

Fine Needle Aspiration Improvements

Team Members:
Janie Goldsworthy,
Kristi Hinner,
Nick Kortan,
Crystal Marshek

Client:
Dr. Elizabeth Burnside,
Assistant Professor,
Chief, Breast Imaging

Advisor:
Professor John Webster

October 15, 2002

Abstract

The following document presents several design alternatives 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. 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. 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. Two needle insertion design possibilities have been pursued out of the original six designs. These include a spring shaped insert and a micro-drill bit insert. These two possibilities have been tested on an enlarged scale to select the top choice. Preliminary testing led us to choose the micro-drill bit design and the prototype is in progress. Following completion of the prototype, testing will begin on various tissues resembling actual breast and cyst tissue.

Table of Contents

Page Number

Client Statement	2
Background information	
Techniques	3-4
Procedure	5-6
Manufacturer	6
Design Constraints	6-7
Alternative Solutions	7-9
Future Plans	9-10
Conclusion	10
Appendix	
PDS	12-14
Mammography	15
Ultrasound	16
References	17

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 fibroadenoma (non-cancerous). Often the patient will be informed of the test results before leaving.

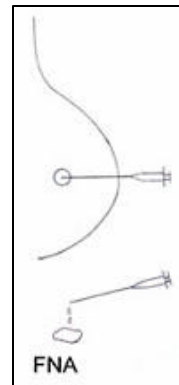
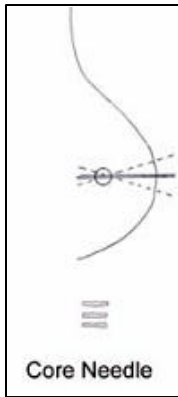


Figure 1: Fine needle aspiration,
<http://www.imaginis.com/breasthealth/biopsy/fine>



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].

Figure 2: Core needle biopsy,
<http://www.imaginis.com/breasthealth/biopsy/fine>

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].

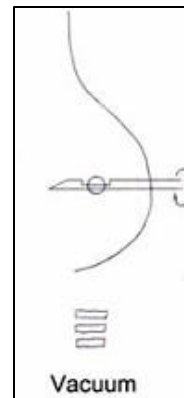
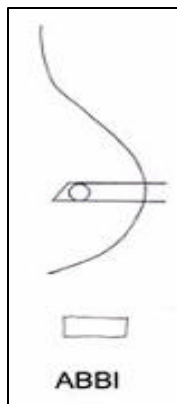


Figure 3: Vacuum-assisted Biopsy,
<http://www.imaginis.com/breasthealth/biopsy/fine>



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 minutes to two hours, but it generally takes less than an hour [13]. A few stitches may be required to close the opening in the skin.

Figure 4: Large Core Bbpsy (ABBI),
<http://www.imaginis.com/breasthealth/biopsy/fine>

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 nonpalpable 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 5mm "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 15-20 strokes [11]. After which, 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 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 pressure. 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 pressure.

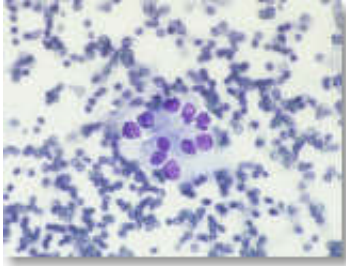


Figure 5: Stained cytological slide,
<http://breastdoctor.com/breast/surgery/>

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 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.

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 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.

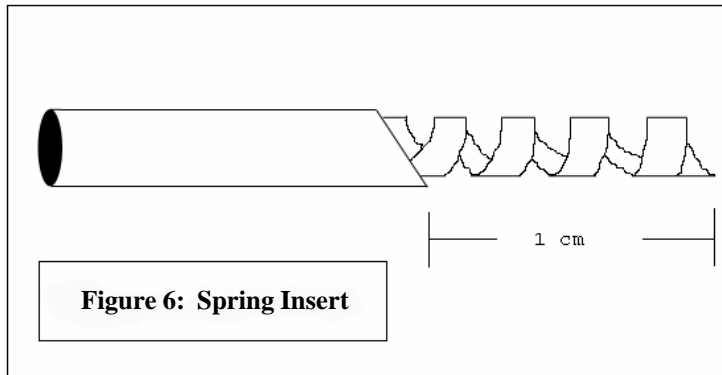
The modifications made to FNA need to follow specific constraints requested by the client. These constraints include the needle gauge remaining between 20-25, but preferable 23. The cost of the needle and equipment should be kept at a minimum (currently the needle cost approximately \$5.00). The cells 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 of un-clumped 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.

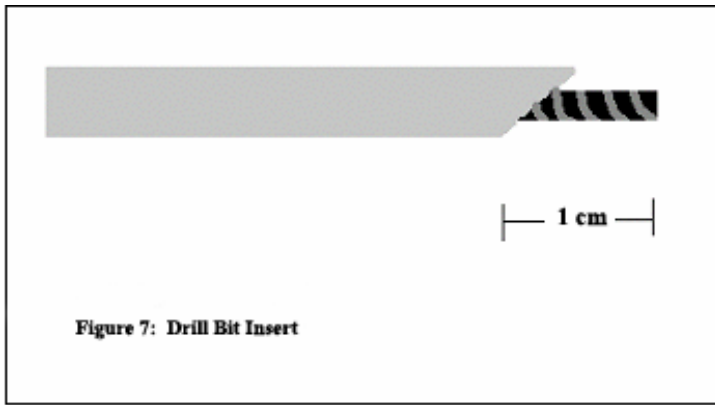
Alternative Solutions

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 help break up the cells. Finally, the wire would be removed.



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.



A second solution is the use of a pre-made micro drill bit (Figure 7). It is possible to purchase drill bits that will fit into a 22 or below gauge needle (see Tables 1 and 2 below). The only obstacle is that these drill bits are only manufactured about one inch in length, and therefore are much too short to be used effectively inside the two to three inch 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 micro enough that the flattened wire will not be rigid enough to extract cells as well as 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.

Comment: For both or just drill tip?

Materials

When it comes to material choice for the prototype, there are multiple options. One readily accessible choice is music wire that may be made of 316 stainless steel wire commonly used in aspiration needles. Other options found for currently produced micro drill bits were

stainless steel, titanium nickel (TiN), 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.

Table 1: (Left) Common FNAB needle dimensions (for regular wall thickness).

Table 2: (Right) Pre-fabricated micro drill bits by industry standard number.

Needle Gauge	Outer Diameter (inches)	Inner Diameter (inches)
23	0.0250	0.013
22	0.0280	0.016
21	0.0320	0.020
20	0.0355	0.024

Drill Bit Number	Outer Diameter (inches)
74	0.0225
75	0.0210
76	0.0200
79	0.0145
80	0.0135

Future Plans

A modification to the fine needle aspiration technique seems imminent, but further investigation of materials, formation of prototypes, and testing still need to be conducted. After testing is conducted, the results will be discussed with the client. With the client's input, designs will be modified and retested. Finally, the most appropriate design will be chosen.

Prototypes of the two best solutions need to be produced. A drill bit will be purchased, but must be lengthened to fit the needle. Possible solutions to this include spot welding, butt welding, or soldering the drill tip onto the insert currently used in the spinal-type needle. A prototype for the spring insert design will be made by grinding the music wire flat with a grinder or sandpaper, or possibly hammering, and then twisting it into the desired spiral. The diameter of all formed wire inserts must not exceed the inside diameter of the needle, which would prevent the wire from smoothly gliding in and out.

After the prototypes are created, testing will be performed. Testing would ideally be performed on living tissue, since non-living tissue does not necessarily exhibit the same characteristics. There is also the possibility that we could test on live tumor-infected rats through Dr. Burnside. Because of the complexity involved in obtaining permission to perform animal tests, needle testing will be performed on non-living tissue while investigation of animal testing is conducted. An attempt will be made to find a non-living tissue with characteristics similar to that of the human breast. Some possible testing specimens include: a breast biopsy sample, lab rats with tumors, a tissue from a mastectomy, a freshly slaughtered piece of meat from a slaughter-house, different cuts of meats from different animals, a hot dog, a piece of fruit (i.e.- kiwi), or a potato.

A specific protocol for testing has not yet been formulated, but testing must involve an attempt to quantify and characterize the tissue obtained. Characteristics to be evaluated 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. Testing should be performed on materials of varying densities since lesions in the breast also have varying densities.

Although the design of our prototype may not have ethical implications, the testing phase will. 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.

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 as well as approval for testing by the Food and Drug Administration. At the same time the product is to begin testing, the designers will also most likely to 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. Of the previous designs proposed, the drill bit and spring insert designs will be pursued. Both designs consist of a wire with a uniquely formed tip that will fit inside the current needle. Testing of these two designs must be performed on a live animal or a nonliving tissue with characteristics similar to the human breast and must be performed to ensure that the modified needle does not cause further harm to the patient by spreading possibly cancerous cells throughout the breast. After testing, one design will be chosen, modified, and retested. A modification to the FNA technique will hopefully allow for the aspiration procedure to be performed more efficiently.

Appendix A – Product Design Specification (PDS)

February 12, 2002

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

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. Other than modifications to just the needle, there could be possible modifications to the techniques as well. The client proposed several suggestions, such as a brush, scoop or drill housed in the tip of 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 greater number of cells from a mass of approximately 1 cm diameter.
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 electrical 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 20-25.

Any material added to the device needs to fit within the hollow of the needle.

Weight:

Needle should not increase more than 3 times its original weight.

Materials:

Hypoallergenic

Non-corrosive

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

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.



Figure 13: Mammogram examination,

<http://www.SiemensMedical.com>

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 key 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]



Figure 14: Ultrasound examination,
<http://www.SiemensMedical.com>

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.

References

1. Bondeson L, L. K. 1997. Prediction of Invasiveness by Aspiration Cytology Applied to Nonpalpable Breast Carcinoma and Tested in 300 Cases. *Diagnostic Cytopathology* 17: 315-320.
2. Boston Scientific. 2002. Surecut Biopsy Needle. Boston Scientific. www.bostonscientific.com
3. BreastDoctor.com. 1998. Making the Diagnosis of Breast Cancer: Palpable Masses. BreastDoctor.com. <http://breastdoctor.com/breast/surgery/>
4. Burnside E. 2002. bburnside@mail.radiology.wisc.edu
5. Cook. 2001. Biopsy and Special Purpose Needles for CT, Ultrasound and MRI. Pages 14. Cook Incorporated, Bloomington, IN.
6. Cook Diagnostic and Interventional Products. 2002. Needles - Biopsy. Cook. <http://www.cookincorporated.com/products/needles/biopsy.html>
7. Fornage B., F. M., Simatos A. 1987. Breast Masses: US-Guided Fine-Needle Aspiration Biopsy. *Radiology* 162: 409-414.
8. Fronczak, F. 2002. fronczak@enr.wisc.edu
9. Hagquist, B. 2002. hagquist@enr.wisc.edu
10. Imaginis. 2002. Methods of Breast Biopsy. Siemens. <http://www.imaginis.com/breasthealth/biopsy/fine>
11. Laboratory Corporation of America. Fine Needle Aspiration Cytology. Laboratory Corporation of America. <http://www.labcorp.com/datasets/labcorp/html/chapter/mono/cy002100.htm>
12. Pisano E., F. L., Caudry D., Sneige N., Frable W., Berg W., Tocino I., Schnitt S., Connolly J., Gatsonis C., McNeil B. 2001. Fine-Needle Aspiration Biopsy of Nonpalpable Breast Lesions in a Multicenter Clinical Trial: Results from the Radiologic Diagnostic Oncology Group V. *Radiology* 219: 785-792.
13. Surgery Channel. 2002. Breast Biopsy. <http://www.surgerychannel.com/breastbiopsy/needle.shtml#fine>
14. Waniorek, G. 2002. District Manager. gwaniorek@cook-inc.com