Strain Sensitive Array for the Study of Bone Surface Mechanics

Goals and Objectives

Long term goals:

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
- can be used to monitor changes in strain *in vivo* over the long term

Goals for duration of the proposed project period (academic year):

- Design, fabricate, test, and characterize a biocompatible prototype strain gauge embedded in a flexible membrane.

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][2][3], 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 [4]. 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] [5] [6]. Currently available strain gauges are too large and too difficult to handle to adequately measure the changes in strain upon implantation of a prosthetic.

In the case of subjects with tumors in bone, 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. Through MEMS technology, we can batch fabricate thousands of miniature strain gauges. Hundreds of gauges 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 (Figure 1).

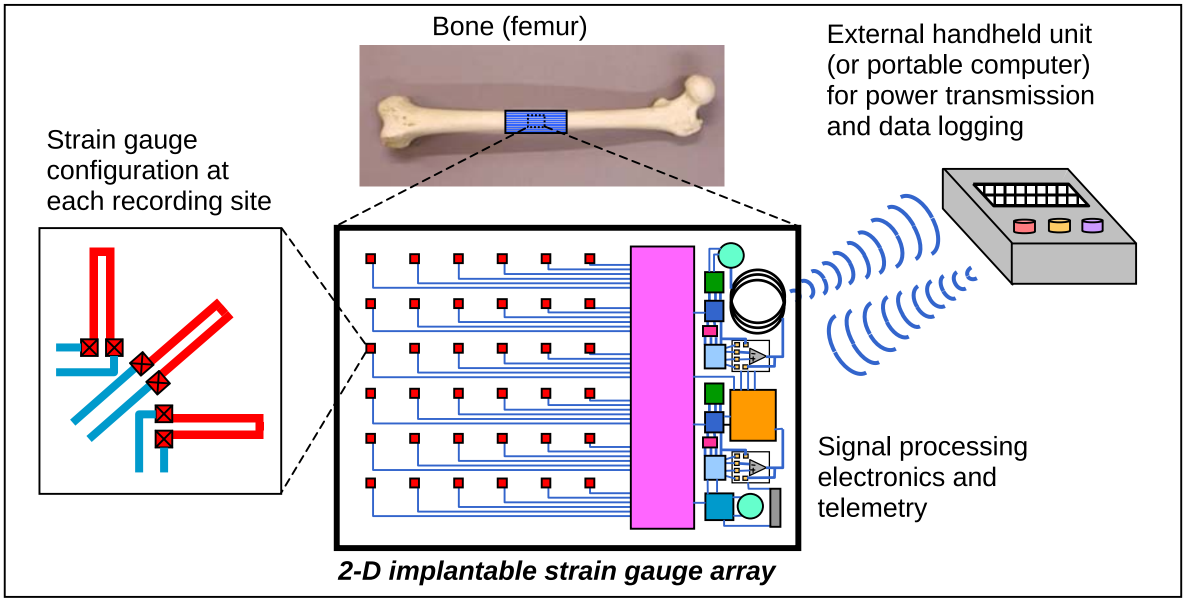

Figure 1. Diagram of an implantable, wireless, strain-sensitive membrane array. The gauge configuration at each recording site allows the complete stress state to be measured.

For the purposes of this initial study, we will focus our efforts on the development of a single strain gauge embedded in a flexible membrane. During the academic year, we will design, fabricate, test, and characterize a biocompatible prototype strain gauge in a flexible membrane.

Significance of the project

Through this research, the ultimate goal is to develop an implantable tool 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 that patient 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.

Preliminary Data

To resolve some initial design issues, the fabricated prototype devices from a thin layer of polydimethyl-siloxane (PDMS), embedded with mock foil "gauges" (Figure 2). PDMS is an attractive material, since it is flexible, easy to work with, and biocompatible. The membrane thickness varies from 1 – 1.5mm, and cutting the staggered slits into the membrane facilitates close coverage of a foam model of a femur. Without slits, the membrane has to be stretched to achieve close contact with the bone surface. The slits, thus, prevent excess strain on the gauges and facilitate proper device positioning.

Preliminary considerations have also been explored on possible gauge materials. Thin film metals, such as nickel-chromium (NiCr), have also been used as strain gauges albeit with less sensitivity compared to polysilicon. Metal gauges are attractive because they are easy to fabricate. Moreover, PDMS membranes with embedded metal interconnects have been recently demonstrated [7].

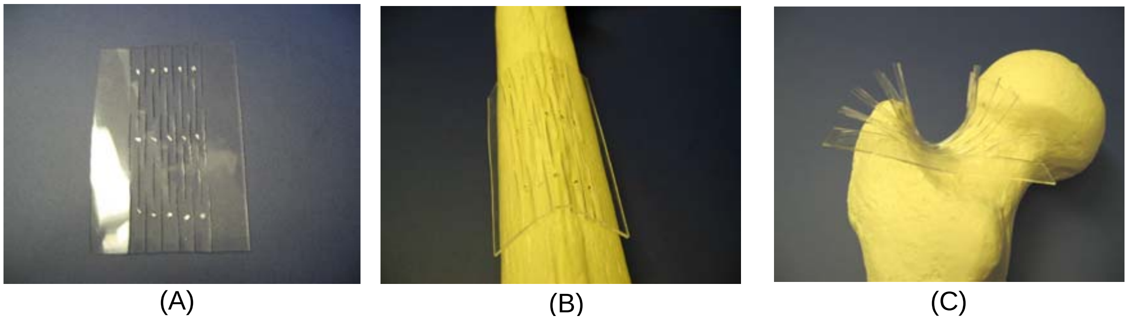

Figure 2. (A) Slotted prototype membrane, as fabricated (5cm × 7cm, 1mm thick). (B) Membrane along bony ridge on posterior aspect of femur. (C) Membrane shows good conformation to bone surface.

Methods

Based on preliminary data and considerations, we intend to design and fabricate metal strain gauges embedded in flexible PDMS membranes. To prove feasibility, single isolated gauges will be designed and fabricated. Thin film metal strain gauges have been previously used to measure strain solely in the direction normal to the membrane [8] [9] [10]. For our application, the primary components of strain are in the plane of the membrane, parallel to the surface of the bone. The performance of the gauges in response to in-plane strain will be simulated using ANSYS, a mechanical finite element analysis tool. Through simulation, we will be able to optimize gauge dimensions and predict the mechanical behavior of the gauges. Also, the strategic length and spacing of the staggered slits (to prevent over-strain) will be determined.

Once the design is finalized the gauges in PDMS membranes will be fabricated in the research cleanroom in Engineering Gateway and in the laboratory of my faculty mentor, Dr. William Tang. The proposed process flow is shown in Figure 3.

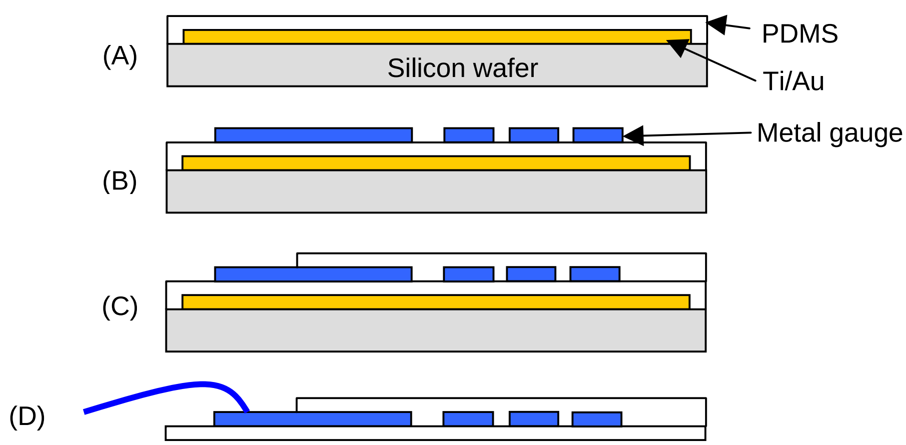

Figure 3. Device cross-section shown at each step. (A) Evaporate thin layer of Ti/Au to facilitate later removal of PDMS from the wafer. Spin on first layer of PDMS. (B) Evaporate and pattern metal gauge. (C) Spin on second layer of PDMS. Use stencil mask to protect bonding pads on electrodes). (D) Bond wires to electrode pads, Cut and peel device off the substrate.

The fabrication of the gauge may result in issues of material incompatibility, if the rate of expansion of PDMS varies from the expansion rate of the metal used in the electrode. In order to maximize the signal, there is a need to maximize the resistance of the gauge. While this depends on the metal used, there will be a need to choose from TiPt and NiCr. Thus, the project time line will essentially be based on material compatibility issues and the quality of signal response.

Once the gauges are fabricated, calibration of each gauge will be performed using the MTS tester in Dr. Keyak's laboratory (Department of Orthopedics, UC Irvine College of Medicine). The MTS tester is a machine that applies a known tensile or compressive load force to the material under test (usually bone). Through this tester, a calibration curve of input strain vs. gauge output can be obtained. If additional amplification and filtering is needed, we will build these circuits on a breadboard. This will be followed with gauge calibration being done in several dimensions. Also, preliminary testing on bone samples, *in vitro*, will be done in Dr. Keyak's laboratory.

Time Line

A plan for accomplishing the goals of this project is outlined in Figure 4.

ID	Task Name	Fall Quarter	Winter Quarter	Spring Quarter
1	Acquire materials			
2	Design gauges and simulate performance			
3	Fabricate prototypes (including process - optimization)			
4	Calibrate strain gauges			
5	Testing bone samples , in vitro			

Figure 4. Overall research plan for the academic period.

Responsibilities

I have already begun designing the strain gauges and will be making the masks. All task details mentioned in Fig. 3 will be performed by me and a graduate student. I will also be involved in collecting and analyzing data from the gauges during the calibration and testing phase of this project. This research will also require me to learn about strain gauges, microfabrication (including photolithography, polymer science, wafer handling, e-beam evaporation) and MEMS technology. I will have to be able to use software programs to design the gauges before I can have them simulated. I will learn how to do finite element analysis using ANSYS prior to making the masks for photolithography.

Itemized budget

The following is the break down for the expenditure. "Lab fees" are the fees charged per month to use the research cleanroom in Engineering Gateway (the Integrated Nanosystems Research Facility – INRF). During the academic year, we expect the time required in the cleanroom to total roughly 2 months. If the fees exceed $500, Dr. Tang has agreed to fund additional lab fees and additional material costs as needed.

Item	Details	Cost
Materials	Metals (NiCr, PtTi, Au) and chemicals for devices, micro fabrication (Wafers, PDMS, Silane) and other consumables like Petri dishes etc., wires, solder, conductive epoxy	$500
Lab Fees	$250/month	$500

References

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