Abstract
The following document presents our final design to modify the current fine needle aspiration (FNA) procedure used to diagnose abnormal cells in breast tissue. FNA is one of four commonly performed techniques used to remove tissue or cells during a breast biopsy. Often a sample taken using FNA is declared insufficient by the cytologist doing the analysis. This can be due to either lack of cells or the cells obtained remain in a clump, which makes analysis difficult. It is for this reason that there is an attempt being made to modify the needle used to perform the FNA in the hopes that the modifications will increase the amount of material exhumed from the site in the breast as well as to break up the cells that are removed. An increase in material would allow the cytologist to diagnose the cells or tissue with only one FNA attempt. Currently, multiple attempts need to be made before adequate material is removed. The needle design chosen is a microdrill bit insert, which has been tested on fixed tissue samples to allow for evaluation of the technique’s success. Results were promising after two series of tests.
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Client Statement

Dr. Elizabeth Burnside, assistant professor and chief of breast imaging, performs between one and four breast biopsies each day. Two biopsy methods often used by Dr. Burnside are core biopsy and fine needle aspiration (FNA). While core biopsy almost always obtains sufficient samples, it poses many disadvantages. One disadvantage is that it is a more invasive procedure [4]. Second, a loud noise occurs during the procedure, which can scare the patient, and third if the mass is found near the ribs there may be a risk of internal injury to the ribs due to this procedure. FNA is the least invasive method for breast biopsies and is most comfortable and affordable for the patient (given that the first sample is sufficient). However, FNA is often unsuccessful due to the difficulty of retrieving a sufficient sample through a small needle (approximately 20-gauge). When an insufficient sample is obtained, either the FNA procedure is repeated or a more invasive biopsy method, such as core biopsy or vacuum-assisted biopsy is performed. The waiting involved with repetition of the FNA procedure often adds to a patient’s already heightened anxiety. As a result of the insufficient samples associated with FNA, many physicians are straying away from this minimally invasive technique.

Dr. Burnside would like us to modify the current FNA needle (Inrad Aspiration Biopsy Needle), by developing a small needle with a unique tip or insert that would maximize the tissue obtained and increase the diagnostic yield of this very valuable procedure.

Background Information

Techniques:

There are approximately four needle aspiration procedures performed to remove tissue or cells. Each procedure differs in how it is performed, the equipment used, and the type and amount of tissue it removes. The four procedures are fine needle aspiration, core needle biopsy, vacuum-assisted biopsy and large core biopsy.

The fine needle aspiration (Figure 1) procedure is fast, minimally painful, and involves no incision. The surgeon uses a fine hollow needle that is sometimes attached to a syringe to extract fluid from a cyst or cells from a solid lesion. Once the needle is removed the sample is delivered to a cytologist, who immediately analyzes the sample. Often the cytologist declares the sample as insufficient (lacking a large enough number of cells in question), in which case the physician either repeats the FNA procedure or uses the core biopsy procedure to obtain a larger sample [4]. In the case that the sample is sufficient, the cytologist will declare the sample as cancer or fibrinoma (non-cancerous). Often the patient will be informed of the test results before leaving.

Figure 1: Fine needle aspiration,
http://www.imaginis.com/breasthealth/biopsy/fine
Core needle biopsy (Figure 2) is similar to fine needle aspiration, but the needle is larger, enabling a larger sample to be obtained. It is performed under local anesthesia and ultrasound (Appendix C) or mammography (Appendix B) is used if the lump cannot be felt. Three to six needle insertions are needed to obtain an adequate sample of tissue [13]. A loud clicking sound may be heard as the samples are being taken and the patient may feel some pressure, but should not feel pain. The procedure takes a few minutes and no stitches are required. Core needle biopsy may provide a more accurate analysis and diagnosis than fine needle aspiration because tissue is removed, rather than just cells. This procedure is not accurate in patients with very small or hard lumps [3, 13].

Vacuum-assisted biopsy (Figure 3) utilizes a vacuum-like device to remove breast tissue. Local anesthesia is used and no incision is made. Mammography is used to guide a breast probe to the lesion. Computers pinpoint the mass and suction draws out the breast tissue. The needle is inserted once to obtain multiple samples. In some cases, the entire lesion may be removed. Vacuum-assisted biopsy is safe, reliable, and valuable for patients who are not candidates for other minimally invasive biopsy techniques and those who wish to avoid surgical biopsy [9, 13].

Large core biopsy, also called advanced breast biopsy instrumentation (ABBI) shown in Figure 4, is an alternative for patients who prefer a less invasive procedure than surgery. Large core biopsy is able to remove a sizeable specimen or an entire lesion using a surgical device and mammography. It combines wire needle localization and the ability to remove a tissue specimen and allows the sample to be removed in one piece. After the region is numbed using a local anesthetic, the localizing needle is guided to the lesion. A very small incision is made and a cannula (i.e., a tube and a cutting device) is passed through the incision. Breast tissue is removed through the tube. The procedure takes 30 min. to 2 h., but it generally takes less than 1 h. [13]. A few stitches may be required to close the opening in the skin.
**FNA Biopsy Procedure:**

Fine needle aspiration may be performed under local anesthesia. After the skin of the breast is cleansed, ultrasound or mammography may be utilized to help the physician guide the needle into the breast and to the non-palpable lesion. Using a small gauge needle to avoid dilution with blood, the needle is inserted into the mass to be used as a cutting tool. Subsequent short 5 mm “in-and-out” motions are performed until material is seen coming up into the hub of the needle [11]. Once material is seen in the hub, negative pressure on the syringe is released and the needle is removed from the body to make slides. If no material is seen in the hub or syringe, the “in-and-out motion” is continued for approximately 15 to 20 strokes [11]. Then, the needle is removed from the body and an attempt is made to transfer the material from the needle to a slide. This procedure is repeated, using a clean needle, until enough material is removed from the site. There is no incision and a very small bandage is put over the site where the needle entered. However, the pathological evaluation can be incomplete because the tissue sample is very small. When used alone, about 10% of breast cancers may be missed [11]. The effectiveness of this procedure depends on the skill of the surgeon or radiologist who performs it.

Dr. Burnside has varied the aspiration technique in an attempt to obtain a larger number of cells. Three attempted variations include the use of: pressure induced by a syringe, a larger diameter needle, and a vacuum assistance device. However, none of the attempts have resulted in a significant increase in the number of cells obtained. The first change in technique, to augment the needle’s spearing of the lesion with a syringe, in theory would assist in packing cells into the hollow of the needle. Using the plunger of a syringe did not obtain a larger number of cells. The cells in the lesion are held tightly together so that when pressure from the syringe is applied, the clump of cells is simply held more tightly at the tip of the needle. The force from the syringe is not sufficient to overcome the forces holding the cells together.

The second attempt was to increase the diameter of the needle. Dr. Burnside used an 18-gauge needle instead of the 25 or 20-gauge needle to extract more cells. This change was not successful because the larger diameter of the 18-gauge needle collects an aggregated sample, which increases the difficulty of the cytological analysis. Also, if a 25 or 20-gauge needle does not collect a large enough sample due to aggregation of the cells in the breast, simply using a larger diameter needle is not likely to obtain a larger sample.

Another attempt to modify the procedure was to use a vacuum assistance device. This device is similar to the syringe, but uses more vacuum. The needle is attached to the device through tubing. The problem that occurred with this technique is that the tubing collapsed due to the high vacuum.

The collected sample is transferred from the physician to the cytologist. Slides are made by touching the end of the needle to the end of a glass slide and releasing one or two drops of the material that was collected. If too much material is released on the slide, the layer will be too thick for optimal interpretation. A thin monolayer of cells is desired. After the material is placed on the first slide, a second slide is set on top of the first allowing the drop to spread. The slides are then fixed with

![Figure 5: Stained cytological slide, http://breastdoctor.com/breast/surgery/](http://breastdoctor.com/breast/surgery/)
95% ethyl alcohol [11]. Slides are made until all the material in the needle is used. The fixed smears are stained and examined by a pathologist under a microscope. Figure 5 is an image of a stained cytological slide containing both normal and cancerous cells. The cancerous cells can be identified by their increased size and purple color.

**Other Needle Manufacturers**

If FNA is such a valuable procedure why haven’t more physicians or needle companies modified the aspiration technique to solve the widely found problem of insufficient samples? Inrad, the company producing the needle Dr. Burnside uses, has not developed modifications to the aspiration technique. Boston Scientific and Cook, two companies also producing aspiration needles have also not developed modifications to aspiration. Dialogue with Gregory Waniorek, District Manager from Cook, revealed his opinion that aspiration is an old-fashioned technique that has been updated by core biopsy. He feels that core biopsy is more accurate and quicker than aspiration. Consequently, Cook has not considered finding a modification to aspiration; in a sense, doing so would be “reinventing the wheel.” Although this sentiment may be shared among many companies, many physicians like Dr. Burnside are faithful to the benefits of aspiration.

**Design Constraints**

The client would like us to modify the needle, so FNA could gain more confidence by medical professionals as a more effective, minimally invasive means of obtaining cell samples over more invasive procedures such as core biopsy. For FNA to gain popularity among breast cancer specialists, a larger undamaged cell sample needs to be obtained on the first attempt.

The modifications made to FNA need to follow specific constraints requested by the client. These constraints include the needle gauge remaining between 20-25, but preferable 23. The cost of the needle and equipment should be kept at a minimum (currently the needle costs approximately $5.00). The cells should not be damaged or be spread too far from the needle tip (approximately 2 mm), due to any modifications made, during excision. The modifications made would penetrate varying density masses and the procedure should only be performed once. The procedure and equipment should remain approximately the same as what is currently used, causing minimal to no pain when performed. The equipment modifications should remain intact within the body (it should not break or fall apart while the procedure is being performed). A successful quantity (approximately six clumps with four to five cells in each clump) of material (material should be separated cells and not whole tissue) would be exhumed on the first attempt, instead of having to repeat the procedure over and over.

**Alternative Design Solutions**

**Prototype Designs**

Two modifications of the current aspiration needle that would meet the design constraints were chosen. These designs include the spring and drill bit inserts. These two designs involve inserting a specialized wire into the currently used needle. The purpose of the specialized wire is to break up the aggregated cells. First the whole needle (with the wire inside) would be inserted
into the breast, as it is currently. Then the specialized wire would be extruded from the tip of the needle into the lesion and rotated to help break up the cells. Finally, the wire would be removed.

![Figure 6: Spring Insert](image)

The spring insert could come from one of two methods. The first method would simply be the purchase of a pre-made spring that is of the dimensions that we need. A problem with this approach may be that at the micro-scale desired, the inner diameter of the spring may be too small for cells to fit thereby detracting from the main benefit of using a spring design. A second form of production would be to flatten wire and then spiral it into a spring design or to buy flat, narrow strips of metal and spiral them into the spring design (Figure 6). This approach may provide a larger inner diameter thus allowing for a greater number of cells to be captured by the insert.

![Figure 7: Drill Bit Insert](image)

A second solution is the use of a pre-made microdrill bit (Figure 7). It is possible to purchase drill bits that will fit into a 22 or smaller gauge needle (see Tables 1 and 2 below). The only obstacle is that these drill bits are only manufactured about 25 mm in length, and therefore are much too short to be used effectively inside 60 mm biopsy needles. A solution involves either welding or soldering another wire onto the end of the drill bit to increase its length, but this is a very difficult task to perform accurately at such a miniature scale.

Both designs would be inserted into the lesion and twisted. As the insert is twisted, cells would travel up the fluting of the shaft and into the needle. These designs would be favorable in
extracting the cells because they not only are able to break up abnormal cellular clusters but extract cells as well. After testing was completed using enlarged-scale prototypes, both spring and drill bit inserts were shown to be effective in dispersing and collecting the testing medium. Disadvantages are that the design may still damage the cells and may remove cells in chunks. Also, the process of forming the wire into a spiral may lead to an irregularly shaped wire that may no longer fit into the needle. In the case of the flattened and twisted wire, the scale may be small enough that the flattened wire will not be rigid enough to extract cells. Also it may defeat the purpose of this design because the inner lumen will be exceptionally small.

Fabrication Methods for Prototypes

Currently, we have three possible modes of production for our prototypes. The first, and most feasible, is the Mechanical Engineering Shop where either the drill bit can be made from a bored out wire or the spring insert could be formed as described above. The second form is to use laser etching to form the fluting of the drill bit. The third involves the use of a geometrically set pattern of acid-catalyzed degradation of a metal wire leaving the drill bit design desired.

Table 1: (Left) Common FNAB needle dimensions (for regular wall thickness).
Table 2: (Right) Pre-fabricated micro drill bits by industry standard number.

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<th>Needle Gauge</th>
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<th>Inner Diameter (inches)</th>
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<td>0.0250</td>
<td>0.013</td>
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<tr>
<td>22</td>
<td>0.0280</td>
<td>0.016</td>
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<tr>
<td>21</td>
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<td>0.020</td>
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<tr>
<td>20</td>
<td>0.0355</td>
<td>0.024</td>
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<table>
<thead>
<tr>
<th>Drill Bit Number</th>
<th>Outer Diameter (inches)</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>80</td>
<td>0.0135</td>
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Final Design Solution

The final design consists of a pre-manufactured microdrill bit (Figure 6) with a 6’’ length and a 0.015 ‘’ diameter and a standard 23 gauge needle. The pre-manufactured long drill bit eliminated the task of finding a method to lengthen a more standard 25 mm length drill bit. The drill bit, manufactured by Electrodes Inc., slides smoothly inside the needle. The drill bit is housed inside the hollow of the needle. During a biopsy procedure, the needle is inserted into the tissue with the drill bit retracted. After the needle is in place, the drill bit is simultaneously twisted and inserted into the tissue. The drill bit is also twisted as it is pulled back into the needle. Finally, the needle is removed from the tissue and the sample is collected from the drill bit.
twisting motion was expected to pull cells up the fluting of the drill bit, which was theorized to collect a larger sample than the original FNA technique. One advantage of the drill bit design is that it not only extracts cells, but also breaks up abnormal cellular clusters. Disadvantages are that the design may damage the cells and may still remove chunks of cells. Also, removal of the sample from the drill bit may be more meticulous for the cytologist than from the needle alone.

**Materials:**
Options found for currently produced microdrill bits were stainless steel, titanium nickel (TiNi), and a cobalt alloy. Despite the many options, the use of the same material that is used in the needle itself would be ideal in order to avoid a galvanic reaction between two different metals in close contact, which would have the possibility of altering the chemical and physical properties of the needle and insert.

**Testing:**
Two series of tests were carried out. The first was performed to get a general idea of the procedure, while the second was performed to determine the effectiveness of the technique. The first test was performed on November 2, 2002 in the Anatomy Lab in Noland Hall. Fixed cat lymph, fat, and mammary tissues (Figures 7) were used for testing. The test entailed performing FNA with the current and modified techniques on each of the tissue samples. Two samples were taken of each tissue using both techniques for a total of 12 samples. All samples were saved on microscope slides for comparison. For more detailed information on the procedure used see appendix D.

The current technique’s results varied from no sample to a clump of tissue. These two extremes are not desirable. The modified technique required a drop of saline to remove the sample from the drill bit, while samples from the current technique were removed without saline. Because of the saline, the drill bit technique appeared to have less material than the current technique. After microscopic analysis, it was determined that cells were present even if they were not seen by the naked eye. The main difference between the two techniques was that the current technique resulted in either a mass of cells or a minimal quantity of cells (Figure 8) depending on the tissue sample, whereas the drill bit sample contained many dispersed cells (Figure 9) which was not dependent on the tissue sample. Pictures from the first test have questionable accuracy since the slides remained exposed for approximately a week before microscopic analysis. Because the first test was performed for a better understanding of the procedure, we were able to make necessary changes due to experimental errors during the second round of tests.
The second round of testing was performed on December 6, 2002 in the Medical Sciences Center. The same procedure was performed as in the first tests, except microscopic pictures were taken immediately after the sample was obtained, and saline was used during both techniques to aid in the removal of the sample. The comparison of samples from current and modified techniques was similar that of the first test.

![Microscopic images of fixed cat lymph, fat and mammary tissue samples obtained using the current technique during the December 6, 2002 test date.](image1)

![Microscopic images of fixed cat lymph, fat and mammary tissue samples obtained using the modified technique during the December 6, 2002 test date.](image2)

Analysis of the pictures taken after testing, leads to a hypothesis that the modified technique obtains a larger quantity of dispersed cells than the original technique. Additional testing followed by a comprehensive analysis should be performed to verify the initial assumption. Initial findings concur with Dr. Burnside’s objective.

**Future Plans**

Significant progress was made this semester with the FNA modification design, but product development is still incomplete. Additional testing, cytologist assistance in analysis of the slides and of the behavior of the tissue and cells, and slight design changes must still be performed. Testing should be performed on materials of varying densities since lesions in the breast also have varying densities. Future testing will eventually need to move beyond non-human, non-living tissue into clinical trials. This will require Board approval at the given hospital as well as approval for testing by the Federal Drug Administration.
Two experimental parameters could be modified. First, each slide should have a more uniform drop of saline to ensure an equal concentration of sample. Second, multiple pictures should be taken of each slide to ensure that the pictures are truly representative of the sample. These two experimental conditions should be changed before further testing is performed. Due to variations caused by different personnel performing FNA, multiple people should perform both techniques to ensure consistency. Future testing should be performed on live samples. There are two possibilities to perform testing on live animals. The first option is to create our own protocol for testing through the Research Animal Resource Center (RARC). The second option is to amend to a principal investigator’s existing protocol and test on the live animals in their lab.

Because of a lack of cytological experience, one ambiguity in this semester’s testing was that it was difficult to determine what on the microscope pictures were cells and what was contamination or bubbles. Except for the relative comparison of slides from the two techniques, determining whether or not the drill bit sample was sufficient still remains irresolute. Attempts were made this semester to find a cytologist to either analyze the samples or teach us how to analyze the samples, but connections were not successfully made. Thus, next semester, a further attempt will be made to find a cytologist to help resolve the uncertainties. Characteristics to be evaluated, by the cytologist, are the tendency of the tissue to aggregate to itself after being removed from the needle (large clumps of tissue are difficult for cytological analysis), the tendency of the material to stick to the needle (sample obtained must be easily removed from the needle), and the amount of damage caused by the device on the sample. A microscopic picture of the sample before and after removal could be employed to determine the amount of damage from the technique. In addition to the characteristics to be evaluated by the cytologist, identification of the components viewed in the microscopic slides should also be determined by the cytologist. Particles are currently visible in the slide, but thorough analysis can not be performed without an expert.

During testing, it was determined that twisting the drill bit during insertion and removal without a knob on the end was difficult, especially when wearing gloves. The knob could also serve as a means of measuring the depth of the drill bit when it is inserted into the mass. Next semester a knob will be added to the end of the drill bit in order to ease the drill bit technique.

Although the design of our prototype may not have ethical implications, the testing phase does. In the early stages it is acceptable to test on foods and dead meat, but more advanced trials will require both animal and then clinical trials. If testing on animals is necessary, we would need to consider such things as how much damage may be caused, how much pain the animal would endure, if analgesics or anesthetics are needed, testing on “normal” animals vs. having to induce cancer to perform tests on “cancerous” tissue, how many animals are required for clinical significance, and what the probability of fatality is. For human testing all the same questions come up along with finding individuals on which to test, gaining their consent, and considering necessary precautions for handling of human tissue. In both animal and human testing that involves cancerous cells, there may be a possibility that seeding of the tumor to other sites may occur.

Since the device would only have a single use, there is less concern with how the material will react with the body but there is still need to test how long the product’s shelf life may be or
probability that a portion of the drill bit would break off inside the patient. These issues have not been addressed as of yet since we were primarily concerned with development of a prototype, but Dr. Burnside has mentioned that animal testing would most likely be possible to begin on rats with tumors. Human trials will require Board approval at the given hospital and if successful, later approval for testing by the Food and Drug Administration. After the first successful test, the designers will also file for patent rights on the device.

Conclusion

Fine needle aspiration (FNA) is a minimally invasive technique that extracts cells from a lesion in the breast to determine if the lesion is cancerous. The client Dr. Elizabeth Burnside prefers using FNA to other biopsy methods, but finds that it often leads to samples lacking in a sufficient number of questionable cells. Dr. Burnside seeks a modification to the current FNA needle that will extract a sufficient sample on the first attempt. To obtain a sufficient sample, the design must loosen the cells before packing them into the needle. The design pursued this semester was a drill bit insert design, which consists of pre-manufactured drill bit that is housed in a standard FNA needle. Testing of this design was performed on fixed cat tissues. Testing results are still somewhat ambiguous, but comparison of the current and modified techniques revealed that the drill bit modification in promising. Further cytological analysis and testing will be performed next semester. A modification to the FNA technique will hopefully allow for the aspiration procedure to be performed more efficiently.
Appendix A – Product Design Specification (PDS)
December 11, 2002

Elizabeth Burnside – Client
John Webster - Advisor
Janie Goldsworthy – Communications
Kristi Hinner - BSAC
Nick Kortan – BWIG
Crystal Marshek - Team Leader

**Title:** Improvement for fine needle aspiration (FNA) used during breast cell biopsies.

**Function:**
A 20-25-gauge aspiration needle is inserted into the breast to extract questionable cells found during ultrasound mammography. Using ultrasound, the needle is positioned at the site where it is used to break up and disperse the cells. Once the cells are loosened, there is a small chance that the hollow of the needle will collect the cells. The client, in the hopes that more cells would be removed for analysis, suggested modifications to the needle.

**Client requirements:**
The client would like us to modify the needle, so FNA could gain more confidence by medical professionals as a more effect, minimally invasive means of obtaining cells samples over more invasive procedures such as core biopsy. For FNA to gain popularity among breast cancer specialists, a larger undamaged cell sample needs to be obtained on the first attempt.

**Design requirements:**

*Physical and Operational Characteristics:*

**Performance requirements:**
Device will be used 1 time.
Obtain a sample of approximately 6 clumps of cells, 4 or 5 cells each.
Constrained to standard 20-25-gauge needle, client prefers 23-gauge.
Any added material to the needle should not extend 1 cm past the tip of the needle.
Needle should remain steady during the procedure.
Large clumps of cells should be avoided due to problems with analysis.
Minimal noise during procedure as to not startle the patient.
Remain minimally invasive.
Should not cause additional pain.
Cells cannot be damaged during the procedure.

**Safety:**
No part of the device should remain in the body after the procedure.
When dislodging cells, device shouldn’t spread cells a large distance from the needle.
Accuracy and Reliability:
The device should obtain cells from varying density masses.

Life in Service:
One use.

Shelf Life:
Should be the same as current needle shelf life.

Operating Environment:
Biological components (blood, fat, tissue).
Body temperature.
Operator should be a medical professional able to judge distance using an ultrasound machine.
If electric component added to the device, shock could be a hazard.

Ergonomics:
Similar to normal needle.
If device requires manual rotation, operator movement should be minimal.

Size:
Needle gauge should be 20 to 25.
Any material added to the device needs to fit within the hollow of the needle.

Weight:
Needle should not increase more than three times its original weight.

Materials:
Hypoallergenic
Noncorrosive
Not brittle
Semi-hard

Aesthetics, Appearance, and Finish:
Outside of needle should remain smooth

Production Characteristics

Quantity:
Client currently only wants one device for testing. If device were successful, a medical company
would need to mass-produce the product.

Target Product Cost:
Less than $5.00 per needle.
Miscellaneous

Standards and Specifications:
Must be FDA approved for human use

Customer:
Affordable
User-friendly
Effective – short time required performing aspiration or cell sample (i.e. – less than 20 minutes)

Patient-related concerns:
Does not cause procedure to be more painful or more difficult

Competition:
No known variations to the standard 20+ gauge needle for FNA use with breasts
May be variation in technique that is more efficient
Appendix B - Mammography

Mammography (Figure 13) is a special type of x-ray imaging used to create detailed images of the breast. Mammography uses low dose x-ray; high contrast, high-resolution film; and an x-ray system designed specifically for imaging the breasts. Successful treatment of breast cancer depends on early diagnosis. Mammography plays a major role in early detection of breast cancers. The US Food and Drug Administration reports that mammography can find 85 to 90 percent of breast cancers in women over 50 and can discover a lump up to two years before it can be felt [10]. The benefits of mammography far outweigh the risks and inconvenience.

Mammography can show changes in the breast well before a woman or her physician can feel them. Once a lump is discovered, mammography can be invaluable in evaluating the lump to determine if it is cancerous. If a breast abnormality is found or confirmed with mammography, additional breast imaging tests such as ultrasound (sonography) or a breast biopsy may be performed. Many times, mammography or ultrasound is used to help the radiologist or surgeon guide the needle to the correct area in the breast during biopsy.

There are two types of mammography exams, screening and diagnostic. Screening mammography is an x-ray examination of the breasts in a woman who is asymptomatic (has no complaints or symptoms of breast cancer). The goal of screening mammography is to detect cancer when it is still too small to be felt by a woman or her physician. Early detection of small breast cancers by screening mammography greatly improves a woman's chances for successful treatment. Screening mammography is recommended each year for women once they reach 40 years of age. In some instances, physicians may recommend beginning screening mammography before age 40 (i.e. if the woman has a strong family history of breast cancer).

Diagnostic mammography is an x-ray examination of the breast in a woman who either has a breast complaint (for example, a breast lump or nipple discharge is found during self-exam) or has had an abnormality found during screening mammography. Diagnostic mammography is more involved and time-consuming than screening mammography and is used to determine exact size and location of breast abnormalities and to image the surrounding tissue and lymph nodes. Typically, several additional views of the breast are imaged and interpreted during diagnostic mammography. Thus, diagnostic mammography is more expensive than screening mammography. Women with breast implants or a personal history of breast cancer will usually require the additional views used in diagnostic mammography [10].
Appendix C - Ultrasound

Breast ultrasound (Figure 14), also known as sonography or ultrasonography, is frequently used to evaluate breast abnormalities that are found with screening or diagnostic mammography or during a physician performed clinical breast exam [4]. Ultrasound allows significant freedom in obtaining images of the breast from almost any orientation. Ultrasound is excellent at imaging cysts (round, fluid-filled, pockets inside the breast). Additionally, ultrasound can often quickly determine if a suspicious area is in fact a cyst (always non-cancerous) or an increased density of solid tissue (dense mass), which may require a biopsy to determine if it is malignant (cancerous). [10]

If a patient’s ultrasound and mammogram results are both negative (no evidence of cancer is seen), but the physician is still concerned about the thickening or mass, then he/she may proceed further with a fine needle aspiration biopsy (FNA) of the area.

Ultrasound vs. Mammography:

Ultrasound has excellent contrast resolution. This means, for example, that an area of fluid (cyst) and an area of normal breast tissue are easy to differentiate on an ultrasound image. However, ultrasound does not have good spatial resolution like mammography, and therefore cannot provide as much detail as a mammogram image. Ultrasound is also unable to image microcalcifications, tiny calcium deposits that are often the first indication of breast cancer. Mammography, on the other hand, is excellent at imaging calcifications. Ultrasound may be able to detect macrocalcifications (larger calcium deposits) in some cases.

Though most true breast lumps will be found by mammography or ultrasound, some abnormalities escape detection on both imaging tests. For example, a lump may be able to be felt but does not appear on mammography or ultrasound images. If this is the case, then fine needle aspiration biopsy (FNA) is often performed. Less than 30% of all breast biopsies are cancerous [10]. In cases where the abnormality is not apparent on mammogram or ultrasound, the chances of cancer are significantly less.
Appendix D - Testing Procedure

November 2, 2002

General Procedure
1) Prepare samples (lymph, fat, mammary)
2) Gather supplies (needles, drill bits, gloves, saline, slides)
3) Label slides

Current Technique Procedure
1) Insert needle into sample
2) Perform subsequent short .5cm “in-and-out” motions
3) Remove the needle from the sample
4) Tap needle on slide (approximately 5 times) to remove cells

Modified Technique Procedure
1) Place 1 drop of saline on slides
2) Place drill bit down hollow of the needle
3) Align the drill bit flush with the tip of the needle
4) One person steadies the sample, while second person performs insertion
5) Insert needle and drill bit into sample approximately 1cm
6) Turn drill bit (approximately .5cm) as it is extended out the tip of the needle
7) Twist drill bit, at full .5cm extension, for approximately 5 twists
8) Continue to twist drill bit as you retract it back into the needle
9) Remove the needle and drill bit combination from the sample
10) Extend the drill bit out of the tip of the needle into the saline on the slide
11) Twist drill bit (approximately 5 times) in saline to release cells
12) Dispose of needle and drill bit

December 6, 2002
Changes that were made to the above procedure during the December 6, 2002 tests include:
1) Adding saline to all slides prior to cell collection
2) Examining all results with a microscope and taking pictures of the results
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