

Testing Device to Improve Diagnostic Yield of Fine Needle Aspiration

Final Design Report

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ABSTRACT

The purpose of our project is to create a testing device to determine which factors 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 chose, constructed, and tested our final prototype.

INTRODUCTION

A biopsy is a medical test involving removal of a sample of tissue from the body. It is the only reliable method for distinguishing benign tumors from cancerous cells which otherwise appear similar on imaging tests. Fine needle aspiration (FNA) is a biopsy procedure that is performed on tissues where a suspicious lump can be felt by using a small needle (from 23 to 25 gauge - from 0.635 to 0.508 mm in diameter) to collect cells. Presently, FNA is operated manually by hand, and repeated procedures are required to accumulate enough samples for conclusive results. The yielding sample from one procedure can be improved by using an automatic oscillation device. Therefore, time consumption and cost will be reduced while increasing patient comfort. We propose a testing fine needle aspiration device that can be operated in various frequencies and stroke depths. Furthermore, from testing results, we will be able to build a fine needle aspiration device that will yield the largest sample in each procedure.

BACKGROUND

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 seven kinds of biopsies:

- **Incisional biopsy:** A small piece of tissue is removed for sectioning and examination. Incisional biopsy is done when the lump, mammographic change, or suspicious rash is too extensive or too big to be removed easily. The best yield is collected using a 14 gauge (2.108 mm in diameter) needle.
- **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. This is an open surgical biopsy.
- **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 an abnormal Pap smear.
- Fine needle aspiration: A small needle is inserted into the lump to withdraw a cell sample for examination. A needle from 23-25 gauge (corresponding to 0.635-0.508 in diameter) is used.
- 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. This type of biopsy requires a circular blade or trephine attached to a pencil-like handle. The instrument is rotated down through the epidermis and dermis to remove skin.
- Bone marrow biopsy: A sample is taken from the pelvic bone. The needle (10-16 gauge: 3.404-1.651 mm in diameter) 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 23 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.

A small needle (usually 23 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).

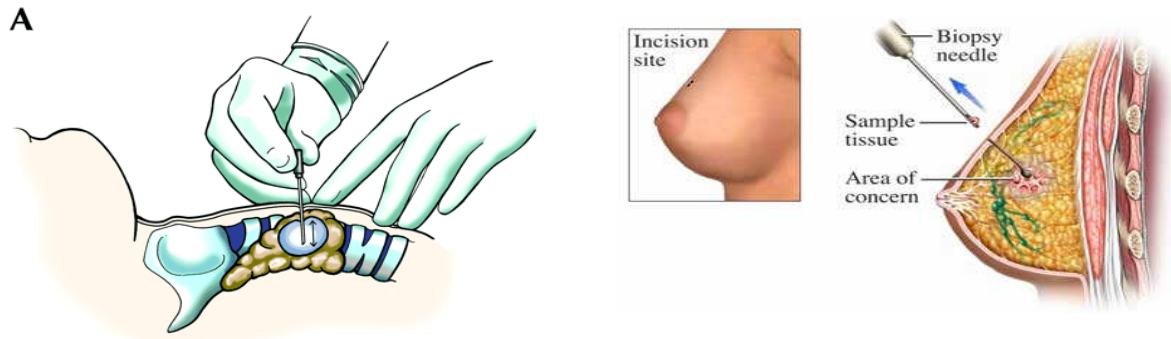


Figure 1. Diagrams showing Fine Needle Aspiration procedures. The first diagram shows a needle being inserted into the suspected mass in a thyroid gland. The second diagram shows a needle inserted into the suspected mass in breast tissue.

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.

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 viable cells for testing. The goal of our project is to maximize tissue sample size in a single, timely procedure. We propose to develop a testing device that automates the current biopsy procedure, and tests the sample yield by varying the frequency and needle stroke. The test results will determine the optimal operating frequency at various stroke lengths to provide a maximum cell yield. 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 final 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. 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 procedures would also decrease the procedure time and increase patient comfort.

DESIGN CONSTRAINTS

Our design was constrained by a set of criteria. These criteria include performance requirements, safety and reliability, 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. 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 10 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.

Accuracy and repeatability ensure the success of the procedures. Precise needle insertion depth is mandatory. The penetration depth must be variable from 10 millimeters to 20 millimeters, and the frequency of the 'in-and-out' needle cycle is variable. The biopsy sample must be retained within the needle shaft, and be easily expelled.

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. Various angles about the needle inclusion point should be attainable by moving the device. The controls for the device should also be easily accessible.

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.

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.

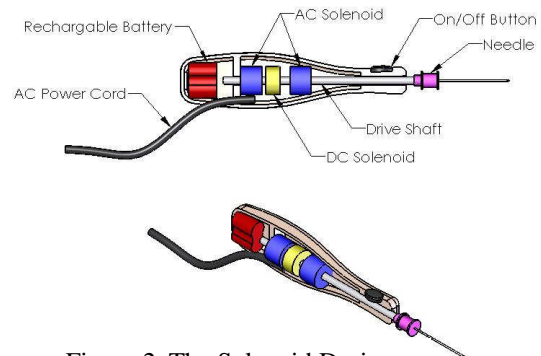


Figure 2. The Solenoid Design.

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.

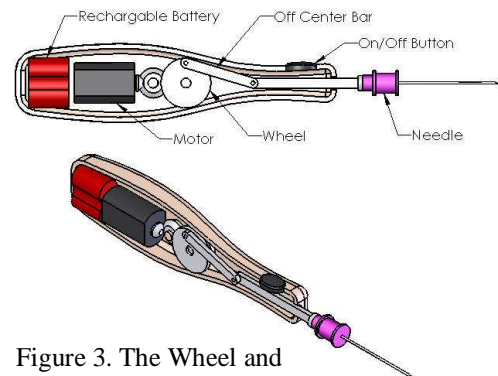


Figure 3. The Wheel and Motor Design.

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 device 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.

There are several pros to this device. 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

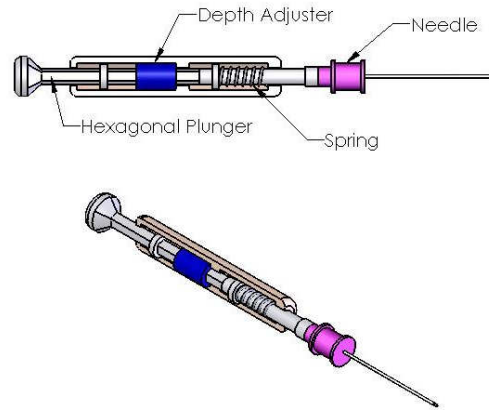


Figure 4. The Manual Mechanical Design.

the pace of the operator'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.

FINAL DESIGN

The final design that we chose incorporates a wheel and motor. A small 9 to 18 volt DC motor has a worm attached to the drive shaft. The motor is used to drive the worm, which turns the corresponding worm gear. The worm gear is placed on a member along with an adjustable wheel. This wheel has several different holes drilled into it to adjust the radii from 0.5 – 1.0 cm. This radii adjustment corresponds to a 1.0 – 2.0 cm needle stroke. A steel shaft can be temporarily attached to the wheel with a #8-3/8 inch screw. The shaft is attached to another linearly constrained member, which is epoxied to a three-way stopcock. A fine needle can be screwed into a stopcock, while a tube and syringe are connected to the stopcock as well to apply vacuum. The syringe operates as a type of vacuum mechanism to help draw cells into the needle shaft. The frequency of the needle can be changed by adjusting the input source voltage to the motor. Based on experimental results, the frequency can increase up to about 6.5 Hz. Overall, the final design is a testing device that will determine which values of frequency, needle stroke, and suction increase cell yield most effectively.

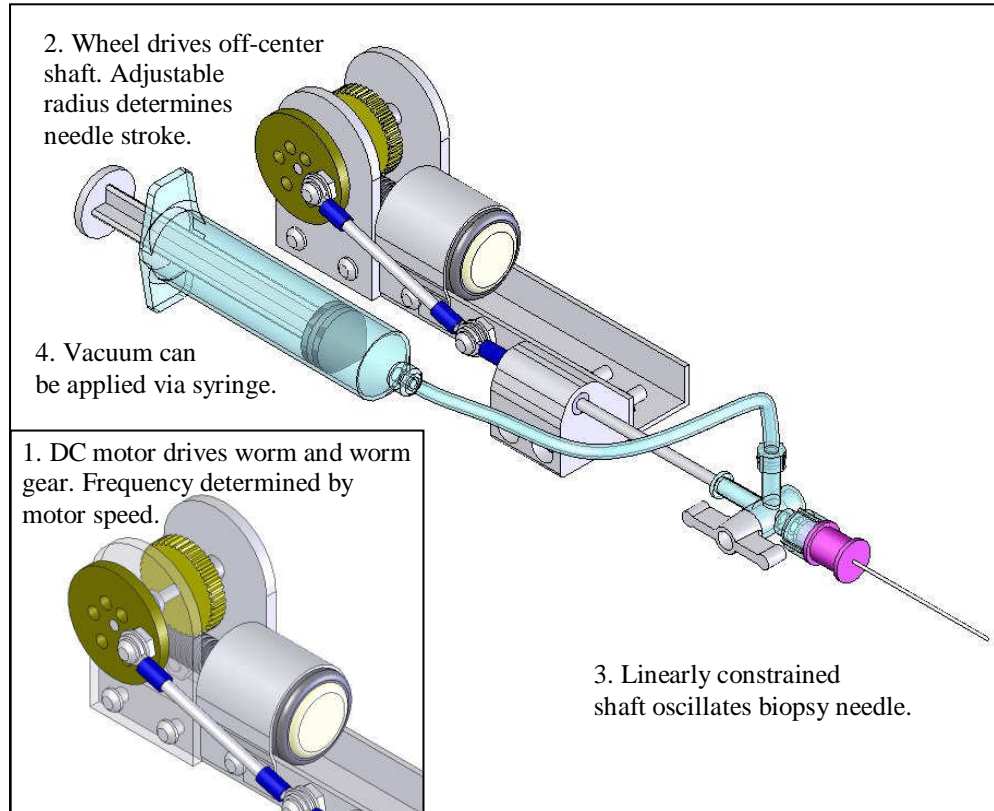


Figure 6. This SolidWorks diagram describes the final design and its functions.

MATERIALS AND METHODS

Most construction was done in the ECB student machine shop. A stock U-channel was used as the support base for the device. A 9-18V DC Motor purchased from Radio Shack was clamped to the U-channel using a slotted sheet of aluminum for easy removal and adjustment. Two drive shaft mounts were machined out of 1/8" aluminum sheet and attached to the aluminum channel. The worm and worm gears were positioned on the motor and drive shaft. To insure proper meshing, the mounts were fastened in slots so adjustments could be made to the drive shaft's position. A modified gear serves as the off-center wheel. Tapped holes were machined at radiuses of 5mm to 10mm at 1mm increments which correspond to a 10mm to 20mm linear stroke. The off-center drive shaft and linear drive shaft were cut to length and then the ends were sanded to a smaller radius so that the pivot ends (#8 electrical ring terminals) could be pressed onto the ends. The off-center drive shaft was screwed into one of the tapped holes corresponding to a specific radius. The linear drive shaft was constrained by two nylon bearings set in a block of aluminum attached to the U-channel. The block was machined down to reduce the weight of the device and increase ergonomic handling. A three way stopcock was epoxied onto the end of the linear drive shaft. The needle was connected to the inline connection and an extension tube and syringe was attached to the remaining connection. The following list is the bill of materials for our device.

- Aluminum U-Channel
- 1" x 1" x 2" Aluminum Block
- 1/8" Aluminum Sheet
- 0.156" Aluminum Sheet
- 1/8" Stainless Steel Rod
- 3.58° R.H./1 Lead/0.333" P.D. Worm
- 1.042" P.D. Worm Gear
- Wheel (Gear) with Tapped Holes
- #8-32 Machine Screws
- #8 Washers
- #8-32 Hex Nuts
- #8-32 Lock Nuts
- #8-32 Electrical Ring Terminals
- 1/8" Nylon Bearings
- 8-19V DC Motor
- 10mL Syringe
- 12" Luer Tubing Extension
- 3-Way Luer Stopcock
- Epoxy
- Power Supply

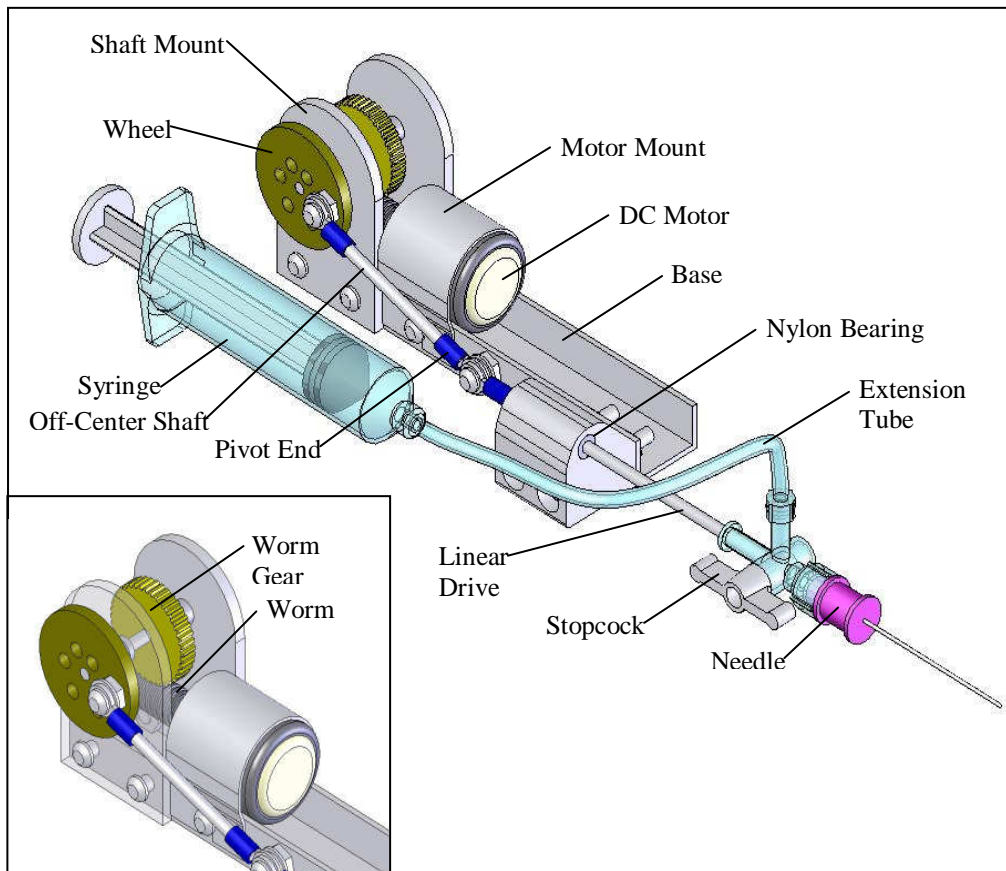


Figure 7. This SolidWorks diagram shows the components of our final design.

TESTING AND RESULTS

Simulated tissues were used to test the device performance at different frequencies and strokes. A gelatinous polymer imitated the environment around the egg yolk “tumor”. This polymer was made by mixing 25mg of agar powder with 100ml water and boiled for 10 minutes until totally dissolved. The solution was poured into a mould and left until it was set. A boiled egg yolk was placed on top of the first layer, then a second layer was poured in until the egg yolk was totally submerged. The phantom was cooled down until firm.

Our device was tested using the following basic procedure. A needle was first inserted into the tumor manually, and then input voltage was slowly increased to a certain value which corresponded to a specific frequency. The device ran for ten seconds while keeping it stationary. Suction was applied using a syringe connected through a stopcock. The frequency was then slowly turned down until fully stopped. The needle was withdrawn and unscrewed from the device. A syringe was used to expel the sample from the needle tip. The maximum sample volume obtained from this device was approximately 0.6mm³.

Our first test was the effect of voltage on the frequency of oscillation. To carry this test out, we used a power supply to provide voltage to the 9-18 volt DC motor. We applied voltage varying from 0 to 18 volts and calculated the resulting oscillation frequency. This frequency was calculated using a LabView virtual instrument program and a LabJack sensing device. The program would sense the closure of an electrical circuit in series (about 2 volts running through the circuit) and register the pulse as a vertical blip on a chart mapping voltage with respect to time. To complete the circuit, each period of oscillation of the rotor arm would bump two wires in close proximity together and create a connection. Each created connection would send a signal to the LabView program. The time interval on the graph was set to five seconds. After five seconds of data collection, the program could be paused and the iterations over a five second interval were counted. The number of pulses divided by the time interval (five seconds) yielded the frequency. Several tests were run with varied voltage to the drive motor.

A test was conducted using a linear oscillation depth of 1 cm with no load on the device of the needle to determine the voltage and frequency relationship. This relationship was determined to be linear (see Figure 8). The equation of the trend line is

$$y = 0.3431x + 0.0709$$

and the regression is high, at 0.9959, showing a strong linear fit.

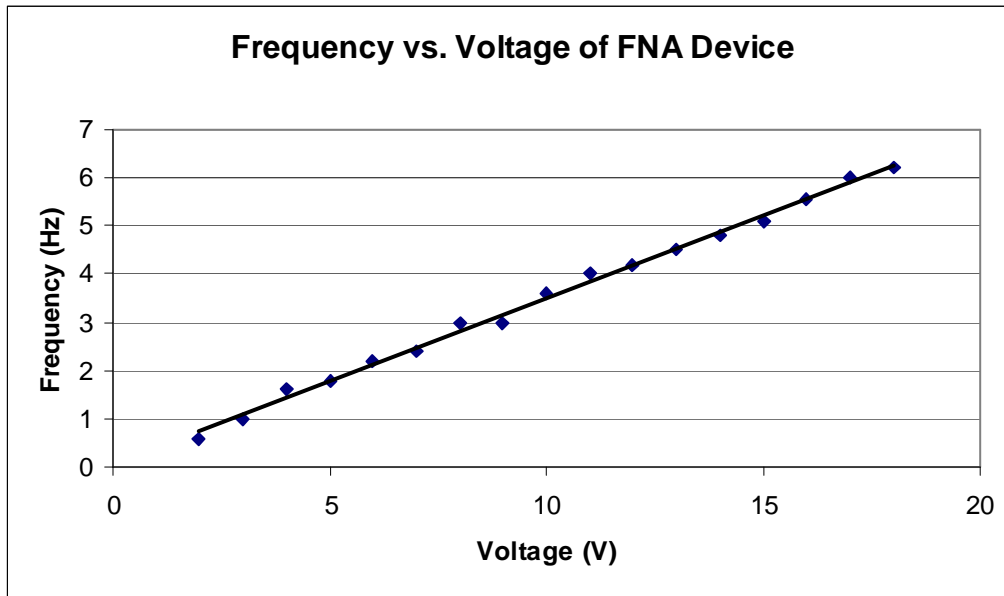


Figure 8: Relationship between frequency and voltage was found to be linear.

This relationship was confirmed using different stroke values and with varied needle loads.

CONCLUSIONS AND FUTURE WORK

In the future, testing will be our main concern. We will be conducting analysis of several aspects of our device. Our initial testing must be done to check our device for repeatability. The results we obtain must be accurately reproduced with each procedure. From the testing results, the importance of stroke depth, frequency, and suction can be found. This will lead to determination of an optimal operating frequency and voltage.

Along with the initial frequency and stroke testing, several other factors must be examined to determine their importance. Motion, harmonics, and waveform paths are all essential to our research. Testing different vacuum devices, drives, isolation techniques, and needle forces are also important. By examining these different aspects, the significance of oscillatory drive versus different vacuum techniques can be determined. Our future device must be dependable and efficient, as well as ergonomic and easy to use. A needle stroke setting should be added that can be change during the procedure. Additional testing of sample volumes must be done with the aid of a pathologist.

We will also be investigating a few different drive devices. Our prototype from this semester was strictly mechanical and electromagnetic. It was the source of positive and negative points. In the future, we hope to look into pneumatic designs as well as hydraulic designs. These designs could potentially ease the methods of drive. We will also look into incorporating a cable line and housing to transfer the linear motion from a stationary device to a more mobile 'pen gripped' needle insertion device. By the end of next semester, we hope to have a new final design that takes the previous testing

guidelines into consideration. We would also like to try the aforementioned varieties of drive devices. Furthermore, we hope to try differing vacuum methods to find the most controllable and efficient vacuums.

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Appendix B: Product Design Specifications

Fine Needle Aspiration (FNA) Device

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December 12, 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 viable cells for testing. The goal of our project is to maximize tissue sample size in a single, timely procedure. We propose to develop a device that automates the current biopsy procedure, and tests the sample yield by varying the frequency and needle stroke. The test results will determine the optimal operating frequency at various stroke lengths to provide a maximum cell yield. The automation of the device will reduce operating time, cost and discomfort for the patient.

Client requirements: The device must:

- be reusable
- be durable
- be user-friendly
- be sanitary to clients standards
- comply with given hospital safety standards
- be dependable and precise
- test variations in frequency and needle stroke

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
 - vi) Vacuum mechanism to draw cells into needle easily operated by second person
 - b) Safety:
 - i) No risk of electric shock
 - ii) Non-toxic and non-allergenic
 - iii) Preserve needle integrity
 - c) Accuracy and Reliability:
 - i) Variable needle insertion depth (10mm to 20mm)
 - ii) Frequency must be variable and measurable

- iii) Biopsy sample must be retained within needle shaft
 - d) Life in Service: Device must be operable over 30 minute interval
 - e) Operating Environment:
 - i) Sterile hospital environment
 - ii) 23°C standard room temperature
 - f) Ergonomics:
 - i) Functional at varying angles of operation without losing maneuverability
 - ii) Controls must be easily accessible
 - g) Size:
 - i) Small and slender
 - ii) Must not restrict maneuverability and accessibility
 - h) Weight:
 - i) Must not strain arm and hand
 - ii) Light weight
 - i) Materials:
 - i) Light weight materials
 - ii) Easily sanitized, especially materials potentially in contact with patient
 - j) Aesthetics, Appearance, and Finish:
 - i) Marketable (aesthetically pleasing to patient and doctor)
 - ii) Maintains professional medical device appearance
- 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 Gun (Patent 7008383)