Device to Improve Diagnostic Yield of Fine Needle Aspiration

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Abstract

The purpose of this project is to improve the current procedure for Fine Needle Aspiration. This procedure is currently manual and requires multiple attempts to yield a viable sample of cells. Our client wants to automate this procedure using a handheld oscillation device. The device must be safe, have an adjustable stroke and frequency, and be ergonomic. In the previous semester, our team built a working prototype of the wheel and motor design. However, this prototype is not reliable for testing, so we propose to build an alternate design for testing, using a pneumatic driving system. With the pneumatic prototype we will begin testing on various phantom tissues and hopefully on human tissue in a clinical setting.

Background

Biopsy

A biopsy is a medical test involving the removal of a sample of tissue from the body for examination by a pathologist. Biopsies are used to indicate any suspected cancerous lumps. They can be performed on any organs in the body, however, different biopsy procedures are performed for different organs of the body. Six kinds of procedures exist:

1.) **Excisional**: the whole area or organ is removed for diagnosis
2.) **Endoscopic**: a fiberoptic endoscope is inserted into the gastrointestinal tract, allowing direct visualization of the abnormal area and pinching off small amounts of tissue.
3.) **Colposcopic**: a gynecological biopsy method to diagnose abnormal pap smears.
4.) **Fine Needle Aspiration**: a small needle is inserted into the lump to withdraw a cell sample for examination.
5.) **Punch**: tests skin cancer, takes small amount of skin.
6.) **Bone Marrow**: a sample is taken from the bone, needle inserted into marrow.

Fine Needle Aspiration (FNA)

Fine Needle Aspiration is a biopsy method, which is used to collect tissue samples from the upper region of the body. Procedures are usually performed on neck cysts, breast tissue, thyroid glands, or anywhere a lump can be felt. The procedure is currently manual and requires repetitive low yield sampling to collect enough viable cells for testing. If the sampling is inconclusive, the doctor must go back and repeat the procedure

Fine Needle Aspiration Procedure

The procedure for this type of biopsy does not seem complicated. A doctor first isolates the mass with his or her index and middle finger. Next, a small needle is inserted into the mass in an in and out motion several times. The needles used for this procedure are usually about 21 to 25 gauge. The needle diameter decreases as the gauge increases. Thus, a 25 gauge needle (diameter ~0.5 mm) is smaller than a 21 gauge needle. On average, about 100 cells should be taken to ensure success of the procedure. After the sample is taken, it is sent to a pathologist to be examined.

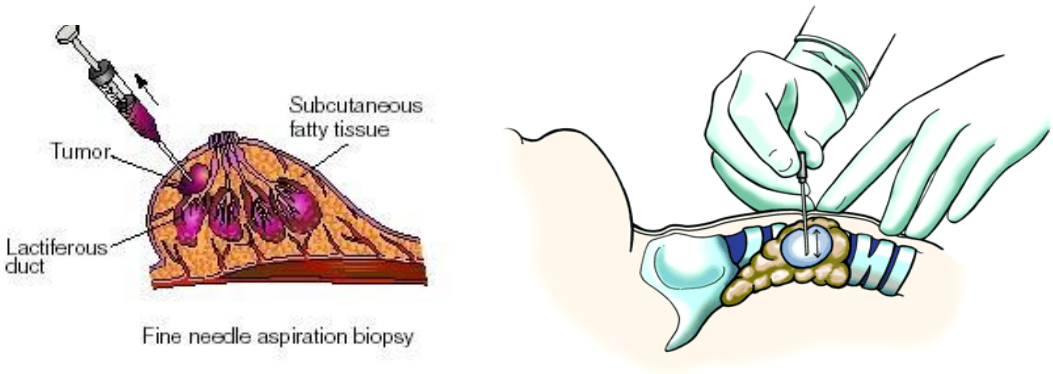

Figure 1: The photo on the left shows the needle being inserted into a suspected mass in the breast tissue. The photo on the right shows how the doctor uses his finger to isolate the mass.

The sample can be categorized in three different ways: malignant, benign, or inconclusive. If the sample is malignant, this means that the mass is growing uncontrollably and possibly spreading to other tissue. If the sample is benign, then the growth is under control and not spreading to other tissue. If the test is inconclusive, the procedure must be repeated. The diagnostic success rate of this procedure is about 70-80%.

Current Device

Currently, this method of biopsy is manual and not very accurate when collecting cell samples the first time. Furthermore, it is rather difficult to collect cell samples from harder tissues, as the needle just moves back and forth with the mass and few cells are actually acquired. The latter reasons are why we strive to improve this procedure.

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 improve this process by maximizing the tissue sample size in a single, timely procedure. We propose to develop an automated needle oscillation device which cooperates with an automated vacuum mechanism. The fine needle aspiration device will be tested on phantom tissues and hopefully on human tissue in clinical setting.

Problem Overview

The design needs to be safe, meaning that it must reduce the fine needle aspiration time and procedure number. The device must be handheld, reusable, and durable. For testing purposes, this device must be able to have variable stroke lengths and frequencies. The needle should be able to penetrate the tissue without breaking or bending. Furthermore, when used for taking samples from harder tissues, the needle must take viable samples, rather than move along with the mass. 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.

Design Constraints

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

The device must test two main variables: frequency and needle stroke depth. The frequency of the device must withstand a constant oscillation that can be varied from 0 to 10 Hz. Moreover, depending on the types of tissues being aspirated and their positions in the body, the needle stroke depth must be adjustable from 5mm to 20mm. The device must also produce a force sufficient to penetrate the skin and mass. Some tissues such as liver and muscle require more force than epidermal or gland tissues. Therefore, we would like to test all tissue with our device.

The device must satisfy several performance requirements. It must be reusable up to 3 tests in 20 minutes, and endure chemical sterilization methods between procedures. The device should operate efficiently at 23 degrees Celsius, and effectively produce a consistent, adequate sample in each procedure.

Safety and reliability are also very important. A locking mechanism will ensure the needle does not penetrate beyond desired boundaries and cause unwanted tissue damage. 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 5 millimeters to 20 millimeters, and the frequency of the ‘in-and-out’ needle cycle must be variable to 10 Hz. The biopsy sample must be retained within the needle shaft so that the pathologists can easily obtain the culture for examination.

The product should be small and operable by one hand. Any cords or wires in the design must not constrain the performance of the device. Furthermore, since fine needle aspiration is operated frequently on the neck when the patient is completely conscious, the noise from this device must be minimal and comfortable for the patients.

The device must be ergonomic. The device should be operable in either the left or right hand and not restrict maneuverability. The maneuver should be possible using only one surgeon and the control of the device must be simple, yet maintain all essential functions. Aesthetics are also considered, and the finished product should not intimidate or concern the patient in appearance.

Previous Achievement

Last semester we were able to build a working prototype using the wheel and motor model (figure 1):

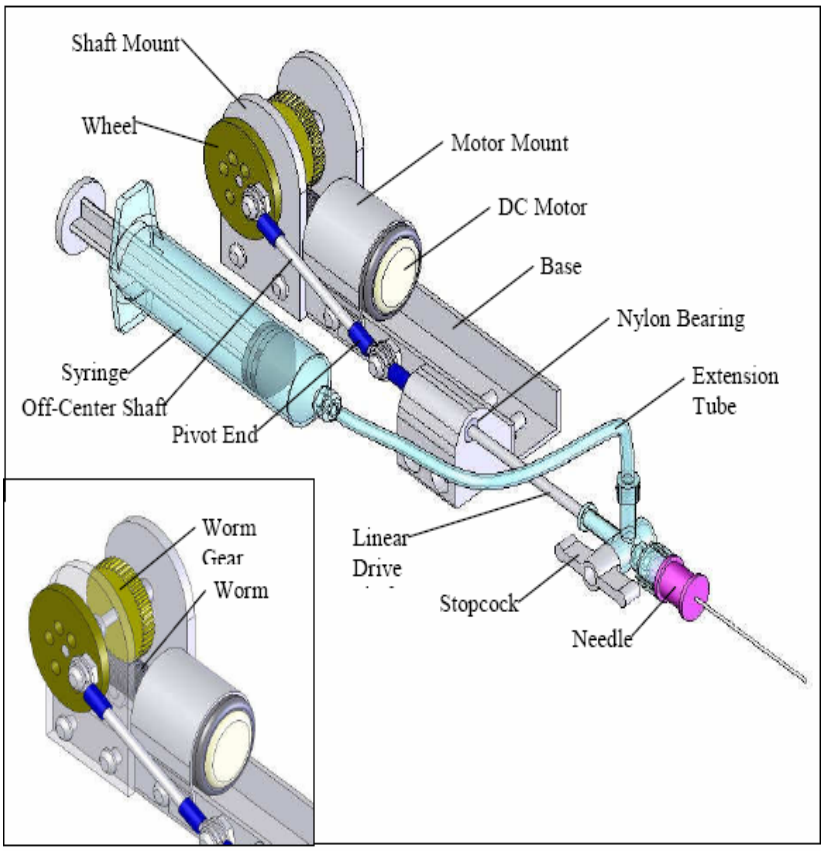

Figure 2: SolidWorks model for the wheel and motor design.

A small 9 to 18 volt DC motor drives a worm gear. The worm gear rotates a matching tooth gear that is mounted on an axel adjacent a radii-adjustable wheel. The radius of this wheel can be varied from 0.5 – 1.0 cm. The radii adjustment corresponds to a 1.0 – 2.0 cm needle stroke. A steel shaft is 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 to the stopcock, while a tube and syringe are connected to the stopcock as well to apply a vacuum. The vacuum is created manually by a second physician, independent of the device operator. The frequency of the needle can be changed by adjusting the input voltage to the motor. Based on experimental results, the frequency can increase up to about 7Hz. There is a linear relationship between the input voltage and the needle oscillation frequency as shown in the following graph. The test is conducted when the device is set to have 1cm needle stroke depth and no load.

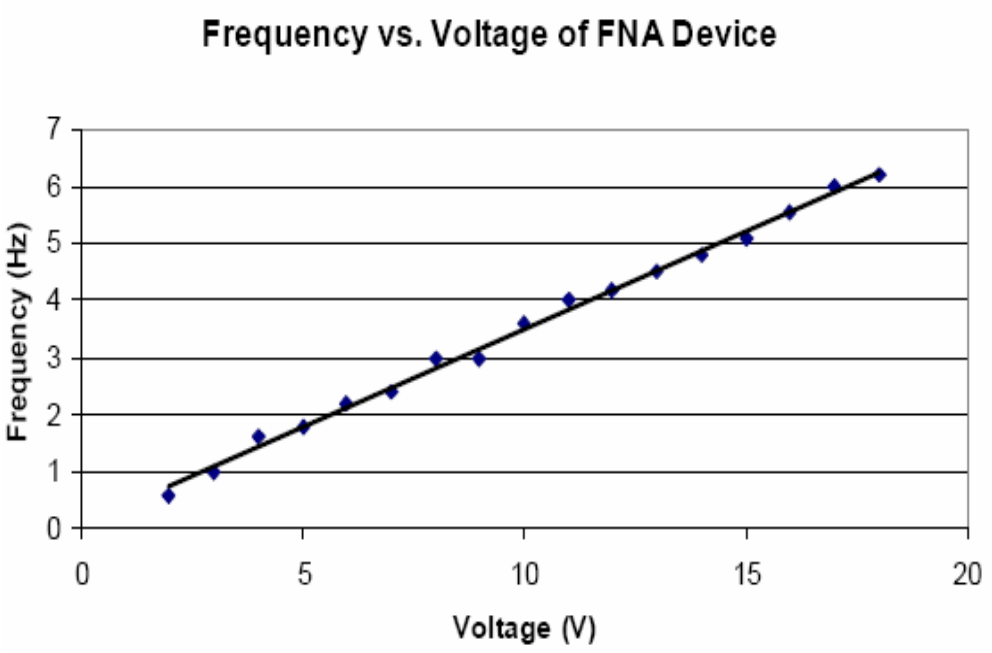

Figure 3: Linear relationship between input voltage and frequency.

The prototype is able to operate at the maximum frequency of 7Hz and yield a sample size approximately 0.63 mm^3 when performed on egg yolk phantom tissue.

The current prototype has some complications that make it unreliable for testing. The worm and rotational gear do not align well and cause grinding accompanied by undesired noise. This is also responsible for the poor fluidity of the device. The prototype has poor repeatability and does not yield a consistent sample size in each procedure. Moreover, in order to adjust the needle stroke in each maneuver, a set pin must be adjusted. This adjustment is time consuming. The prototype also exhibits strong inertial vibration. This is an inconvenience to the operator.

Alternate Designs

Improvement to Current Device

The previous device is shown on the right, made primarily of metal (aluminum and steel). There were several complications with the prototype.

Improving the current device would entail enhancing a wheel and motor drive constructed last year. The wheel and motor drive utilizes a beam member mounted to a rotational wheel by a rotational joint. The beam is offset from the center of the wheel (variable radius) and connected via a hinge joint. The assembly uses the rotation of the

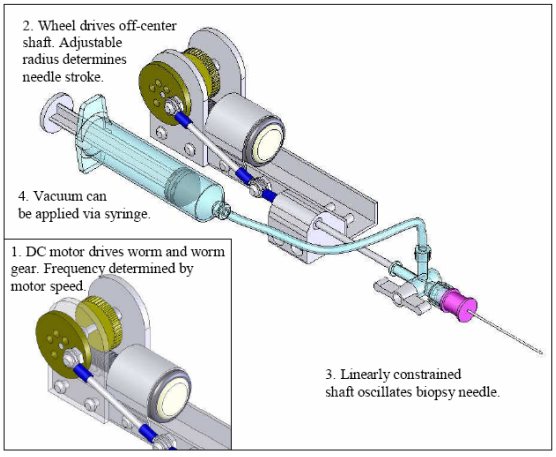

Figure 4: SolidWorks model for the wheel and motor.

wheel to produce linear motion through the members. The drive mechanism is similar to that of a piston. The wheel is driven by a 9-18 volt DC motor. The motor is linked to the wheel via a worm and gear set. The worm gear provides the additional torque necessary to drive the linear motion to optimal force.

The improved device would use the aforementioned assembly to drive the needle. The components would be housed in an ABS plastic encasement. ABS plastic is light and durable, and not susceptible to humidity fluctuations. This is important so that the meshing and alignment of gears and dynamic components is maintained. The encasement would mount all parts in a similar location to the image. However, the gray housing would be entirely replaced with a single machined stock of ABS plastic. This would ensure that components do not shift out of alignment. Additionally, all current nylon bearings would be replaced with Delrin plastic. Delrin is also resistant to humidity. The bearings would not constrict about the axel members and cause unwanted friction. Delrin plastic is also very strong.

The advantages to improving the prototype are significant. The new components would allow our prototype to run fluidly. The device would not grind and misalignment would be nearly eliminated. The device would also be smaller, lighter and more ergonomic. The ABS plastic housing is a very light alternative. The new prototype would attempt to better fit to the hand. Additionally, the motor and gear placement would only have to be set one time, and necessary adjustments would be minimal. The motor would also be mounted to the prototype, and eliminate any slipping. Delrin plastic bearings would facilitate a smooth motion for all dynamic axels. The components are also found locally, and the idea is novel.

The disadvantages of this idea are also apparent. There is a drop in needle force relative to the prototype as the frequency is lowered. This would present a problem as consistency would be lost, and testing data would become invalid. A consistent force must be put on the needle with respect to the device. Additionally, the motion is still not entirely linear. The wheel produces angular motion while linear motion is preferred. Inertial vibrations may still exist as well.

Pneumatic Drive

The pneumatic drive utilizes a small pneumatic actuator to produce linear motion. The actuator will be mounted inside a device and oscillate in and out of the cylinder. The device will use a stopper to limit the travel of the actuator. This stopper may be a threaded collar that can be adjusted. The stop will allow the device to vary in stroke length. The actuator would be preferably ABS plastic. The actuator is driven in and out via pressure from a source. The source is regulated from about 0 to 30 pounds per square inch (PSI) and is located remotely from the device. Alternating between an open and closed position is conducted by two three-channel pneumatic valves, also located remotely from the device. The valves control the flow to the extended or contracted position of the actuator. These valves are then controlled by a square wave voltage signal (voltage ranges from 0 to +9 volts with sufficient current). When both valves are on, the actuator extends, and when both valves are off, the actuator contracts. During motion, one valve allows pressure through to the actuator, and the

Figure 5: Pneumatic actuator

other valve allows exhaustion of unwanted pressure from the opposing side of the actuator. The signal driving these valves is produced via software and interfacing tools. The software is written in LabView, and a LabJack interfaces with the software to produce usable voltage. The signal is then amplified either through a mosfet, relay, or operational amplifier.

The advantages of this design are numerous. The ergonomics of this option are strong. The actuator is light and small. All motion is linear, and there is only one true mechanical component within the device and drive. The force applied from the actuator to the needle is consistent, regardless of frequency. This force can be adjusted by regulation of the input pressure. The needle stroke is also easier to adjust, and fine adjustments are possible. This can be done by stopping the path of the actuator at a certain length. Also, the acoustics of the device are low volume and unimposing. The frequency can be set exactly by use of the software. The software will also integrate a function to run single needle iterations. This will allow the user to place the needle properly. Additionally, the actuator runs very fluidly and efficiently.

Some of the disadvantages of this device are the pressure tubes that would connect the device to the pressure source. These tubes potentially become hazardous. Also, an actuator's motion is absolute. The device would have to be fully open or fully closed. Thus only a square wave drive is allowable. If a sine wave is desirable, a different set of valves must be incorporated.

Conceptual Design

Other than the wheel and motor design and the pneumatic, we researched other potential power sources as well. Although several options were considered, the two most intriguing alternatives were sonic scalers and vibration motors. These innovations are included as a reminder that, although they are not currently part of our prototype design, they nonetheless may later enhance and improve the device.

Sonic Scalers

Sonic scalers, along with ultrasonic scalers, are currently applied in the dental industry in treating periodontal disease. The technique requires extensive cleaning under and between the gum and teeth, and these apparatuses do so by oscillating and vibrating a very small hooked metal appendage. In addition, the scalers used by dentists release small amounts of water to ease access under the gums. This is similar to the necessary application of our FNA device, given the hooked appendage is replaced with a needle.

Ultrasonic scalers, which make use of a magnetostrictive motor that converts magnetic energy into motion, were immediately disregarded as overly powerful. They are small, but create a frequency output of up to 15 kHz (15,000 Hz), which is vastly beyond the 10 Hz max we require. Sonic scalers, on the other hand, make use of an air-turbine unit and are much less powerful at a maximum of 6,000 Hz. However, this is still much more than needed and sonic scalers are quite heavy at 15.5 pounds. They are also expensive at around $200. For these reasons, sonic scalers at this time do not seem practical for our design.

Vibration Motor

An interesting alternative, or perhaps addition, to our design is the utilization of a vibration motor. They are incredibly small, having a length shorter than 20 mm, a diameter of less than 6

mm, and weighing less than a gram. This is extremely advantageous in terms of ergonomic capabilities; the smaller the device, the more easily it can be maneuvered for the procedure. Unfortunately, the only ones found were too weak to move the needle with enough force to penetrate the skin (all under one Newton). Though disheartening, this realization proposes another option – perhaps these tiny motors could be used to vibrate the needle such as to potentially increase sample yield. This is a definite consideration as our client, Dr. Frederick Kelcz, initially suggested in his problem statement to design a device that will "hold the needle, vibrate it at a rate with controllable frequency, stroke and suction in a manner that is more efficient than the manual method currently performed." Therefore, adding a vibration motor to the design may very well improve our device.

Materials

These designs require several components. All electrical components will be powered by a power source with variable rating from 0 to 32 Volts and 0 to 5 amps. Wires are also necessary. Other transistors may include, but are not limited to, operational amplifiers, MOSFETs and relays. Necessary housing materials include stock ABS plastic for encasements and Delrin bearings for axels and rotational components. Shafts and members may also be constructed of plastic. A motor will be necessary for the first alternate design, as well as hinges and a stopcock. The second design will require a pneumatic actuator and a frequency control device. A pressure regulator is necessary to supply adequate pressure, and valves are needed to control pneumatic flow.

Design Matrix

Determining a final design is never easy, especially when we already had a semester's worth of work on one design over the other. The only fair way to choose one over the other is through a design matrix, where we weighted both designs on eight different categories based on how important they were to our client and ourselves (safety was all-or-nothing). The matrix is shown below, totaled out of a possible 100 points. Given the results, we have chosen to change directions and pursue the pneumatic device.

Feature (possible points)	Improved Motor and Wheel	Pneumatic
Safety (Essential)	Yes	Yes
Ergonomics (10)	2	7
Durability (10)	5	7
Repeatability (22)	14	17
Frequency Adjustability (22)	16	20
Stroke Adjustability (22)	10	15
Patient Comfort (10)	5	6
Cost (4)	4	4
TOTAL (100)	56	**76**

Figure 6: Design Matrix

Competition

The fine needle aspiration competition is relatively thin, as most procedures are still done manually and require multiple passes. There are primarily two devices, however, that serve as alternatives to the manual method, although they are a far cry from an automated method.

Cameco Syringe Pistol

The Cameco Syringe Pistol (or Gun), shown at right, boasts a constant suction during procedure. The suction, however, is trigger-based and – though easier withdraw than a simple syringe – still requires the doctor to manually withdraw the cells. There is also specimen filter within to prevent the cells from making it into the syringe. Yet the device is bulky and expensive, and therefore is not widely used.

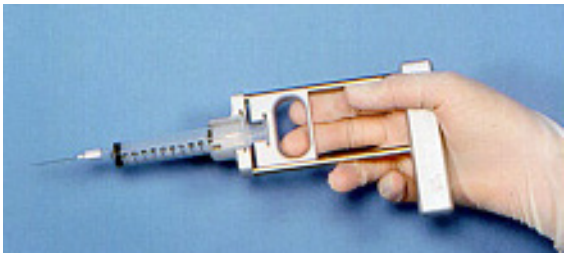

Figure 7: Cameco Syringe Pistol

Tao Aspirator

The Tao Aspirator (also known as a Pencil-Grip Syringe Holder), shown at left, is a more practical alternative to the manual method. It is much smaller than the Cameco Syringe Pistol and offers a close hand-to-needle distance for a more agile approach. One hand can support the mass while the other operates the aspirator. Perhaps the most thrilling innovation of the Tao Aspirator is its automatic suction. The button on the side can be set to automatically withdraw the plunger to that point. The device also has a preset and precise amount of suction that can be applied.

Figure 8: Tao Aspirator

Despite the advantages that both of these devices have, neither one possesses an automated needle drive mechanism, which is what we hope to accomplish.

Future Work

Our current plan for the rest of the semester is foremost to construct a working pneumatic prototype. We have already begun initial attempts, mostly just learning how all the parts will work together. Unfortunately there is still much to determine, including how to supply enough voltage to the valves that will run the actuator, how we will transfer the actuator's extension and retraction into a needle, and how we will house the actual handheld device. Initially we will create the vacuum suction to withdraw the cells manually by drawing back a syringe.

Once the prototype is built, we will proceed to test it on phantom tissue, and with success move on to animal and human tissue in a clinical setting. Dr. Kelcz has already told us that human testing is possible with a pathologist to evaluate the sample.

Other paths we will pursue after an initial prototype include developing an automated vacuum system to eliminate the manual-syringe method. We can perhaps use the Tao Aspirator's precedence in this to our advantage. In addition, we plan to pursue the possibility of a vibration motor in vibrating the needle to potentially increase sample size. If a vibration motor is added, we can compare test results from the previous pneumatic prototype to those with the addition of the vibrating needle to determine if it aids in the quality of the sample.

Finally, we plan to patent all designs that we think are worthwhile. These include, but are not limited to, the wheel and motor design, the pneumatic design, the vibration motor use on the needle, and any other subsequent designs, with which we come up.

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APPENDIX B

Fine Needle Aspiration (FNA) Device

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March 14, 2007

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 on human tissues. 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 client's standards
- comply with given hospital safety standards
- be dependable and precise
- test variations in frequency and needle stroke
- be operable on human tissues
- have automated vacuum mechanism

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
   vii) Audibly comfortable to patient

b) Safety:
   i) No risk of electric shock
   ii) Non-toxic and non-allergenic
   iii) Preserve needle integrity
   iv) Reset needle to zero position automatically
   v) Emergency stop

vi) Minimize tissue damage

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
iv) Needle locale information always available

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) Tao Aspirator