Dynamically Oscillated Biopsy Needle

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Abstract
Breast biopsies are performed to test for cancerous cells and to determine if surgical removal of the mass is necessary. This procedure involves inserting a needle into the tissue to gather a sample for testing and, if necessary, to mark the position for surgical removal. However, problems arise during needle insertion due to the nonhomogeneous nature of breast tissue, including bending of the needle and deformation of the tissue. Both cause inaccurate placement of the needle tip with respect to the tumor site in question. To increase the accuracy of needle placement, this project offers a new method of needle insertion. Experimental data suggests that dynamic actuation of the needle during insertion increases cutting force and decreases friction, thereby making it easier for the needle to cut through tough tissue. This is expected to reduce the effects of needle bending and tissue deformation. To quantitatively analyze this effect, a testing fixture was built to directly measure the resistive force on the needle as it is inserted into a tissue sample. During testing, the needle is actuated at varying frequencies and amplitudes of oscillation using an inertial piezoelectric actuator. This allows for determination of the most effective oscillation parameters for increasing the cutting efficiency of the needle during insertion. In preparation, two mathematical models of the system were built. The first was a dynamic model of the mass-spring system that the actuator is mounted on. This was used to verify the dynamic response of the system and to determine the parameters of the design, including spring constants and voltage input to the piezoelectric actuator. The second model was an ABAQUS finite element analysis. This was used in an attempt to better understand the dynamic interaction between the needle and tissue. Few such models exist, so it provides valuable insight into the problems associated with needle insertion.
The Need for Project

A method of decreasing adverse effects to biopsy needles during insertion is required to increase the accuracy of breast biopsies. During breast biopsy procedures, doctors use a needle to penetrate the patient’s skin and collect a sample of tissue from the site of the tumor. In order to get to the tumor site, the needle has to pass through various layers of soft and tough tissue, causing the needle to bend or create a “snowplow effect,” where the tissue deforms. The goal of this project is to create a device to attach to these needles that decreases the margin of error associated with the snow-plow effect and needle bending, and increases the accuracy of breast biopsy procedures.

The Design Project Objectives and Requirements

The purpose of this project is to increase the accuracy of biopsy needle placement by analyzing the effects of dynamically actuating the needle during insertion into tissue.

Design Objectives

The objective of this design project was to observe the effects of dynamically actuating a standard biopsy needle during insertion into a representative tissue sample, also known as a phantom. These results were analyzed in an attempt to quantitatively determine the effects of dynamic actuation on accuracy of needle placement during breast biopsies.

Design Requirements

Research suggests that dynamic oscillation of the needle during insertion results in a 10-20% decrease in tumor deflection and a 50-60% decrease in insertion force. The device will be tested to determine the numerical force values associated with standard insertion and dynamically actuated insertion. The goal of this testing is to show that force reduction due to actuation is significant and consistent with other experiments. A reduction in insertion force will also result in a reduction of tumor deflection.

Design Concepts Considered

Designs for this project were separated into three main areas and were selected based on practicality and effectiveness at achieving the project objectives. There were three major areas of concern in choosing a final design for the project. Due to their high complexity, a design was selected in each area before progressing to the next. These areas fall under the categories: type and method of oscillation, mounting method, and test fixture design.

Type and Method of Oscillation

This area involved choosing the type of dynamic oscillation and designing a method to achieve that oscillation. There were three options
for the type of oscillation; linear oscillation, rotary oscillation, or a combination of the two. Linear oscillation was chosen for this project because research showed it to be the most effective and practical.

Several different options were examined for the method of achieving linear oscillation. These options included a DC motor, piezoelectric inertial actuator, electromagnetic shaker, and a voice coil. The piezoelectric inertial actuator was chosen for three reasons: 1. It has a flexible output frequency and amplitude of oscillation, 2. One of these was available for use in testing for our project, and 3. The force output was in the required range of 5 – 10 N.

**Mounting Method**

The key desire in the piezoelectric mounting design was the ability to easily vary the parameters of the system and therefore the oscillation characteristics. One of the options considered included clamping around the actuator and mounting the clamp to a diaphragm, spring system, magnetic system, or pneumatic piston. The chosen solution was to mount the piezoelectric actuator to an additional fixture which would be suspended on a spring system. This method was chosen because of the simplicity in design and dynamic modeling.

**Testing**

Design of the test procedure was based around the need to quantitatively analyze the cutting efficiency of the needle at various frequencies and amplitudes of oscillation. There are many ways of accomplishing this. The chosen method for this project was to directly measure the resistive force on the needle as it is inserted into a tissue sample representative of the breast. Less resistive force during insertion indicates a greater cutting efficiency and vice versa. In order to do this, a linear drive system was designed to advance the piezoelectric fixture with attached needle into a sample tray. A single axis force sensor will mount to the piezoelectric fixture and directly measure resistive force.

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**Recommended Design Concept**

*The biopsy needle is oscillated linearly by an inertial-mass piezoelectric actuator. This provides a wide range of oscillation frequencies up to*

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**Design Description**

The proposed design features an inertial-mass piezoelectric actuator as the driving mechanism for needle oscillation. A 100 g mass is attached to a piezoelectric actuator. The vibration of this mass when voltage is applied to the piezoelectric creates a force on the system.
In order to transmit this force to the needle, a drive shaft is connected to the output side of the actuator. At the far end of the shaft, a Luer-type adapter connects the mass-piezoelectric system to the needle. By industry standard, all small gauge needles feature a Luer-type hub for interconnection with medical devices. The drive shaft passes through a linear bearing to ensure that the system creates motion only in the intended direction. The drive shaft threads into a plate which is supported on each side by 4 springs, facilitating oscillation of the system.

The system described above is enclosed in a two-piece shell. For the testing phase of the project, the shell is directly mounted to a linear drive system. For the final, hand-held product, the shell will be contained within an ergonomic handle.

The testing fixture consists of two stages, linked together by an ACME-thread linear guide screw and a support shaft. One stage houses a motor, which drives the guide screw, and the other stage holds representative tissue samples. The needle enclosure is mounted on a bracket and driven toward the sample stage by the lead screw.

**Analytical and Experimental Investigations**

The key analytical question regarding the proposed design was the determination of the required spring constant values, weight of the inertial mass, and voltage input to the actuator. These issues were addressed by creating a dynamic model of the proposed system and then experimentally solving for these values using MATLAB and SimuLink. The figure to the left shows the steady-state dynamic response of the system with the addition of anticipated effects from the needle/tissue interaction.

Finite element analysis was performed to approximate the various forces acting on the needle during insertion. Due to the complexity of human tissue and the difficulties using finite element software, a truly accurate representative model could not be fully created. However, a simplified model was created to show stress concentrations and the effects of tumor displacement with respect to needle insertion.

**Key Advantages of Recommended Concept**

The proposed design of the piezoelectric fixture offers several advantages as compared to the design concepts which considered rotational actuation or linear actuation using other methods. Key among these advantages is the overall simplicity of the design. This is due to the
fact that design features no moving parts other than the piezoelectric actuator. The design also offers far more versatility during testing than other designs because the oscillation parameters, including force output and frequency, can easily be changed by varying the input voltage to the actuator. In addition, the piezoelectric actuator allows for easy testing of the full range of oscillation frequency of 150 to 5000 Hz.

Advantages in the testing fixture lie in the fact that it was designed to serve two functions. The first is the stated goal of quantitatively analyzing the cutting efficiency of the needle with varying oscillation parameters. The second is to use the linear drive system in conjunction with a 3D x-ray machine to visually analyze the dynamic interaction between the needle and tissue. This system will be set up at Massachusetts General Hospital and is replacing the static analysis that is currently being used.

**Financial Issues**

This testing system would cost an estimated $5000 to build from scratch.

The major components of the design are the piezoelectric actuator, load cell, and supporting electronics. These components are available for use at Professor Jalili’s Piezoactive Systems Lab and did not need to be purchased for this project. However, these also constitute the highest cost at approximately $5000. Further work on this project would require the purchase of these components.

**Recommended Improvements**

The future design should progress towards a more compact and ergonomic device. Further modifications could be made to support more needle types.

The current device was designed as a proof of concept using what materials and equipment were available to the group. Its main purpose was to show that dynamic actuation of the needle during insertion into the breast increases the accuracy of needle placement. Once the most effective oscillation is found, it will be possible to tailor the design around those parameters and decrease the overall size of the system. This system could then be packaged into a handheld device and provided to physicians for use during the breast biopsy procedure.

Another area designated for improvement is the needle coupling mechanism. Our device works well with needles that use a Luer-lock hub, but it cannot attach to larger coring needles. Ideally, a version of the device which can attach to these needles would be designed.