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Simple Implantable Wireless Sensor Platform to Measure Pressure and Force

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Abstract

Smart implants have the potential to enable personalized care regimens for patients. However, the integration of smart implants into daily clinical practice is limited by the size and cost of available sensing technology. Passive resonant sensors are an attractive alternative to traditional sensing technologies because they obviate the need for on-sensor signal conditioning or telemetry and are substantially simpler, smaller, less expensive, and more robust than other sensing methods. We have developed a novel simple, passive sensing platform that is adaptable to a variety of applications. Sensors consist of only two disconnected parallel Archimedean spiral coils and an intervening solid dielectric layer. When exposed to force or pressure, the resonant frequency of the circuit shifts which can be measured wirelessly. We fabricated prototype pressure sensors and force sensors and compared their performance to a lumped parameter model which predicts sensor behavior. The sensors exhibited a linear response ($R^2 > 0.91$) to dynamic changes in pressure or force with excellent sensitivity. Experimental data were within 13.3% and 6.2% of the values predicted by the model for force and pressure respectively. Results demonstrate that the sensors can be adapted to measure various measurands through a span of sensitivities and ranges by appropriate selection of the intervening layer.

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Competing Interests:

Dr. Ledet is a co-inventor on US patent 9,662,066 which is related to the technology presented in this manuscript. Dr. Ledet is also co-founder and an equity holder in inSense Medical, LLC which holds the rights to the patent.

Keywords

Sensor; passive resonator; wireless; force; pressure

Introduction

The use of patient-specific data to drive personal care regimens has significant potential for optimizing medical treatments.¹ One approach to collecting patient-specific data is through the use of “smart implants”. Smart implants serve not only a therapeutic capacity, but also are instrumented with sensing technology to provide diagnostic data. In orthopaedic surgery, the relatively large size of the implants provides an ideal vehicle for introducing diagnostic technology into the body.

Smart implants also have value as research tools. The measurement of *in vivo* forces in orthopaedic implants has been used to provide a better understanding of knee,² hip,³ spine,⁴ shoulder,⁵ and fracture fixation biomechanics.⁶ Yet, despite the potential clinical value, the use of smart implants has thus far been limited to small cohorts of patients. This is largely due to the complexity and expense of the sensing technology.^{7,8}

Smart orthopaedic implants have traditionally been instrumented with strain gauges and telemetry systems. These require a power source, signal conditioning circuitry, and a telemetry system to transduce and wirelessly transmit data.^{8,9} Even with low power integrated circuits and inductive coupling for power, these circuits are complex and the large footprint requires substantial modifications to the host implant to incorporate the circuits.⁷ Fundamentally, the integration of smart implants into daily clinical practice is limited by the size and cost of available sensing technology and the required modifications to host implants.^{7,8}

Passive resonant sensors are an attractive alternative to traditional sensing technologies;¹⁰ they consist only of a passively powered resonant circuit (no on-board battery or power storage) whose resonant behavior is altered by the measurand of interest.¹¹ Resonant circuits consist of an inductive element (L) and capacitive element (C) whose interaction allows the circuit to preferentially absorb energy (and resonate) at a given frequency. Sensing is achieved through a variable inductive or capacitive element.¹⁰ A change in inductance or capacitance shifts the resonant frequency of the sensor which can be wirelessly interrogated using a coupled external antenna.¹² This obviates the need for remote (on-sensor) signal conditioning or telemetry and allows the sensors to be substantially simpler, smaller, less expensive, and more robust than other sensing methods.

We have developed a novel, passive sensing platform that is adaptable to a variety of applications.^{13–15} Sensors consist of only two disconnected parallel Archimedean spiral coils separated by a solid intervening dielectric layer (Figure 1). The disconnected coils inductively and capacitively couple to form a resonant circuit whose resonance is dependent on the separation distance between the coils.¹⁴ When exposed to a stimulus (i.e. force or pressure), changes in displacement between the two coils shifts the resonant frequency of the circuit which can then be measured wirelessly.

This sensor platform is adaptable to a variety of geometries, sizes, sensitivities, and ranges. We have developed a lumped constant circuit model of the two coils to predict sensor performance. The purpose of this study was to fabricate and test prototype wireless sensors that measure pressure or force and to compare performance of the sensors to our lumped parameter model.

Methods

Sensor Description

Fundamentally, the sensors are passive displacement transducers. Any stimulus that affects a change in the displacement between the two coils (l) causes a shift in the resonant frequency of the sensor. The sensitivity to a particular measurand (i.e. force or pressure) is dictated by the properties of the intervening dielectric layer. If the intervening layer has material properties such that it deforms under low forces, the sensor can be used to measure small changes in force. If the intervening layer deforms with a change in temperature, the sensor can be used transduce temperature, etc.

The resonant frequency of the sensor can be detected wirelessly by monitoring the spectrum of the return loss parameter (S_{11} parameter) via a network analyzer or using the well-established grid dip method.¹⁶

Sensor Behavior

Although the system contains no discrete electrical components or connections between the two coils, the resonant behavior of the system can be approximated as a lumped constant LC circuit. We have developed a model to calculate the total distributed inductance (L_T) and total capacitance (C_T) of the two-coil system. The lumped parameter model was developed by adapting inductive power transfer theory for planar spiral antennas. Approximations of mutual capacitance between the two coils, parasitic capacitance between turns of a single coil, inductive coupling between coils, and single coil inductance based on inductive power transfer were used to model the system.

Determination of the total distributed inductance and total capacitance allows for prediction of sensor resonant frequency (f_0) by the simplified expression:

$$f_0 = \frac{1}{2\pi\sqrt{L_T C_T}} \quad \#(1)$$

The self-inductance of a single planar spiral coil (L_{Coil}) can be modeled as:¹⁷

$$L_{coil} = \frac{\mu_0 n^2 d_{avg} c_1}{2} \left(\ln\left(\frac{c_2}{\rho}\right) + c_3 \rho + c_4 \rho^2 \right) \quad \#(2)$$

Where μ_0 is the permeability of free space, n is the number turns in the coil, d_{avg} is the average diameter of the coil ($d_{avg} = (d_{out} + d_{in})/2$), where d_{in} and d_{out} are the inner and outer

diameters of the coil, respectively, and $p = (d_{out} - d_{in}) / (d_{out} + d_{in})$. The constants c_1 , c_2 , c_3 , and c_4 are empirical corrections for a circular coil geometry and are 1.0, 2.46, 0 and 0.2, respectively. These constants have been previously derived in detail by Mohan *et al* for planar spiral coils.¹⁷

From applications in wireless power transfer,¹⁸ the mutual inductance between two planar coils (L_M) is determined by approximating each turn of the coil as a circular ring and by summing the mutual inductance (M) between each turn of the first coil (i) with each turn of the second coil (j):¹⁹

$$L_M = \sum_{i=1}^n \sum_{j=1}^n M_{ij} \quad \#(3)$$

These inductances contribute to the lumped constant circuit approximation. The total distributed inductance of the system is the inductances of each coil and mutual inductance between coils configured in parallel:²⁰

$$L_T = \frac{L_1 L_2 - L_M^2}{L_1 + L_2 - 2L_M} \quad \#(4)$$

where L_T is the total distributed inductance of the circuit, L_1 and L_2 are the self-inductances of each of the individual coils and L_M is the mutual inductance between the two coils.

Even though the system lacks a discrete capacitor, the sensors exhibit both capacitive coupling between the two coils and self-capacitance of a single coil. The single coil capacitance is achieved through coupling between adjacent turns within the same coil and as such, the individual coils exhibit self-resonant behavior.¹⁸

The total capacitance of electrically connected, stacked spiral inductors is well defined.²¹ However, there are several assumptions inherent in these calculations (such as perfect inductive coupling between inductors and negligible inter-turn capacitive coupling) that are not valid for disconnected coils.²² For our sensors, we have approximated the total capacitance of the system (C_T) as

$$C_T = 2C_S + C_M \quad \#(5)$$

where C_M is capacitive coupling between the two coils and C_S is capacitance of a single coil.

The capacitive coupling between the two coils can be approximated as a parallel plate capacitor with the two coils separated by a distance l_{int} :

$$C_M = \frac{\epsilon_0 \epsilon_{int} A}{l_{int}} \quad \#(6)$$

where ϵ_{int} is the effective permittivity of the intervening layer, ϵ_0 is the permittivity of free space, and A is the area of the capacitor (total area of the turns of the coil). In the case of the coils, the area of the capacitor (A) can be calculated by multiplying the length of the coil (l) by the width of the coil (T_W).

$$A = T_W l = T_W \left[\frac{\pi(T_W + T_S)}{(2T_W + 2T_S)^2} [d_{out}^2 - d_{in}^2] \right] \quad \#(7)$$

Where, T_S is the spacing between turns of the coil, T_W is the coil width, n is the number of turns in the coil, d_{in} and d_{out} are the inner and outer diameter of the coil, respectively.²³

If the intervening dielectric layer is heterogeneous, the effective permittivity of the intervening layer can be determined by averaging the volumetric permittivity of the materials between the two coils.¹³

From these relationships, the capacitance of a single coil (C_S) is approximated as:¹⁸

$$C_S = C_{PUL} \epsilon_{eff} \frac{1}{n} \quad \#(8)$$

where C_{PUL} is the capacitance per unit length of the coil in free space and (ϵ_{eff}) is the effective permittivity of the surrounding dielectric materials and is calculated using conformal mapping.²⁴ To account for the voltage drop between adjacent turns in the same coil, the length of the conductor in the coil (l) is divided by the number of turns (n) within the coil.²⁵

The equivalent circuit model that combines these individual parameter estimates is shown in Figure 2. The equivalent circuit and its approximations (Equations 1–8) are used to predict sensor behavior.

Sensor Fabrication

To test the lumped parameter model, prototype sensors were fabricated in batches on wafers using a combination of photolithography and electrodeposition. In brief, 1 mm thick glass wafers were coated in a sacrificial nickel layer which was then coated with a negative photoresist. Using a mask of the coil geometry, the photoresist was selectively cross-linked through UV exposure and the non-crosslinked material was etched away. Copper layers 10 μm thick were electro deposited onto the wafer to make the coils and then the remaining photoresist was then etched away. Each wafer was then diced to isolate the individual coils. The coils were then assembled into sensors by curing a solid dielectric layer between them.

The choice of material for the intervening layer was based on the desired behavior of the sensor. Pressure sensors were fabricated with a platinum silicone closed cell foam intervening layer which deforms with changes in hydrostatic pressure. Force sensors were fabricated with a polydimethylsiloxane (PDMS) intervening layer which deforms under axial forces.

Force Sensor Validation

The coils used to fabricate force sensors had an inner diameter of 0.01 mm, an outer diameter of 12 mm, inter-turn spacing of 50 μm , and a coil turn width of 160 μm (Figure 1). To make the sensor sensitive to axial force, a 160 μm layer of PDMS (Sigma-Aldrich, St. Louis, MO) was cured between coil pairs. Three force sensors were fabricated and experimentally tested to validate their performance.

Each sensor was loaded axially with a mechanical testing machine (Instron, Norwood, MA). Sensors were loaded up to 55 N at a rate of 0.001 mm/sec with a 30 second hold at 11 N, 22 N, 33 N, and 44 N. Each sensor was loaded five times to 55 N with a 300 second recovery between tests. Displacement and applied force were measured by the mechanical testing machine. Sensor resonant frequency was measured wirelessly at a distance of 2 mm using a four turn, 4 cm diameter wound antenna connected to a network analyzer (E5062A, Agilent Technologies, Santa Clara, CA). Return loss spectra were captured and exported for analysis at a rate of approximately 1 Hz. Based on data from the five runs, mean frequency values for each sensor and a 95% confidence interval were calculated and plotted. The force-frequency sensitivity of each sensor was determined and the goodness of fit was also calculated using linear regression.

Pressure Sensor Validation

The coils used to fabricate pressure sensors had an inner diameter 5.25 mm, an outer diameter of 11 mm, inter-turn spacing of 50 μm , and a coil turn width of 100 μm (Figure 1). To make the sensor sensitive to changes in hydrostatic pressure, a 1.0 mm layer of platinum silicone closed cell foam (Soma Foama 25, Smooth On Inc, Macungie, PA) was cured between pairs of coils. Three pressure sensors were fabricated and experimentally tested to validate their performance.

For testing, sensors were placed in a chamber and submerged in a column of deionized water. Sensor frequency was measured wirelessly at a distance of 5 mm using a 4 turn, 1 cm diameter wound antenna connected to a network analyzer. Return loss spectra were captured for analysis at a rate of 1 Hz. A calibrated reference pressure transducer (P51, SSI, Janesville, WI) was placed in the chamber at the same height as the wireless sensors to measure applied pressure. Resonant frequency and applied pressure were collected over the course of two hours during cyclic pressure changes between 10 and 110 mmHg. The goodness of fit was calculated using linear regression and pressure-frequency sensitivity was determined for each sensor.

Results

Force Sensing

Three force sensors were fabricated and tested. As predicted by the lumped parameter model, increasing axial compressive load caused resonant frequency to decrease proportionally. The mean sensitivity of the three sensors was 5.22 kHz/N. The response to axial load was linear with goodness of fit greater than 0.91 for each sensor, as shown in Figure 3. Using the material properties of PDMS, this response was predicted well by Equations 1–8 with less than a 13.3% error relative to the lumped parameter model in all cases. Results of a typical dynamic force test are shown in Figure 4. The force-frequency sensitivity of each sensor and the goodness of fit are shown in Table 1.

Pressure Sensing

Three pressure sensors were fabricated and tested. As predicted by the lumped parameter model, increasing hydrostatic pressure caused resonant frequency to decrease proportionally. The mean sensitivity of the sensors was 6.68 kHz/mmHg. The response to changes in hydrostatic pressure was highly linear with goodness of fit greater than 0.98 for each sensor, as shown in Figure 5 and Table 1. Using the material properties of the silicone foam, this response was predicted well by Equations 1–8 with less than a 6.2% error relative to the lumped parameter model in all cases. Results of a typical dynamic pressure test are shown in Figure 6. Importantly, there was little-to-no drift in baseline resonant response over the course of the testing.

Discussion

We have validated the performance of a simple passive wireless sensing system and compared experimental data to our lumped parameter model. Results demonstrate that our simple sensors can be adapted to measure different measurands (e.g. force and pressure) through a span of sensitivities and ranges. Fundamentally, the sensors are sensitive to changes in displacement, and thus almost any stimulus that causes a change in displacement between the coils can be measured by the sensors. The amount of displacement is dictated by the material properties of the intervening layer and thus the response of the sensor to a mechanical stimulus is also dictated primarily by the properties of the intervening solid dielectric layer.

For force and pressure, the material properties of the intervening dielectric layer and the fundamental laws of mechanics govern the force-displacement and pressure-displacement relationships to dictate how much displacement is caused by a given force or pressure. The magnitude of change in frequency that results from a change in displacement is governed by Equations 1–8. These relationships result in a wide range of forces or pressures that can be measured based solely on the appropriate selection of the intervening layer and of the geometry of the coils. For any planar spiral coil, Equations 1–8 can be used to predict the behavior of the sensor. However, for other geometries, the model, including the constants c_1 – c_4 in Equation 2, would need to be adapted.

From these feasibility data, we have demonstrated the functionality of sensors of two different coil geometries. Results show that the sensor technology is amenable to various coil geometries which can be controlled to further customize the functionality of the sensor and tailor its resonant frequency. In this study, the two types of sensors were composed of microfabricated coils of different geometries, demonstrating that the displacement-frequency transduction is adaptable for various configurations.

We can adapt the sensors to measure a broad range of pressures or forces based on the design of the coils and the selection of the intervening layer. The pressure sensors that were used for this study were being developed for a clinical application where pressures typically range from about 10 mmHg to 110 mmHg. Thus, we chose to test them in this clinically relevant range. By altering the intervening layer to one with different material properties (i.e. different modulus of elasticity and Poisson's ratio) or by changing the intervening layer thickness or by changing the coil geometry, we can control the effective range of the sensor and its sensitivity.

Other wireless sensors transduce pressure through variable capacitors or inductors with values dependent on the deflection of a membrane suspended above a sealed cavity.²⁶ Device fabrication is a complex, multistep process with multiple components, a membrane for each pressure range, and a hermetically sealed cavity that contains a gas for reference pressure.^{27–29} In contrast, our results demonstrate the potential for a relatively simple pair of disconnected parallel spiral coils with a solid intervening layer as an adaptable platform for wireless sensing of pressure or force.

Because the sensors are comprised of only three components (two coils and intervening solid layer), materials can be chosen for implantable applications which are biocompatible and hydrophobic making the sensors fully functional in an aqueous environment. We have conducted preliminary testing in water and saline at ambient temperature (22° C) and body temperature (37° C) that demonstrate sensor functionality. Changes in temperature cause a small shift in the resting resonant frequency but do not affect sensor sensitivity (data not shown). Proximity to metal can interfere with communication between sensor and reader but a dielectric layer between the coils and metal minimizes this artifact (data not shown).

The response of the sensor system can be customized by simply changing the thickness of the intervening layer or selecting a solid dielectric with different material properties. The lack of electrical connections or discrete components gives this technology far fewer failure modes, potentially allowing it to be more robust than alternative sensor systems – an important property for implantable applications. In addition to its simplicity, the sensor response is linear with sensitivities of 6.68 kHz/mmHg for pressure and 5.22 kHz/N for force which compare well with other passive sensors.^{10,30}

Overall, this sensor technology shows great promise as a simple wireless force or pressure transducer. One limitation of the current system is the limited distance at which the sensors can be read. Ongoing work is focused on maximizing the read range of the sensors using a custom reader and antenna system. Preliminary data demonstrate read range up to 8.9 cm with optimal pairing of antenna with sensors (data not shown).

By optimizing the size and using materials appropriate for long term implantation, this technology could be used to instrument the next generation of smart orthopedic implants to provide new sources of patient-specific data. Further research is required to prepare the technology for *in vivo* use.

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Highlights:

- A simple passive wireless sensor is described.
- A lumped parameter model of sensor behavior is presented.
- Prototype force and pressure sensors were fabricated and tested.
- Sensors demonstrated a linear response to changes in force or pressure.
- Sensor performance agreed well with the lumped parameter model.
- The sensors presented have potential to enable smart orthopaedic implants.

Figure 1:

Sensors are comprised of only two Archimedean coils and an intervening solid dielectric (left). Prototype pressure (center) and force (right) sensors were fabricated for testing.

Figure 2:

The equivalent circuit model predicts resonant behavior of the sensors based on individual coil inductance and capacitance as well as the mutual inductance and capacitance between coils.

Figure 3:

All force sensors were sensitive to changes in axial load. Average sensitivity of the sensors was 5.22 kHz/N. The response was linear with an average R^2 of 0.943. Error bars (95% confidence interval) are shown for each sensor based on five replicates of testing.

Figure 4:

Forces were applied in a stepwise fashion up to 55 N (dotted line) with a 30 second hold at 11 N, 22 N, 33 N, and 44 N while frequency (solid line) was sampled. Data shown are for a single load cycle for a single sensor.

Figure 5:

All pressure sensors were sensitive to changes in hydrostatic pressure. Average sensitivity of the sensors was 6.65 kHz/mmHg. The response was highly linear with an average R^2 of 0.993. Error bars (95% confidence interval) are shown for each sensor based on five replicates of testing.

Figure 6:

Pressures were applied in a stepwise fashion up to 110 mmHg (dotted line) while frequency (solid line) was sampled. Data shown are for a single pressure cycle for a single sensor.

Table 1:

Sensitivity and linearity of all force and pressure sensors.

Force Sensor	Sensitivity (kHz/N)	Linearity (R ²)	Pressure Sensor	Sensitivity (kHz/mm Hg)	Linearity (R ²)
1	-5.73	0.983	1	-6.80	0.996
2	-5.02	0.931	2	-6.52	0.989
3	-4.90	0.916	3	-6.66	0.994
Average	-5.22	0.943	Average	-6.65	0.993