Device for Improving Diagnostic Yield of Fine Needle Aspiration

Preliminary Design Report

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ABSTRACT

The purpose of our project is to improve the diagnostic yield of fine needle aspiration. Currently, our client uses a manual technique that requires multiple procedures in order to obtain an adequate tissue sample. Our client wants to automate this procedure with a handheld device. The device must be safe, have an adjustable needle stroke and frequency, and be reusable. This will reduce operating time and increase yield, accuracy, and reliability. After analysis of several design options, we have chosen a Wheel and Motor Design for our final prototype.

BACKGROUND

Problem Statement

Fine needle aspiration is a biopsy method of collecting tissue samples. The procedure is currently manual and requires repetitive low yield sampling to collect enough cells for testing. The goal of our project is to maximize tissue sample size in a single, timely procedure. We intend to develop a device that automates the current biopsy procedure using precise needle oscillation and vacuum techniques. The automation of the device will reduce operating time, cost and discomfort for the patient.

Problem Overview

The design needs to be safe, meaning that it must reduce the fine needle aspiration time and number of procedures. The device must be handheld, reusable, and durable. It must have an adjustable needle stroke and frequency. The needle should be able to penetrate the tissue without breaking or bending. Patient comfort is also highly prioritized. The device should be able to withstand typical hospital sterilization methods, and should be dependable and precise.

Problem Motivation

The device would reduce the time and number of procedures compared to the current method. By incorporating an automatic oscillation method, the amount of tissue collected in one operation would increase. The device can be customized for each procedure by adjusting the depth and frequency of the needle. A locking mechanism would prevent the needle from changing depth during the procedure. Increasing the sample yield would reduce procedure time because only one sample would need to be analyzed by the pathologist. Reduction in the number of passes by the needle would also decrease the procedure time and increase patient comfort.

Biopsy

A biopsy is a medical test involving the removal of a sample of tissue from the body for examination by a pathologist. A biopsy test indicates any suspected cancerous lumps. It can be performed on any organs, and depending on the nature of each organ, major biopsy surgery or a small operation can be chosen. There are currently over six kinds of biopsies:

- Excisional biopsy: A whole suspected area or a whole organ is removed for accurate diagnosis. This type of biopsy is preferable on organs that are dangerous to cut into without removing the whole organ.
- Endoscopic biopsy: A fiberoptic endoscope is inserted in to the gastrointestinal tract, allowing the direct visualization of the abnormal area and the pinching off of small amounts of tissue.
- Colposcopic biopsy: A gynecologic procedure that is recommended for patients with abnormal Pap smear.
- Fine needle aspiration: A small needle is inserted into the lump to withdraw a cell sample for examination.
- Punch biopsy: A procedure that uses a biopsy punch (small version of a cookie cutter) to cut out a small piece of skin (3-4 mm in diameter) to test for skin cancer.
- Bone marrow biopsy: A sample is taken from the pelvic bone. The needle is inserted into the marrow space to withdraw cells. This biopsy is used to diagnose the cause of abnormal blood counts, such as a high white cell count.

After a sample of cells or tissues is collected, it will be stained by a chemical and examined under a microscope by a pathologist.

Fine Needle Aspiration (FNA)

Fine Needle Aspiration is a special type of biopsy that involves a fine needle (from 21 to 25 gauge) to collect a small sample of cell fluid or tissue. Based on the diagnosis of these cells, a pathologist will be able to conclude if the suspected lump is benign, malignant or non-definitive. If inconclusive, a repeat procedure must be done. Fine needle aspiration is usually performed in tissues such as neck lymph nodes, neck cysts, parotid gland, thyroid gland, inside the mouth, or anywhere that a lump can be felt.

Fine Needle Aspiration Procedure

A small needle (usually 21 gauge) is held by the doctor between his/her index finger and his/her thumb. The skin overlying the mass is prepared with a sponge containing 70% isopropyl alcohol. The lump is then immobilized by the doctor's other hand between the index finger and the middle finger. The small needle is inserted into the mass in a to and fro fashion for several times with a rapid, gentle, stabbing motion. When the cells are collected in the needle, a syringe with its plunger already retracted will be attached immediately to the needle to expel the sample onto a clean glass slide. It is then prepared for staining and examining. An average number of 100 cells should be taken to ensure the success of the procedure (Figure 1).

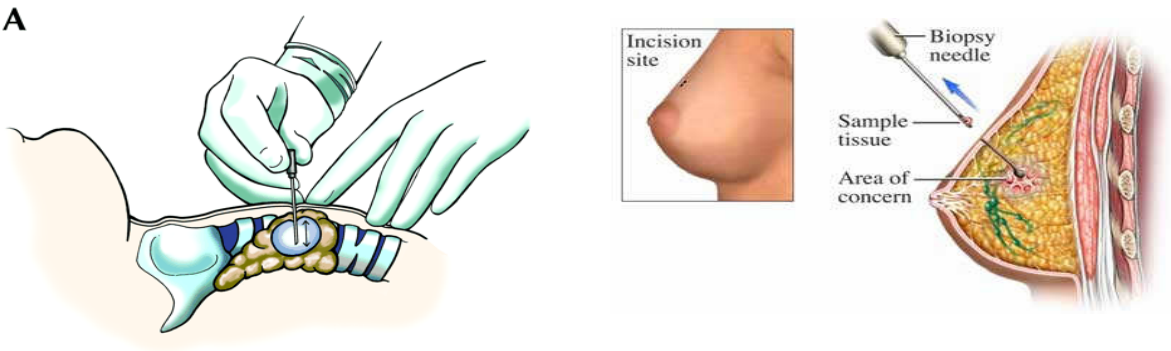

Figure 1. Diagrams showing Fine Needle Aspiration procedures. The first diagram shows a needle being inserted into the suspected mass in a thyroid gland. The second diagram shows a needle inserted into the suspected mass in breast tissue.

Fine needle aspiration has a diagnostic success rate of 70%-80%. If the tissue is diagnosed to be benign, the growth of the abnormal mass is under control, non-cancerous and is not spreading to other tissue. If it is concluded to be malignant, then the mass is cancerous, growing uncontrollably, and spreading to other tissues. This result will signify doctors of the appropriate treatment, such as chemical treatment or even surgery. Fine needle aspiration procedures fail when no conclusion can be made because of inadequate number and quality of cells. In such a case, the procedure needs to be repeated, or may even lead to a surgical biopsy.

Design Constraints

Our design was constrained by a set of criteria. These criteria include performance requirements, safety and reliability, patient comfort, accuracy and repeatability, dimensions and weight, ergonomics, and shelf life.

First of all, the device must satisfy performance requirements. The device must be reusable up to 3 tests in 20 minutes, and subject to chemical sterilization methods between procedures. The machine must also produce forces great enough to penetrate all necessary tissues encountered in the body. Such tissues include, but are not limited to, muscle, adipose, epidermal, gland tissues, etc. The device must also be able to withstand constant oscillation variable to 20 Hz. The device should operate efficiently at 23 degrees Celsius, and efficiently produce a consistent, adequate sample.

Safety and reliability are also very important. The needle penetration depth must be variable and lock between 5 and 20 millimeters. The power supply should be portable, with no risk of electric shock. All materials must be non-toxic and non-allergenic. Needle integrity must be preserved as well, with no bending or blunting.

It is imperative that patient comfort is also upheld. The patient should experience no greater pain than is accompanied by the current manual method. Audible production by the device should be minimal, and not scare the patient or irritate the ears. Procedure time must be quickened to comfort the patient and lower the costs to both the patient and the practitioner.

Accuracy and repeatability ensure the success of the procedures. Precise needle insertion depth is mandatory. The penetration depth must be variable from 5 millimeters to 20 millimeters, and the frequency of the 'in-and-out' needle cycle is variable to 20 Hz. The biopsy sample must be retained within the needle shaft, and the sample size mean should be approximately 100 cells.

The dimensions of the product must conform to the ability to use with one hand. An operator should not feel strain on the arm or hand from the weight of the tool, and easy maneuvering must be possible. Less weight and hand-conforming dimensions are desirable.

Ergonomics ensure that the machine is easily operated. The device should be operable in either the left or right hand and not restrict maneuverability. Various angles about the needle inclusion point should be attainable by moving the device. The controls for the device should also be easily accessible. Aesthetics are also considered, and the finished product should not intimidate or concern the patient in appearance.

Current Devices

Currently, our client uses a manual aspiration biopsy technique. A fine needle is held in the hand and inserted into the tissue. This needle is sometimes accompanied by a syringe to aid in suction of the desired tissue into the needle shaft. This technique requires multiple attempts to collect an adequate sample of tissue to be tested. The current technique is successful after repeated procedures; however, many difficulties still exist. This technique does not provide an accurate way to collect cell samples from harder tissues. When the needle is inserted, it often moves the hardened tissue mass around, rather than collecting a cell sample. Also, it is often difficult to collect enough tissue during the first procedure. By automating the FNA procedure, our client would be able to rapidly insert the needle and collect an adequate sample through an oscillatory needle motion. Our client would like to decrease both the procedure time and cost to the patient by creating an automated device.

Competition

Several devices have been developed that automate the current fine needle aspiration procedure. A Syringe Gun was developed by Cameco that applies a constant suction to the tissue using a trigger and syringe. A specimen filter inside the syringe prevents cells from entering it. However, this device is much more expensive than the current technique and is more difficult to use. Because of these reasons, many doctors have not obtained this device. The second method uses a Vacuum Needle. This device uses partial withdrawal of the needle to create suction. However, it has undergone limited testing and is not widely used by doctors. A United States patent was recently issued for a Fine Needle Aspiration Gun. This patent proposes a vibratory needle motion using two different methods. The first involves an external motor that drives the needle shaft. Because this device contains external components and cords, our client is not interested. The second method involves two opposing solenoids to linearly drive the needle shaft. However, this device has not been tested or marketed. Overall, testing done by a variety

of researchers shows that none of these devices seem to have an advantage over the current manual method.

MATERIALS

Electrical components of the designs aim to create linear oscillatory motion. This is accomplished by use of electromagnetism in solenoids and rotors. A power source is also used, including AC power, batteries, etc. Switches and potentiometers to adjust oscillation and power may be included as well. Mechanical components involve housing and mounts, springs, needle, gears, and a drive shaft.

ALTERNATE DESIGNS

Solenoid Design

The solenoid design consists of two AC solenoids and one DC solenoid. The DC solenoid is attached to a drive shaft and set between the two AC solenoids. A rechargeable battery or AC to DC circuitry will supply direct current to the center solenoid so that one end will be continually positive and the other negative. The AC solenoids will be supplied with AC current from a wall outlet via a cord. The AC current will cause a momentary repulsion between the DC solenoid and one AC solenoid and a corresponding attraction to the other AC solenoid. The AC current will then switch polarity and attract/repel the DC solenoid in the opposite direction. This will create a linear oscillation of the DC solenoid and drive the shaft. The biopsy needle will be attached to the drive shaft by a standard luer connection.

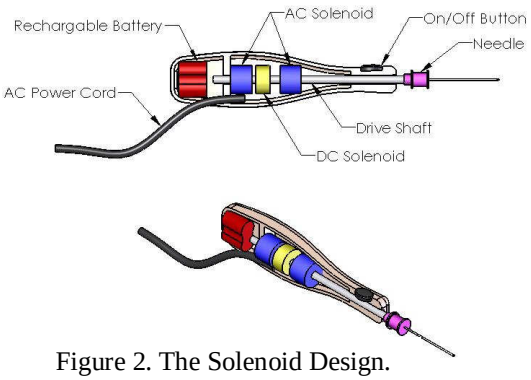

Figure 2. The Solenoid Design.

Stroke of the needle can be changed by varying the distance between the two AC solenoids. This would be adjusted mechanically along the side of the device. Oscillation frequency can be adjusted by changing the AC frequency. Frequency will be adjusted by a dial located on the rear portion of the device. Both oscillation depth and frequency controls would be located away from the grip to avoid accidental adjustments. The device will have a one-handed pen-like grip to provide easy manipulation and control. The on/off switch will be located on top of the device near the grip for easy control.

This design has several advantages. All motion is linear and the drive shaft and needle are the only moving parts. This causes very little vibration and reduces mechanical wear and tear. Depth and frequency adjustments are also easy to control and change. Using electronics introduces the possibility of electrical shock. Electrical safety concerns must be carefully addressed to assure that the patient will be harmed during the procedure. The design also includes a cord to supply the device with alternating current. This could be a hazard in busy operating conditions where the cord may be pulled or snagged during the

procedure. It may also limit the accessibility of the device. The use of magnetic fields would also limit the device to areas away from MRI machines.

Alternatives to this design may include using two DC solenoids. One DC solenoid could be attached to a drive shaft. A second solenoid would repel or attract the first solenoid in opposition to a spring. By turning the second solenoid on and off, the drive shaft would be moved back and forth linearly. This would eliminate the need for AC power and therefore the cord.

Wheel and Motor Design

The wheel and motor design uses an off-center member to convert rotational motion into linear motion much like a piston. A DC motor, powered by a rechargeable battery, will rotate a wheel. A member will be attached to the wheel off-center so that it may pivot. The other end of this member will be connected to a linearly constrained member. By rotating the wheel, motion will be converted into linear oscillations. The needle would be connected to the linear member by a standard luer connection.

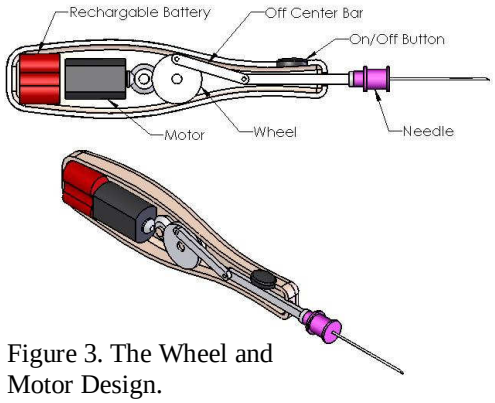

Figure 3. The Wheel and Motor Design.

The stroke of the needle can be adjusted by changing the radius of the wheel. Oscillation frequency can be adjusted by varying the motor speed. A dial near the rear of the device will be used to avoid accidental changes. The device will have a one handed pen-like grip to provide easy manipulation and control. The on/off switch will be located on top of the device near the grip for easy control.

This design is easy to build and uses common off the self parts. It runs only on DC current and can be powered by an internal rechargeable battery. This would eliminate the need for a cord which could be a potential safety hazard if it is pulled or caught during a procedure. Without a cord it can also be easy manipulated and portable. Since all motion is not linear, vibration is a concern. The design contains several moving parts which increase the chance of mechanical failure and the need for maintenance. The oscillation stroke is also difficult to adjust since it requires changing the radius of the wheel. This could be done by either making the wheel replaceable or making the pivot point of the member adjustable; neither option being very simple.

Manual Mechanical Design

The manual/mechanical design is a biopsy drive device constituted strictly of mechanical components. The design appears to that of a standard 'clicking' pen, in which the compression of a top-mounted trigger protrudes the needle at the opposing end of the device. Ergonomics of the mechanical design would best be imitated by the grasping of a syringe between the index finger and middle finger, and the use of the thumb to activate the trigger. Upon each compression of the trigger, recoil would again bring the thumb up to the 'ready' position for activation. The machine would be approximately the size of a standard pen, or about six inches in length, and one-quarter of an inch in diameter. The top button would be directly linked to the needle insertion mount via an internal, linear compression spring. This spring and mounting components would be encased in a non-allergenic plastic housing. This spring would aid in producing the force to penetrate tissues and effectively collect sample cells. The spring can also be used to store potential energy as it is compressed, and then accelerate the needle at the speed required to pierce the desired tissue. Rapid firing of the needle would occur by quickening the pace of activation of the trigger, variable to the pace of human control (about 4Hz). The depth of penetration of the needle is governed by a stop on the trigger, limiting the length of compression and insertion. This stop is manually adjusted along helical threads by the torsion of the hexagonal plunger. This stop is variable from 5 millimeters to 20 millimeters, and the insertion depth directly coincides in equal insertion magnitude.

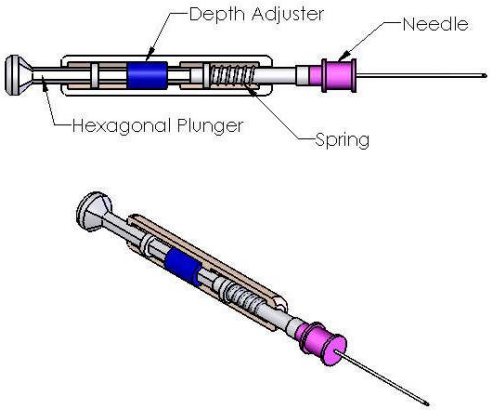

Figure 4. The Manual Mechanical Design.

There are several pros to this tool. The elimination of electrical components eases the complexity of the design. There is no battery life, cords, or electromechanical components of concern. A second positive point is the linear nature of the device. Since all motion is longitudinal, there is no 'wobbling' or latitudinal motion. This helps ensure patient comfort, as the needle will move strictly in and out. Another pro is the dimensions and weight of the device: small and light. The device will be easy to hold in one hand. A simple interface would also be used. Since there are less than 4 controls total, the device is easy to understand.

This device also has many cons. Perhaps the most significant and hindering aspect is the ergonomics. Accuracy is less attainable by the grip of the device. All precision is created by the placement of the forearm and hand. The fingers are unable to aim the device, as it is difficult to maneuver the grasp of the device. The apparatus must be manually operated, and thus the frequency of needle penetration is dependent solely on the pace of the machinist's thumb. Since the operator must also exert force to compress the internal spring, the machine is subject to unwanted thrust from the thumb and instability of the hand. Lastly, the insertion of the needle is variable only to the rate of

trigger activation (no more than 4 Hz), which is no quicker than that of the manual methods currently used.

DESIGN MATRIX

In order to select a final design, we created a matrix that weighted ten features based on their importance to our client. Each alternate design was rated on a scale of points for each feature, with a grand total of 100 points possible.

Feature (possible points)	Solenoid	Wheel and Motor	Manual/Mechanical
Ergonomics (10)	8	7	6
Durability (6)	3	4	6
Oscillation Adjustability (12)	10	8	11
Repeatability (15)	12	12	8
Accuracy (12)	11	11	7
Patient Comfort (15)	14	12	10
Cost (4)	1	3	4
Safety (20)	12	16	8
Interface (6)	5	5	2
TOTAL (100)	**76**	**78**	**62**

Figure 5. Design matrix showing scores for our alternate designs.

After rating our alternate designs, it was found that the Wheel and Motor Design scored the highest. Because of this result, we have chosen it as our final design.

FUTURE WORK

In the upcoming weeks, we must accomplish several tasks. Our tasks include finalizing a detailed design, compiling a list of materials and ordering materials, constructing a prototype, testing and modifying the prototype, and then finalizing the design and presenting it.

The detailed design is to be created first. The design will take necessary criteria into account, and exhibit the optimal methods. This detailed design should include all parts and materials necessary. It should also stipulate any machining work or manipulation of ordered parts to comply with the design. A list of parts and prices is also necessary. The design should have specific focus on a vacuum method of drawing cells into the needle shaft. This vacuum is in need of attention.

Secondly, we will order materials. The materials are stated in the final design. We will price all parts ordered according to budget, with an attempt to minimize the lead time on all parts. As soon as we have the parts to begin prototyping, we will move into the next phase.

The prototype will be built as blueprinted by the final design. All necessary modifications to the design will be documented and later tested. The construction of the prototype will be subject to methods ensuring exactness, durability, and function.

Testing will commence following prototype assembly. Testing will include, but is not limited to: oscillation frequency, penetration depth, repeatability, accuracy, ease of use, sterilization methods, ergonomics, patient comfort, reliability, safety, durability, etc. After testing, modifications will be made based on the results. These tests will help ensure the validity of our design and aid in creating the optimum biopsy device.

After validation and modification are complete, we will finalize our product. We will then create a presentation of the product, and deliver the device to our client.

Appendix A: References

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Appendix B: Product Design Specifications

Fine Needle Aspiration (FNA) Device

Chris Goplen, Tu Hoang Anh Mai, Kristen Seashore, Jason Tham
October 24, 2006

Function: Fine needle aspiration is a biopsy method of collecting tissue samples. The procedure is currently manual and requires repetitive low yield sampling to collect enough cells for testing. The goal of our project is to maximize tissue sample size in a single, timely procedure. We intend to develop a device that automates the current biopsy procedure using precise needle oscillation and vacuum techniques. The automation of the device will reduce operating time, cost and discomfort for the patient.

Client requirements: The device must:

- be operable with one hand
- be reusable
- be durable
- be user-friendly
- be sanitary to clients standards
- comply with given safety standards
- be dependable and precise

Design requirements:

1) Physical and Operational Characteristics
   a) Performance Requirements:
      i) Reusable
      ii) Withstand constant oscillation
      iii) Withstand multiple procedures
      iv) Withstand sterilization methods
      v) Needle force requirements

   b) Safety:
      i) Precise needle penetration depth (locking mechanism)
      ii) Cordless
      iii) No risk of electric shock
      iv) Non-toxic and non-allergenic
      v) Preserve needle integrity

   c) Accuracy and Reliability:
      i) Low battery warning
      ii) Precise needle insertion depth (5mm to 20mm)
      iii) Frequency must be variable up to 20Hz
      iv) Biopsy sample must be retained within needle shaft

d) Life in Service: Device must be operable over 30 minute interval

e) Shelf Life: At least 1 year

f) Operating Environment:
   i) Sterile hospital environment
   ii) 23˚C standard room temperature

g) Ergonomics:
   i) Must be operational in one hand (right/left compatible)
   ii) Functional at varying angles of operation without losing maneuverability
   iii) Controls must be easily accessible

h) Size:
   i) Handheld
   ii) Must not restrict maneuverability and accessibility

i) Weight:
   i) Must not strain arm and hand
   ii) Light weight

j) Materials:
   i) Light weight materials
   ii) Easily sanitized materials

k) Aesthetics, Appearance, and Finish:
   i) Marketable
   ii) Hospital-friendly

2) Production Characteristics
   a) Quantity: 1 prototype

   b) Target Product Cost: minimal, constrained by budget

3) Miscellaneous
   a) Standards and Specifications: FDA approval (human testing standards)

   b) Customer:
      i) Minimal training
      ii) Low production costs
      iii) User-friendly

   c) Patient-related concerns:
      i) Sterilized between uses

ii) Minimal time, cost and pain
iii) Professional aesthetics

d) Competition
   i) Manual fine needle aspiration technique
   ii) Cameco Syringe Gun
   iii) Vacuum needle
   iv) Fine Needle Aspiration Gun (Patent 7008383)