Materials Tester for Breast Tissue *In Vivo*

*Design Team*
William Gearan, Michael Kapust, Christopher LaRue, Nicholas Lauretano

*Design Advisor*
Prof. Sinan Müftü

*Abstract*
It is widely accepted that the *in vivo* properties of breast tissue differ from its *ex vivo* properties, yet no direct measurements of *in vivo* properties have been made. The purpose of this project was to develop a device that could measure these *in vivo* properties during surgery to fill this gap. A search of existing products and patents has turned up devices that are either intended for *ex vivo* testing or not designed for breast tissue measurements. After establishing design criteria, developing several contrasting design concepts, and performing extensive proof-of-concept testing, a hand-held surgical indenter was designed. This device utilizes an indenter sphere of known radius, a linear actuator, and a load cell to develop force-displacement curves. Using Hertz contact theory, the modulus of elasticity of the tissue can then be determined. A stabilization ring and linear displacement potentiometer are used to filter out any movements of the device relative to the test surface. For ease of use, the testing is automated using a LabVIEW virtual interface for test execution and data collection. To determine its accuracy, the device was compared to a table-top universal tester using raw chicken breast.

*For more information, please contact s.muftu@neu.edu.*
The Need for Project

Currently, no device exists to measure the in vivo properties of breast tissue, which are believed to be different than ex vivo properties. New breast cancer screening technologies and theories that are being developed rely on the modulus of elasticity of breast tissue. While there has been extensive research on breast tissue conducted in the past, all testing has been performed on ex vivo tissue. Many researchers have theorized that tissue still in the body, or in vivo, has different material properties than ex vivo tissue because of factors such as blood pressure. Since no device existed to measure these in vivo properties of breast tissue, a new device needed to be designed and built for testing.

The Design Project Objectives and Requirements

The goal of the project was to develop a hand-held materials tester than could be utilized during a normal breast surgery.

Design Objectives

The device must be able to measure displacement and force to determine Young’s modulus. The device must be easy to operate and usable during a normal breast surgery, as no special surgery will be performed for testing. It must also be able to be sterilized and/or utilize a sterile drape to be used in an operating room.

Design Requirements

The device must perform the entire test in approximately 30 to 120 seconds, depending on the type of surgery being performed. It must also be small and hand-held, with the option to be attached to a fixture. The device should feature visual feedback for the operator during testing. The test displacement must be controlled and no larger than 3-5mm, with force accurately being measured simultaneously. The test should be controlled and data collected through computer software such as LabVIEW.

Design Concepts Considered

Both a tensile tester and an indentation tester were developed and compared to decide on a final design. Existing technologies for materials testing were researched prior to the development of the device. Almost all devices were not designed for in vivo testing. Any device that met this criteria was arthroscopic, which would require a separate surgery and violate one of the main design goals. Two main design concepts
were developed: a tensile tester and an indentation tester.

**Tensile Tester**

The first design utilized tensile testing as the material testing method. The device would have two tissue clamps, with one fixed and one moving at a controlled displacement with an attached load cell. This design contained several issues, such as long testing times and possible permanent damage to tissue because of additional incisions.

**Indentation Design**

This design utilizes the theory of contact mechanics. By using a universal testing machine (CETR) raw chicken breast was indented using a spherical indenter as proof-of-concept. Reasonably repeatable load-displacement curves were obtained, proving this theory would work for the device design. Due to quick set up, minimal test time, ease of operation, and no tissue damage, it was decided that the hand-held materials tester should be an indenter. This design indents a spherical tip into the surface of the test material a known distance and measures the resulting force.

**Recommended Design Concept**

The design is a hand-held indenter driven by a linear actuator, with measurements from an attached load cell. The device also incorporates a stabilization ring to quantify movements during testing.

**Design Description**

The recommended design incorporates a linear actuator, a miniature s-beam load cell, an Arduino microcontroller for displacement control, and a LabVIEW interface for data collection. The linear motion is driven by a precision stepper motor and contains an optical encoder to measure the exact displacement achieved. The load cell is mounted in-line between the end of the actuator and the end of the indenter tip to measure reaction forces from the tested material. Using these measurements, a force-displacement curve is created to solve for the value of Young’s modulus using Hertz contact theory.

In addition to the main components, a stabilization ring is
mounted to the end of the device and surrounds the indenter tip. This ring is attached to spring-loaded shafts that are free to retract into the housing. This ring serves multiple purposes. First, it acts as a safety to prevent accidental loads on the indenter tip that could damage the load cell. Next, it provides a surface contact that will help the surgeon keep the device steady during testing. Finally, the shafts are attached to a linear displacement potentiometer that tracks any displacement of the device perpendicular to the test surface due to effects such as patient breathing or hand movements of the surgeon. This measurement helps to post-process the data and increase the accuracy of the displacement measurements.

All components except the DAQ and power supply are contained inside a gun-shaped housing that is easy for the surgeon to hold. The test is automated, requiring only the push of a button to begin testing. The housing also contains an OLED screen that provides feedback, such as warnings that the surgeon’s hand has moved too much or that the test has completed.

**Experimental Investigations**

To prove that contact mechanics testing was viable for inelastic breast tissue, testing was conducted using a table-top indenter and chicken breast. By varying material thicknesses and indentation depths, two important conclusions were found. First, the minimum thickness of material was approximately 20mm, much smaller than any tissue that will be tested. Second, the theory of contact mechanics holds true to an indentation depth of 3mm. By meeting these criteria, the Young’s modulus of the chicken breast measured during testing matched known values.

**Analytical Investigations**

The major concern with adding the stabilization ring to the design was the potential that forces applied by the ring would
interfere with the readings. If the deformation field or stress field created by the ring extended into the deformation or stress fields of the indenter, the measurements would reflect this interaction. To investigate this possibility, and to help determine the appropriate ring size, finite element software was used to simulate the interaction of the device with the tissue. The deformation fields shown do merge with one another, but only at the micrometer level, which is acceptable and expected. The interference of the stress fields is negligible.

**Key Advantages of Recommended Concept**

The main advantage to this device over other testers is the stabilization ring and lack of advanced set-up required. The stabilization ring allows for accurate post-processing of data not found in other similar in vivo testers. Additionally, the simple set-up requires no special surgery or additional incisions required by other similar testers.

**Financial Issues**

The first prototype costs were approximately $2,200. Future development costs will be higher to meet health and safety requirements. This design utilized many off the shelf components as well as in-house machining and data acquisition resources to keep costs to a minimum. Even with the high cost of high precision miniature components, such as an $800 load cell/amplifier combination, the final prototype was approximately $2,200. Compared to many other materials testers on the market, this price is comparably low.

For future builds, the development costs would increase due to the medical standards that this device will need to eventually meet before it can be used in an operating room.

**Recommended Improvements**

Future work would include developing a sterile drape for the primary goal of this device was to create a materials tester for measuring in vivo breast tissue properties. At this
operating room use and creating an optional stabilization arm for when performing longer tests. phase, the final device meets the measurement, ease of operation, test time, and case of use goals that were set forth. To allow for operating room use, future goals would include the development of a sterile drape that would fit over the device to keep it separated from the sterile field of an operating table, while not hindering test accuracy.

Additionally, an optional stabilization arm could be developed so longer tests could be conducted. This arm would allow for the device to quickly be mounted with no modifications, and would eliminate the larger hand tremors that could result from fatigue over a longer test.