Strain Sensitive Array for the Study of Bone Surface Mechanics

Goals and Objectives

Long Term Goal

To develop a wireless, implantable device for measuring strain at multiple sites over the surface of a bone that can provide greater resolution than previously attainable, and be used to monitor changes in strain *in vivo* over the long term .

The goals for Summer 2004 are:

- Further electrical and mechanical characterization of the device.
- Resolving interface issues between the device and bone.
- Laboratory and *in vitro* testing of the device.

Introduction

Strain (deformation of a material) is an important measure for studying osteoporosis, tumors in bone, and designs of joint prostheses. However, measurement of strain on the surface of bone with high fidelity has been extremely difficult due to the lack of suitable tools. Current strain gauges are relatively large in size (2 mm by 5 mm gauge) and are difficult to mount on bone. As a result, strain gauges are not used very often, and when they are used, the fewest possible are used. In addition, when one uses relatively few gauges, one must know where to put the gauge if one wants to measure strain at the site of maximum or minimum strain. Because the strain gradients in bone can be extreme [1], mounting a gauge just a few mm or a cm away from the peak strain (or minimum strain) can lead to grossly understated (or overstated) measured values. Finally, with a gauge measuring 5 mm in length, the local strain cannot be measured and only an average strain in the region covered by the gauge is measured.

When measuring strain to evaluate a prosthesis design, localized changes in strain are thought to be key indicators that potentially destructive bone remodeling will occur [2]. For example, if strain decreases upon implantation of a prosthesis, bone will remodel to become less dense (bone resorption) and prosthesis failure can result. Bone resorption is a major clinical problem in orthopedics. On the other hand, if strain increases, the patient can experience pain and bone hypertrophy can result. This situation occurs near the distal tip of the femoral component of a hip prosthesis [3] [4] [5]. Currently available strain gauges are too large and too difficult to handle to adequately measure the changes in strain upon implantation of a prosthetic.

Furthermore, in the case of patients with bone tumors, implantation of an easy-to-use strain gauge array over the surface of the bone near the tumor could allow inexpensive monitoring of strains at the tumor site post-treatment. If the strain during walking increased over time, fracture would be likely and a more aggressive follow-up treatment would be required. In contrast, decreasing strain over time would indicate successful medical treatment.

A two-dimensional array of microscale gauges in a membrane that can be easily affixed to the bone will facilitate more complete and accurate strain data acquisition. Entire areas can be probed and peak strains easily found and monitored. Combined with signal processing electronics, real time high fidelity resolution of strain development on the surface of live bone can be achieved. Using micro-fabrication technology, we could batch fabricate hundreds of gauges that could be placed in a 5mm square area (the size of a single strain gauge currently used today) and offer orders of magnitude higher resolution than currently attainable. Ultimately the goal is to develop a wireless, implantable array that can be attached to the bone's surface. The array will be embedded in a flexible polymer membrane (a "skin"), enabling real time data logging of strain on the bone surface (Fig.1).

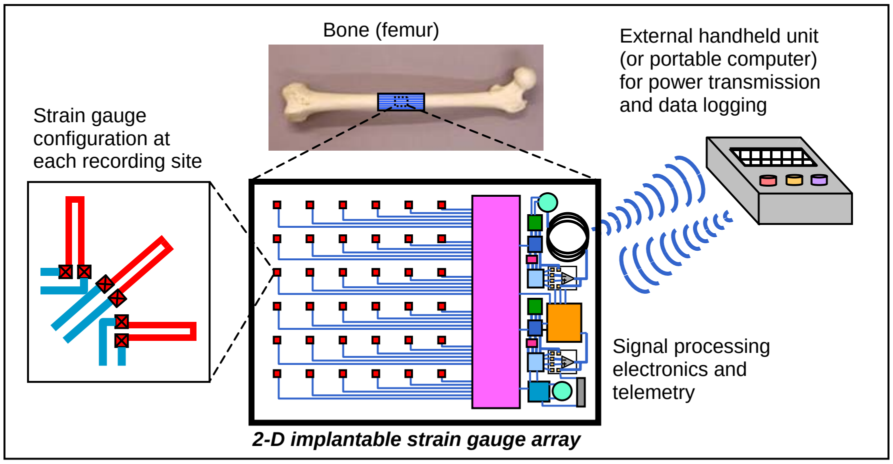


Fig 1. Diagram of an implantable, wireless, strain-sensitive membrane array. The gauge configuration at each recording site allows the complete stress state to be measured.

<u>Significance of the project</u>:

Through this research we will ultimately develop an implantable device to provide high-resolution mechanical data from live bone in real time. With this device, physicians can diagnose bone disorders at the early stages where it can be corrected using relatively noninvasive procedures that patients can easily recover from. Moreover, after major bone surgery such as bone tumor removal or the insertion of a prosthetic, scientists and physicians will be able to monitor how the bone is healing after the surgery. Bone surface strain is a strong indicator of the bone's response to mechanical loading, and thus provides an important post-treatment metric of the bone's recovery. The device that we are developing will have a major impact on the diagnosis and treatment of bone disease.

<u>Preliminary Data</u>

During the 2003 - 2004 academic year, we successfully designed and fabricated prototype devices. The primary strain sensing mechanism is through piezoresistors. Piezoresistivity is a reversible phenomenon, in which a resistor exhibits a change in resistance when an external stress is applied. This fractional change in resistance is proportional to the applied strain, and it persists as long as the applied stress remains. The piezoresistive effect is quantitatively expressed by a gauge factor, *G*, which is defined as the proportional change in resistance per unit strain:

$$G = \frac{\Delta R}{R\varepsilon} \qquad (1)$$

where R = nominal resistance, ε = strain, and ΔR = resulting change in resistance. This change in resistance arises from two important factors: (a) the change in the resistivity of the material, and (b) the change in the physical dimensions of the resistor as the material is deformed [6]. Strain is related to stress *(σ)* as expressed in Hooke's law:

$$\sigma = E\varepsilon \qquad (2)$$

where E = Young's modulus or the modulus of elasticity of the material of interest. Stress and strain can be tensile, compressive, or shear. It is important to understand the interaction of stresses and strains on strain gauges so that their structural changes can be accounted for in the design process.

We designed a strain gauge that maximizes sensitivity. The gauge material we chose was metal since it can be embedded inside a flexible substrate [7]. We simulated the mechanical characteristics of thin-film metal strain gauges embedded in a poly-dimethyl-siloxane (PDMS, silicone rubber) membrane with various loading conditions using the ANSYS® finite element analysis tool. Gauges with 3 - 38 turns were simulated under compressive and tensile stress in the x and y directions as well as tensile stresses in both directions simultaneously. For example, Fig. 2 shows the undeformed gauge embedded in PDMS. Upon subjecting this gauge to 10 Pa uniform compressive stress, the resulting deformed gauge is shown in Fig 3a. A tensile uniform compressive stress elongates the device as shown in Fig 3b. Values of strain were calculated from the simulation data for the various geometries. In all cases, we observed a linear relationship in the increase in strain with the increase in number of turns, which is expected as stress on longer gauges produces more strain. Upon analyzing the stress contours for both compressive and tensile forces for both the devices, we were able to demonstrate that the external stresses were effectively transmitted through the PDMS layer to the thin-film metal, validating our approach. An example of a stress contour is shown in Fig. 4.

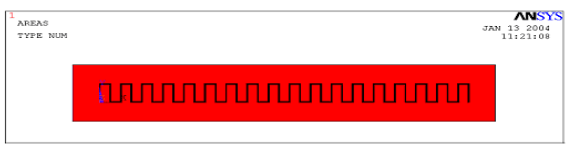


Fig 2. Undeformed 18 turn gauge embedded in PDMS. The black regions represented the metal while the red represents the surrounding PDMS membrane.

(a) (b)

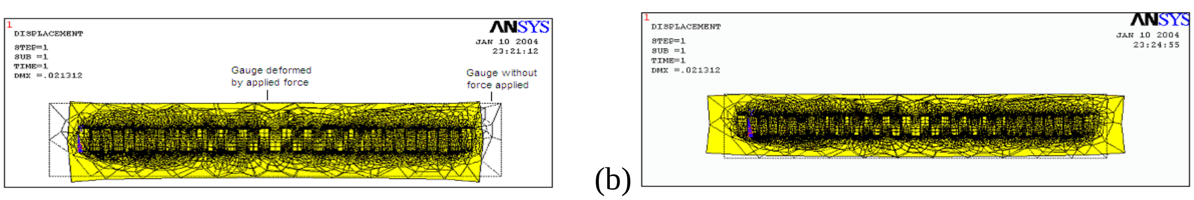


Fig 3. Simulated plots of the reference strain gauge by ANSYS® (a) with a compressive stress of 10 Pa and (b) with a tensile stress of 10 Pa applied along x-axis (horizontal axis). The dotted-line rectangle shows the device when no stress was applied. The yellow region represented the deformed strain gauge after stress was applied.

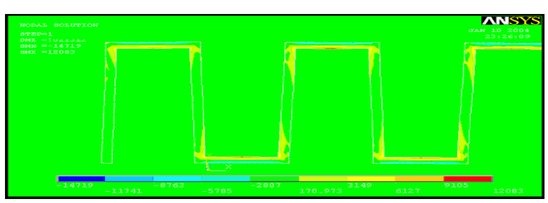


Fig 4: Simulated contour plots of the reference strain gauge by ANSYS with a tensile stress of 10 Pa applied along x-axis. The color scale shows the stress value range from –14719 Pa (dark blue) to 12083 Pa (red). The green background indicated the value of stress acting on the PDMS to be –2807 Pa. High stress areas are in the corners of the gauge, as expected.

After completing the simulation, we fabricated the device. A simple one mask process was used (Fig. 5). Microfabrication masks were drawn using Macromedia Freehand 10.0 and designs were implemented on flexible transparency films. A thin chromium adhesion layer (5nm) and gold gauge layer (40nm) was sandwiched between two layers of PDMS (50μm each). Processing steps used to achieve this profile include metal sputtering and photolithographical patterning.

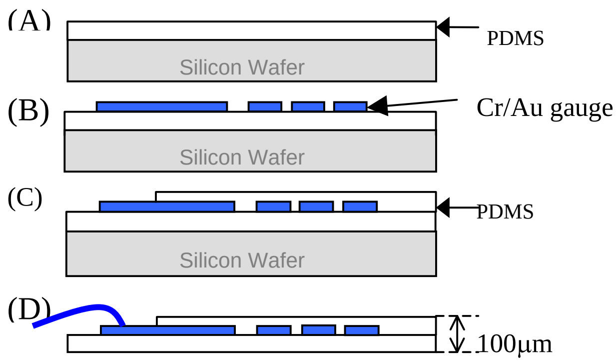
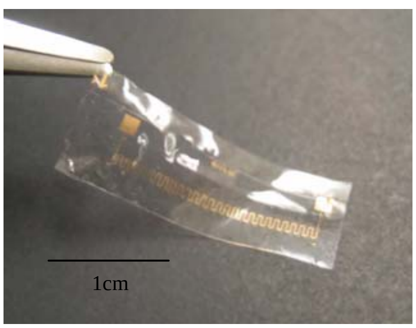


Fig 5. A) PDMS is spun on a silicon wafer. B) Metal is patterned on PDMS using photolithography C) A second layer of PDMS is spun on, which encases the metal gauge. D) Device is peeled off silicon wafer and is tested.

Finished devices are shown in Fig. 6. These first generation prototypes are relatively large in size to facilitate easy fabrication (2 cm × 1 cm). Once characterization and process optimization are complete, we intend to drastically miniaturize the device.

(a)



(b)

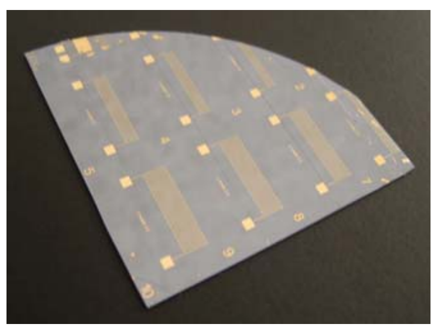


Fig. 6: a) Fabricated gauge with a thin film of gold sandwiched between two layers of 50um thick PDMS. b) Array of gauges on one quarter of a silicon wafer, prior to wire bonding and peeling off the substrate.

Preliminary characterization tests using a tensile tester were performed to evaluate the adhesion of the devices to rigid polyurethane foam that mimics the surface and consistency of real bone (Fig. 7). Both silicone sealant and poly-methyl-methacrylate (PMMA) were tested as adhesives (both are biocompatible). Silicone sealant proved to be a superior adhesive, as the entire device could sustain up to 110% strain before ripping down the center. However, the adhesion sites remained intact.

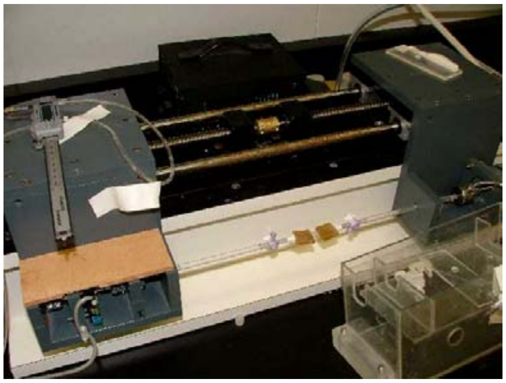
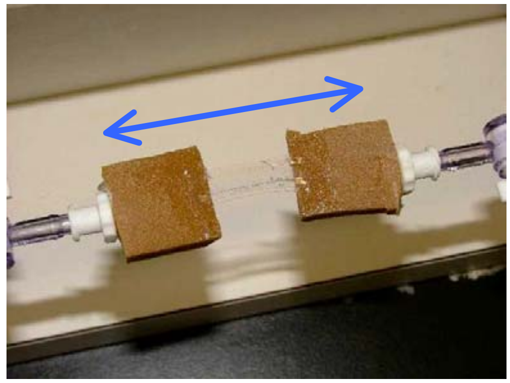
(a)  (b) 

Fig. 7: a) Photo of tensile tester. b) Close-up of device under test. Device is subject to tensile forces until breaking. Direction of applied force shown (blue arrow). Device is glued on either end to rigid foam using silicone sealant.

Methods

During Summer 2004, we intend to further test and characterize these devices. Thorough electrical and mechanical tests will be performed. For example, the gauges will be subject to various amounts of deformation, and the resulting signal change will be measured. A tensile test, similar to that performed to verify silicone sealant adhesion, will be performed in which we monitor the electrical signal of the thin metal gauge until the gauge fails. We expect the amount of strain at gauge failure to be significantly smaller than 110%, the failure strain of the encapsulating PDMS layers.

Adhesives for adhering the device to bone will also be further investigated. PMMA and silicone sealant have already been tested. Other types of biological adhesives such as cyanoacrylate, enzymatic glues (CelTak, matrigel, collagen), and UV-curable adhesives will be explored. The gauges must be placed as close to the bone as possible to capture the strain signal, but a balance must be met between the amount of adhesive necessary to secure the device to the bone and minimizing the effect of the adhesive on the actual measurement.

Gauge calibration and testing will also be performed using a MTS servo-hydraulic testing machine. This machine can apply a specific deformation to a material and measure force, strain, etc. Unlike the tensile tester used for testing the effectiveness of the glue, the MTS tester will allow a larger area to be affixed to the machine for a more comprehensive test. For this test the entire gauge will be affixed to a single piece of rigid, high-density polyurethane foam 1 – 2mm thick (identical to the foam used in the initial tensile tests). The actual foam thickness will be selected so that the stiffness of the material under the gauge is comparable to that under a gauge mounted on a femoral shaft. Initially, silicone gel will be used to attach the membrane to the foam. 1% strain will be generated by the MTS tester and the effect of the strain on the device will be analyzed (Fig. 8) [8]. Through this procedure, we can obtain a calibration curve of measured strain vs. gauge output. If additional amplification and filtering are needed, we will build these circuits on a breadboard. Gauge calibration under tension, compression, and torsion will be performed.

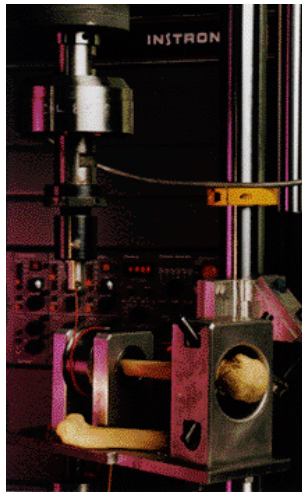


Fig 8. MTS servo hydraulic tester. The tester will allow tension, compression and torsion tests [8].

Gauge calibration will be performed in the plane of the membrane at 0º, 45º, and 90º to the longitudinal axis of the gauge. To assess the effect of out-of-plane bending on gauge performance, the foam will be subjected to four-point bending with the gauge first on the tensile side and then on the compressive side of the foam. We expect gauge output to reflect a small axial strain comparable to that measured by an extensometer mounted across the gauge, and that the effects of gauge warping on output performance will be negligible, and hence may be ignored in the future. This test is especially important because bone surfaces are curved and could cause the gauges to warp when mounted. If curved surfaces do result in a small gauge offset, output could be set to zero at the start of data collection.

Once the device calibration is complete and an optimal adhesive is found, *in vitro* bone testing will begin. Multiple devices will be affixed to the neck and subtrochanteric regions of a proximal femur, and the bone will be loaded to simulate a single-limb stance condition. Using the calibration curves, we will determine the magnitudes of the strains along the axes of the gauges.

Time Line

A plan for accomplishing the goals of this project over summer has been outlined in Fig. 9.

ID	Task Name	June / July	August	September
1	Test strain gauges in the lab (mechanical and electrical tests)			
2	Further investigate device adhesion issues			
3	Calibrate strain gauges			
4	Testing bone samples , in vitro			

Fig. 9 Overall research plan for the summer period

Responsibilities

Over the past two and a half quarters, I have received considerable exposure to several techniques such as micro-fabrication (including photolithography, polymer science, wafer handling, metal deposition) and material properties of adhesives. I have used finite element analysis software (ANSYS®) in order to simulate the effect of stress on the membrane. The results of our device design and simulation work will be presented in IEEE-BIBE Conference, [9]. I have already designed the strain gauges and have made the masks for fabrication. I have worked with a graduate student to fabricate the device in the research cleanroom. I have also been involved in studying adhesion properties of the membrane over bone-simulating surfaces using several different biocompatible adhesives. Over the summer, I will be involved in collecting and analyzing data from the gauges during the calibration and testing phase of this project. I will continue working with other adhesives in order to find the best one for this application. I will need to design tests in order to compare adhesion properties. Meanwhile, optimization of the fabrication process will also be carried out in parallel by a graduate student, with input from me.

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