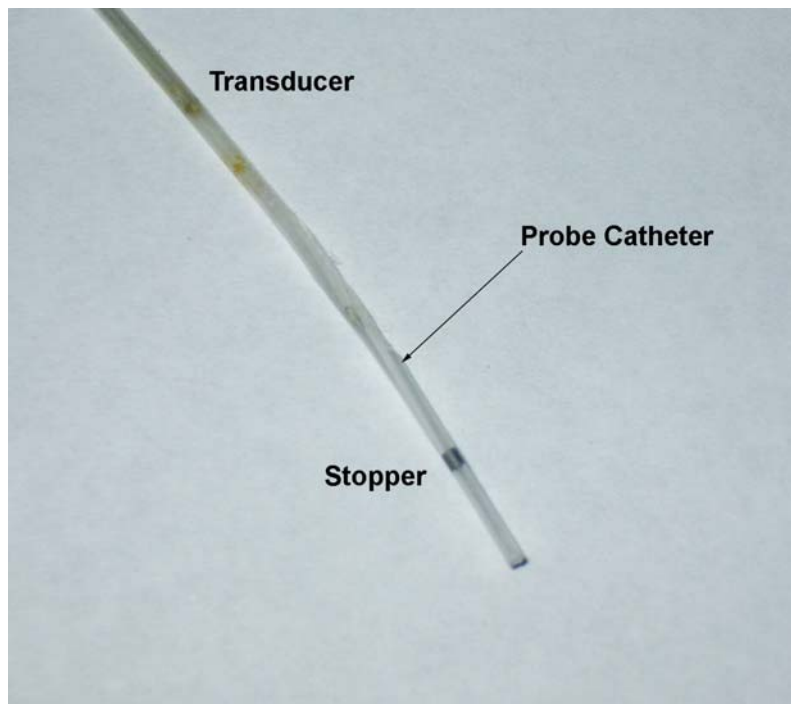


Figure 2. 40 MHz Discovery IVUS probe used for testing, on loan from Medical Physics, UW-Madison.

§5.2 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. 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.

The basic biopsy procedure will be modified when using the catheter based IVUS probe (Figure 3). 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.

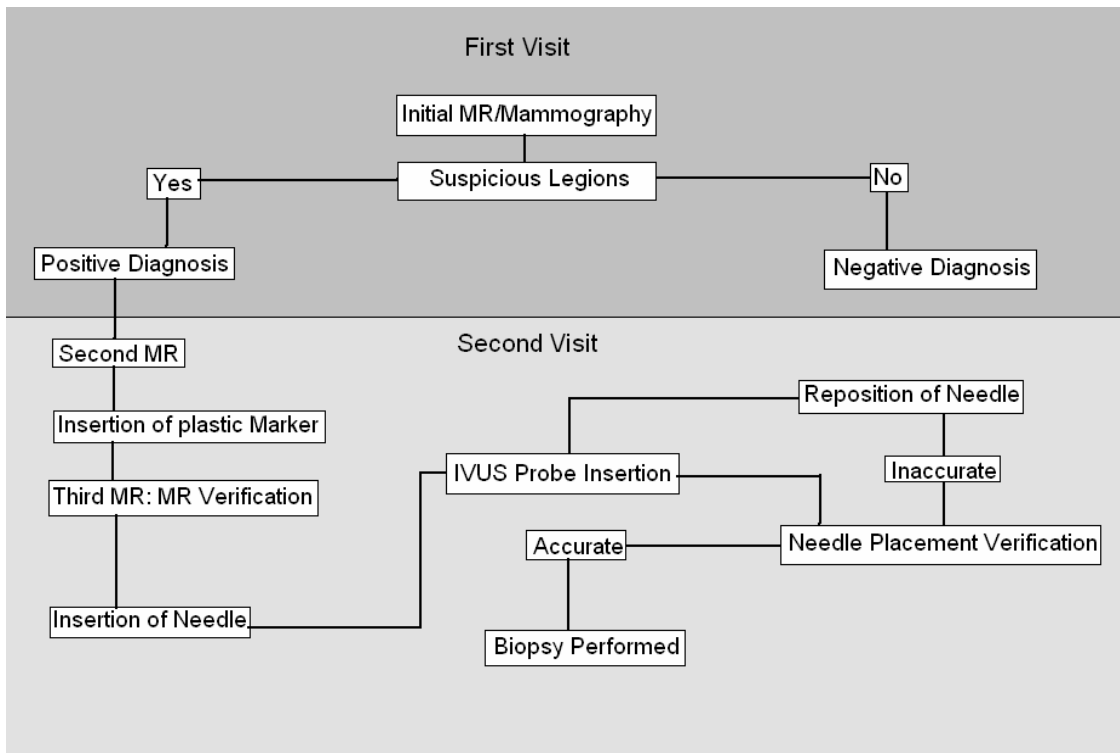


Figure 3. A flow chart modeling the revised biopsy procedure.

§5.3 Imaging Guide

Due to the extremely high echogenic interface of the needle-to-tissue interface and poor probe positioning, an insertable plastic imaging guide was created (Figure 4). Ultrasonic reflection is mostly due to impedance mismatches between materials. The IVUS probe currently sits inside a plastic based catheter, so the impedance difference between plastic insert and the plastic catheter should be reduced. Furthermore, by placing the probe in contact with the plastic, the reflection from the interface can be removed by adjusting the gain. Zeroing the gain from 0-0.2 mm removes the artifact from the insert but does not significantly reduce the imaging space.

Adjustment of the position of the IVUS probe is required to provide accurate characterization of the tissue around the needle in 3-D. If the IVUS probe alone is fed down the needle, its placement is unknown, and may be placed against the back wall of the needle preventing any imaging of the surrounding tissue. The plastic insert is designed to push the probe close to the tissue to maximize the imaging of surrounding tissue rather than the area within the needle (Figure 5). The plastic insert also allows for easier manipulation of the probe's position along the longitudinal axis of the needle. The user can easily grip the end of the insert to adjust position of the probe. The probe is attached to the insert with silicon providing some viscoelastic damping, filtering out high frequency vibrations that lead to motion artifact. A groove was etched into the cylindrical piece to allow a secure fit for the probe catheter. The effects of inserting the plastic piece into the core biopsy needle during image acquisition are summarized in *Results*.

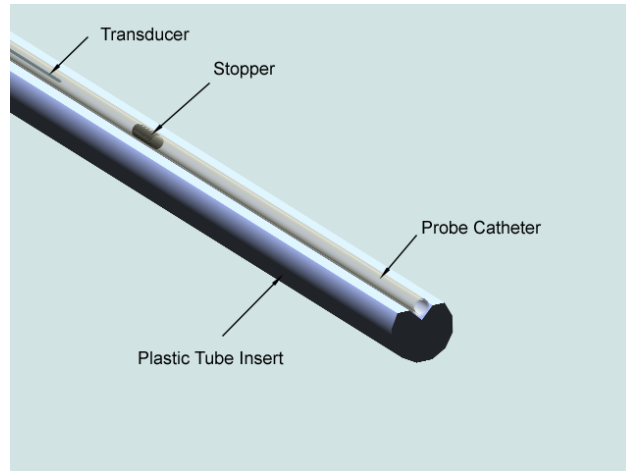


Figure 4. A graphical drawing of the IVUS probe with the plastic insert

The plastic insert was constructed from a 3.2 mm soft plastic rod found at a local hobby store. It was machined using a manual mill and a rod guide created from plexi-glass. This construction required gluing of the rod to the rod guide with a hot glue gun. Full scale implementation should be done using injection molded parts.



Figure 5. A 9 gauge core biopsy needle with the plastic insert

§5.4 MRI Compatibility

In order for a device to operate in the MR environment, it must be MR safe, operate in the MR environment, and not effect the MR acquisition. The proposed design is a Zone III device, meaning that is must be MR compatible in the imaging area, but not during MR acquisition. The primary concern in Zone III is the magnetism of the materials used to construct the device. No ferrous materials can be used; however, there are comparable metals and ceramics with low magnetic susceptibility that can be substituted. Also, the wiring of any produced device should be void of current loops [2].

While the probe in question was not MRI compatible due to the use of ferrous materials in the catheter and the motor; compatibility could be easily achieved, given the manufacturing resources. The conventional electric motor that is currently used to rotate the probe is the primary problem. In order to repair this problem an air driven motor is suggested. Compressed air is required to perform the biopsy procedure; hence, it is an ideal power source for a non-magnetic motor. Currently no motors satisfying the specifications of the device have been developed; however, many similar motors exist. Ideally, the motor will rotate at 1800 rpm, but as the reconstruction of images is dependent on the rotation, adjustments could be made to allow variable rotation. A pneumatic system was not constructed due to a lack of time and limited knowledge on ultrasound reconstruction. However, an outline for such a device was developed (Figure 6).

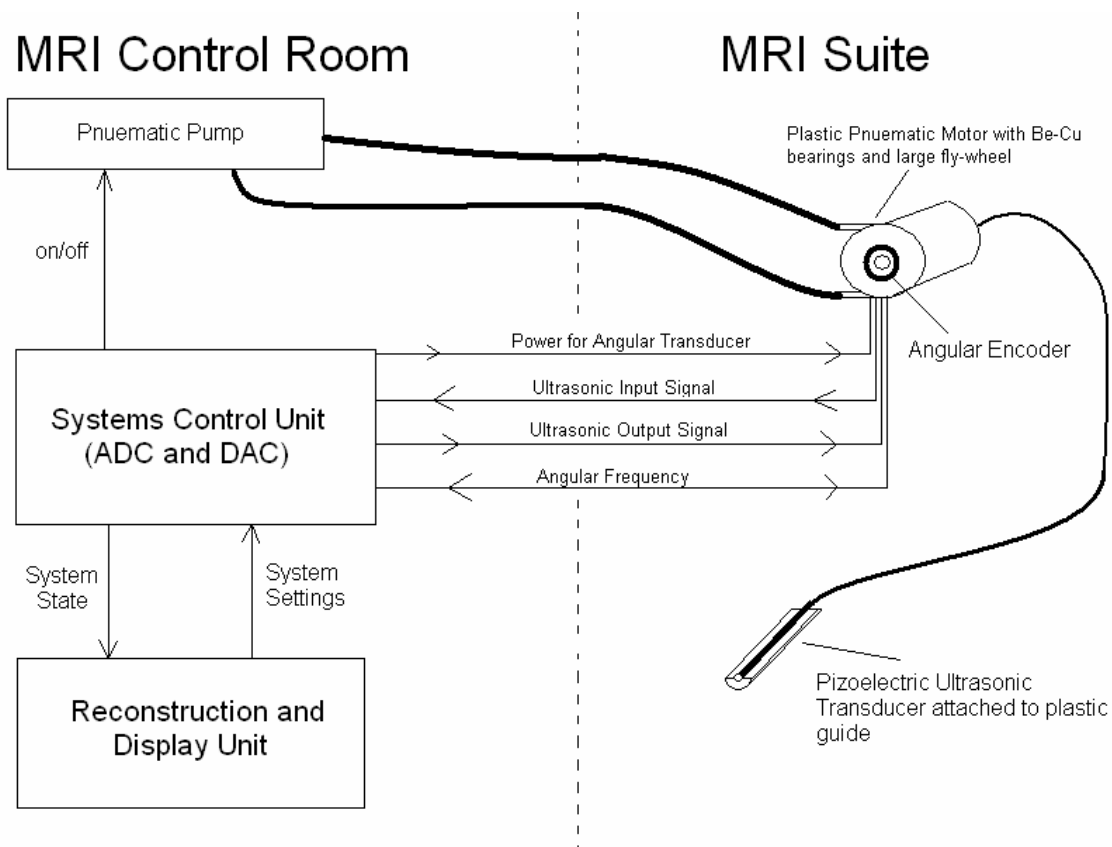


Figure 6. An outline for a pneumatically driven IVUS probe system.

§6. Methods and Materials

Tests were conducted under the direction Dr. Jim Zebzeski from the Department of Medical Physics located in the Medical Sciences building. All testing was done using 40 MHz Discovery probes attached to an electric control and image reconstruction system. Testing protocol was developed according to the regulations regarding the use of the IVUS system. In order to prevent motor burnout, the probe was turned on just long enough to obtain a steady image, and then turned off until the next image. The probe system was always flushed with water to ensure that the ultrasonic sound waves would pass through the catheter to image the surrounding area. The gain on the ultrasound machine was checked so that the signals furthest

away from the probe were being amplified more than the objects closest to the probe. This eliminates much of the noise created by the needle. All testing was recorded continuously on VHS tape and then digitally captured.

In nearly all cases, the probe was first inserted into an untreated phantom and images were obtained. Calcifications were then mimicked using “8 in 1: Sun Ripened Fruit Mineral Treat,” which contained 22.5 to 27% calcium by weight. Small pieces, approximately 3 to 4 mm in diameter, were manually inserted in the phantom with the probe placed nearby to obtain an image.

§6.1 Phantom #1 Ultrasonic Gel with Calcifications

To evaluate the raw imaging power of the IVUS system, an imaging test was first performed using a hollow plastic tube filled with ultrasonic gel. The ultrasonic gel allowed for imaging of a homogeneous system and allowed the sole imaging of individual calcifications without background interference. In triplicate, images were taken of the probe in a pure ultrasonic gel and then compared to images taken from a solution with intermixed calcifications 0.5-2.0 mm in diameter.

§6.2 Phantom #2 Orange Slices and Pulp

To evaluate the effectiveness of IVUS detection of calcification in a medium with significant interference an imaging test was done using an orange. A fresh navel orange was ground into a pulp and put into a hollow plastic tube. Images were taken of the baseline phantom and a phantom with calcification interlaced in triplicate. Images were also taken of individual slices from the orange with and without simulated calcifications.

§6.3 Phantom #3 Water with Suros Needle w/wo insert

To evaluate the effectiveness of the IVUS probe within a core biopsy needle, images were taken of water with the probe inside a needle. The needle used was a 9 gauge MRI compatible vacuum assisted core biopsy needle manufactured by Suros Surgical [9]. Three trials were taken for each of the following conditions: probe alone, probe inside needle, and probe inside the needle with plastic insert.

§6.4 Phantom #4 Turkey

Raw turkey breast is an accurate model of human breast tissue because it has similar acoustical impedance. Trials were taken in triplicate of both a normal and a calcified turkey breast under the following conditions: probe alone, probe with needle, and probe inside needle with plastic insert.

§7. Results

§7.1 Phantom #1 Ultrasonic Gel

Calcifications were easy to identify using ultrasound gel containing simulated calcifications (Figure 7). No background noise is noted with gel alone, while possible simulated calcifications appear as bright spots. The surrounding profile located at the edge of the image is the hollow plastic tube.



Figure 7. Ultrasound gel with probe alone in hollow plastic tube without simulated calcification (left) and with simulated calcification (X) (right). The profile of the hollow plastic tube is visible near the edge of each image.

§7.2 Phantom #2 Orange Slices and Pulp

Images from orange slices were inconclusive. Phantoms containing simulated calcifications appeared extremely similar to those without (Figure 8). Exact location of simulated calcifications was difficult, if not impossible, to determine. It is possible that fresh orange tissue contains enough calcium to cause background noise. It is not known how well fresh orange simulates breast tissue.

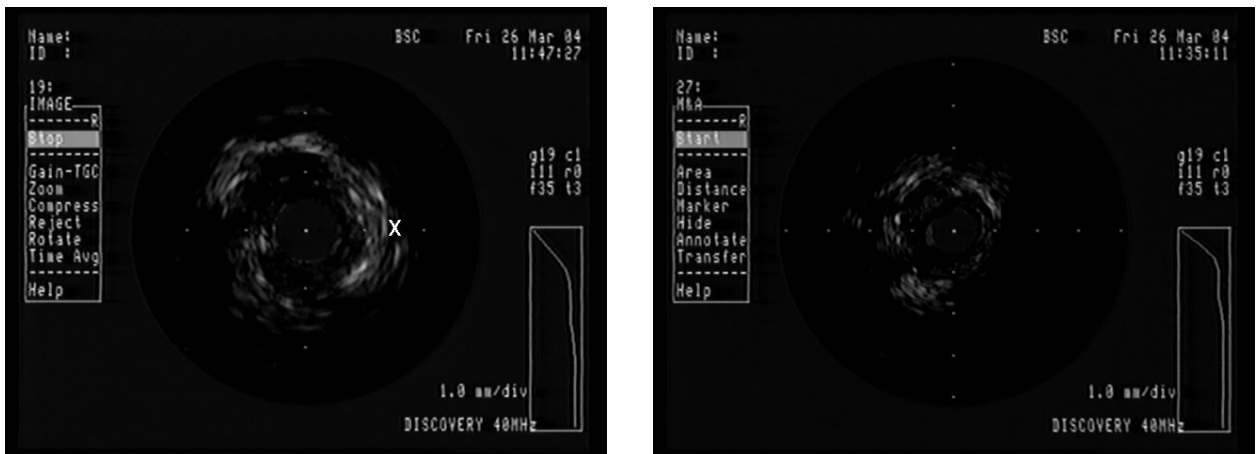


Figure 8. Orange slice with probe alone without simulated calcification (left) and with simulated calcification (X) (right).

§7.3 Phantom #3 Water with Suros Needle w/wo insert

A strong, sharp profile of the biopsy needle was visible in the absence of the plastic insert; little background noise was noted in either case (Figure 9, 10). Addition of the plastic insert reduced needle artifact.

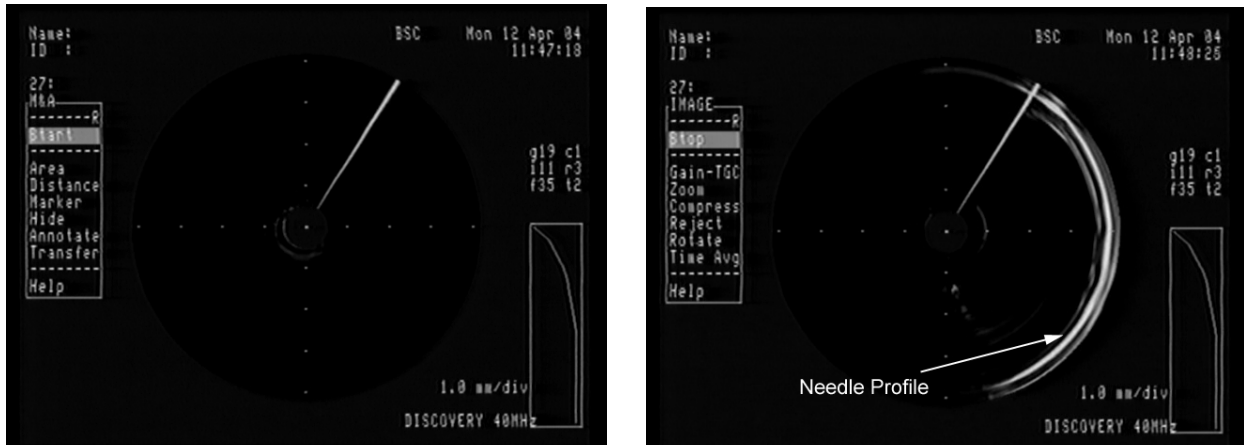


Figure 9. Probe alone in water (left). Probe in needle in water (center). Probe in needle with plastic insert in water (right).

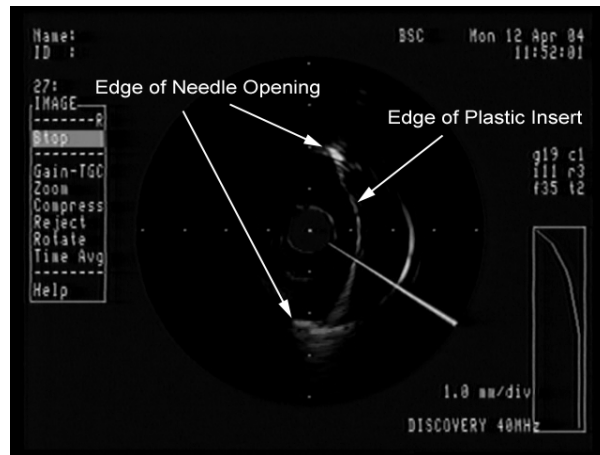


Figure 10. Probe in needle with plastic insert in water (right).

§7.4 Phantom #4 Turkey

Very little background noise was noted with the probe alone in raw turkey breast, and simulated calcifications were easy to detect (Figure 11A, 11B). Strong reflection occurred from the inner walls of the biopsy needle when the probe was inserted (Figure 11C). It was difficult to distinguish the cutaway portion of the needle opening from the remainder of its profile. Calcifications were still visible (Figure 11D). Needle artifact was greatly reduced when the plastic insert was used, and calcifications stood out more against the black background (Figure 11E, 11F). The plastic insert was weakly visible. In some tests the very edges of the needle opening remained highly visible, but in all cases the remainder of the needle profile was faint. The location of the needle could be determined by identifying these bright edges in some images. In general, distinguishing the needle profile from the cutaway portion (where tissue was located) was much easier in video footage versus a static image. As the probe was fed in and out through the tissue, the cutaway portion of the image changed greatly as tissue passed by the transducer, while the portion of the image showing the needle profile remained nearly static.

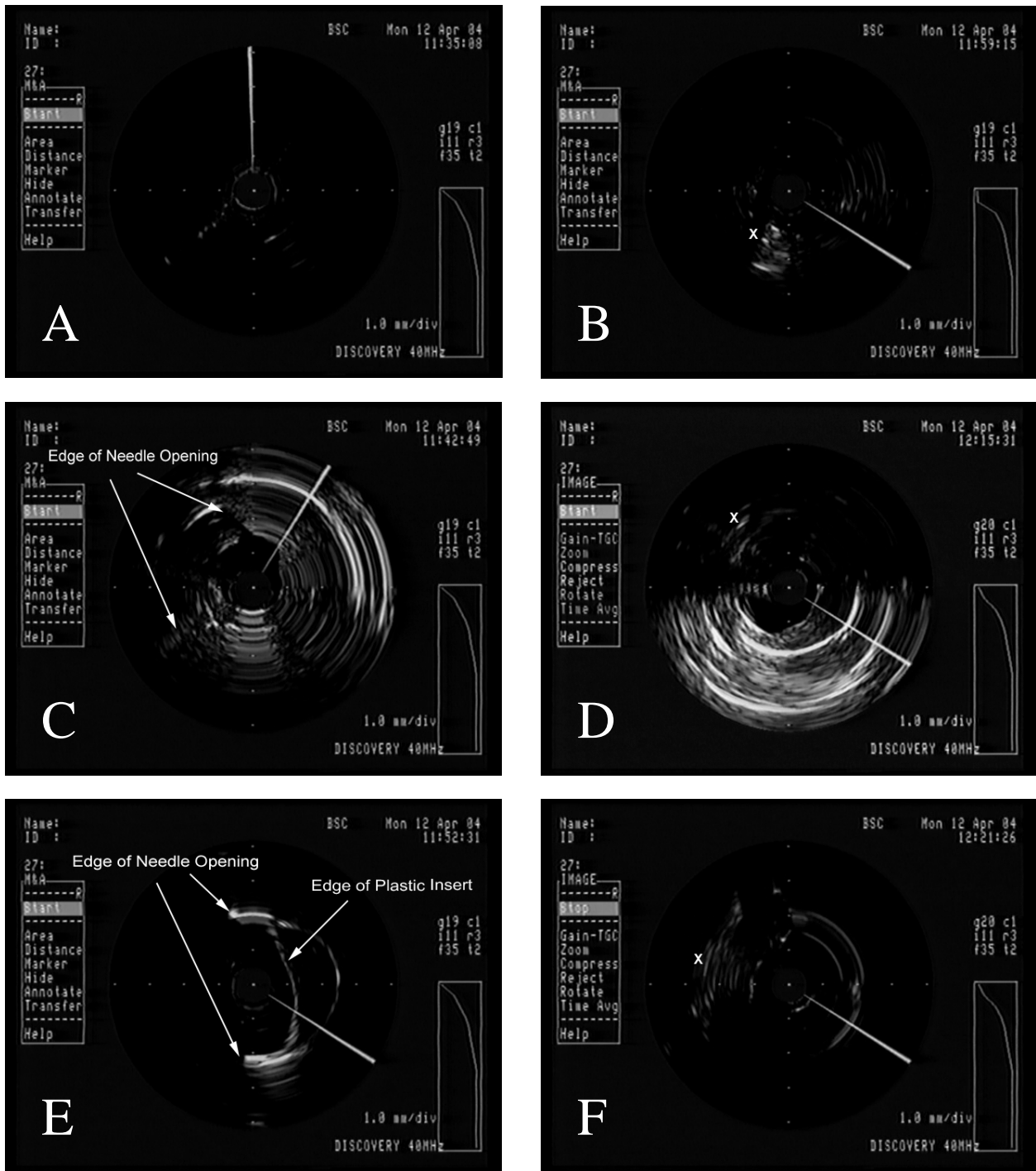


Figure 11. Phantom is raw turkey breast without simulated calcifications (left: A, C, E) and with simulated calcifications (X) (right: B, D, F). Imaging type is probe alone (top: A, B), probe in needle (middle: C, D), and probe in needle with plastic insert (bottom: E, F).

§8. Discussion

The catheter-based IVUS system is a promising one, especially when the plastic insert is used in conjunction with the probe. In the final phantom, the raw turkey breast, calcifications were clearly visible against a black background. The turkey breast is an excellent model for human breast tissue; we believe similar results are possible with a real specimen. The plastic insert removed most of the needle artifact in the turkey phantom, allowing higher contrast for viewing calcifications. Better imaging was also possible with the plastic insert as the transducer was always positioned at the opening of the biopsy needle. Without the insert, the transducer was positioned closer to the needle wall in some images, limiting the viewing angle.

In tests completed so far, the probe was not glued to the plastic insert as in the final design. Rather, the two were held together by hand while insertion into the needle. Images should be obtained with the probe glued to the insert, so as to characterize the viscoelastic effect the glue may have on the system. Additionally, the phantoms did not test the ability of the IVUS probe to differentiate breast tumors from normal tissue. Rather, only simulated calcifications were used. If the probe is not able to correctly identify breast tumors, its application is severely limited.

§9. Future Work – Potential Problems

To bring this design to market, there are many avenues that could be pursued, each with distinct pros and cons. One avenue that could be pursued is a complete redesign of the IVUS system. While this method would require an extensive amount of work, it may be the most practical long term solution. Currently IVUS probes are manufactured to fit in the smallest of arteries, and hence are costly (\$1000/procedure). In the case of biopsies, the probe may be much larger, and therefore less costly. This system could also include the redesign of the motor to

allow for MRI compatibility. Hospitals should be able to use the same IVUS equipment they currently have, by simply using a new probe. However, this method may take an extended period of time to develop.

The quickest way bring the system to market is to perfect the current method and evaluate it with more complex phantoms. The first phantom that could be tested would be a mammography coupled phantom. A mammogram may be taken of one of the current phantoms to determine the size, shape, and distribution of calcifications. This could be done at the medical physics labs using a Siemens ultrasound machine with an 8 MHz linear probe. Also, phantoms have not been done with real tissue. Additionally, tumors could be simulated in turkey breast using olive pieces. Such tests must be performed to validate the system. This method will not be MRI compatible; however, it could be used with mammogram guided biopsies.

§10. References

1. Burke, T.M. and Carrott, D.T. 2002. Optical correlator assisted detection of calcifications for breast biopsy. US Patent, 6,421,454.
2. Chinzei K, Kikinis R, Jolesz F. 1999. MR Compatibility of Mechatronic Devices: Design Criteria. Proc. MICCAI 99 Lecture Notes in Computer Science. 1679:1020-31.
3. Core Needle Biopsy. Imaginis. Last Updated: January 5, 2001. Date Accessed: February 8, 2004. URL: <http://imaginis.com/breasthealth/biopsy/core.asp>.
4. Diagnosis by Biopsy. 2003. The Breast Center at Southern Illinois University School of Medicine. Date Accessed: February 9, 2004. URL: <http://www.siumed.edu/breastcenter/diagnosis.html>.
5. Dubinsky, T.J. 2003. Method and apparatus for sonographic examination, biopsy, and excision. US Patent, 6,669,643.
6. Lees W. 1999. 3 and 4 Dimensional Ultrasound Imaging. *Medicamundi*. 43(3):23-30
7. Nissen S. 2001. Coronary angiography and intravascular ultrasound. *Am J Cardiol*. 87(4A):15A-20A
8. Signs & symptoms. (2003) *National Breast Cancer Institute*. Retrieved February 11, 2004 from http://www.nationalbreastcancer.org/signs_and_symptoms_/index.html
9. Suros Surgical: Product Line. 2004. Suros Surgical. Retrived April 24, 2004 for <http://www.surossurgical.com>.
10. Trevino, M. (2003, December 12) Calcifications may be presage invasive breast cancer. *Diagnostic Imaging Online*. Retrieved February 11, 2004 from <http://www.diagnosticimaging.com/dinews/2003121201.shtml>
11. Yock, P., Johnson, E., and David, D. Intravascular ultrasound:Development and clinical potential. *American Journal of CardiacImaging* 2(185)

Appendix A.

Project Design Specification

May 5, 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 .5-1mm
- 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. The overall cost for a patient undergoing core breast biopsy procedures has the potential to be 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 as well as an extended procedural time. 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. Additionally, IVUS single-use probes can be quite costly, ranging from \$1000 to \$1500 each. At this current time the actual cost of the procedure is unknown, and it is therefore difficult to predict whether or not it will prove financially advantageous when considering the overall costs of treating the 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.

Appendix C. Project Expenses

<u>Item</u>	<u>Cost</u>
Cuttle Bone	\$5.00
Turkey Breast	\$8.00
Plastic Insert Material	\$4.00
Use of IVUS probes	\$0.00
<u>Machining Help</u>	<u>\$0.00</u>
Total	\$17.00

Appendix D. Needle Schematic

