A WIRELESS MICROSENSOR FOR MONITORING FLOW AND PRESSURE IN A BLOOD VESSEL UTILIZING A DUAL-INDUCTOR ANTENNA STENT AND TWO PRESSURE SENSORS

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ABSTRACT

This paper reports a micromachined antenna stent (stentenna) that is integrated with implantable microsensors for wireless sensing of blood flow and pressure with no battery. A device that has 20-mm length and 3.5-mm diameter (after expansion) is fabricated from 50 µm thick stainless steel foil by using batch-compatible micro-electro-discharge machining. This is coupled to two micromachined capacitive pressure sensors of approximately 1.4x1.8x0.5 mm^3 dimensions. A 0.5-µm thick parylene layer provides electrical insulation. The integrated device is deployed inside a silicone mock artery with a standard angioplasty balloon. The planar structure is plastically deformed to a tubular shape, resulting in dual helical coils with 50-60 nH each. These L-C tanks are used to wirelessly probe pressures at two points along a channel for flow-rate detection. Fluidic experiments that emulate a blockage in the mock artery demonstrate that the resonant impedance and phase provided by the LC-tanks to a separate transmitting coil shift by 5-40 MHz over flow-rate change of 150-300 mL/min. Pressure sensitivity is 273 ppm/Torr, which is >100x higher than past results.

I. INTRODUCTION

Stents are chronically implanted by balloon angioplasty to physically expand and scaffold coronary and other arteries that have been narrowed by plaque. However, re-closures often occur due to further plaque deposition or spasms. Wireless monitoring of cardiac parameters such as blood pressure and flow can provide advance notice of such failures. Past reports have showed passive telemetric sensing of pressure using a microchip with a planar thin film inductor fabricated together with a micromachined capacitive pressure sensor [1-3]. This L-C tank circuit couples to a separate external transmitting coil via mutual inductance. The change in pressure can be detected by the shift in the frequency at which the external coil shows a characteristic dip in impedance and phase.

It has recently been shown that a stent can be obtained by plastically reshaping a planar microstructure which is cut from planar metal foil and expanded into to a tubular shape by inflation of an angioplasty balloon on which the device is mounted [4]. The stents were fabricated by batch-compatible micro-electro-discharge machining (µEDM) [5] and offered the same radial strength and better axial compliance than commercial stents. However, these stents were simply mechanical devices. A following effort developed a method by which breakable links in a stent transform it into an inductive coil as it was expanded during deployment [6]. This technique allowed a stent to serve as an antenna. Static pressure in air and liquid ambient was telemetrically measured using the antenna stent, named stentenna. Unfortunately, the sensitivity was rather low, and flow measurements were also impossible. This paper describes a new dual-inductor stentenna, and its integration of two Si micromachined capacitive pressure sensors to implement a wireless flow-sensing system which offers high sensitivity.

II. DESIGN & FABRICATION

The planar design of the dual-inductor stentenna is illustrated in Fig. 1. It has a series of cross bands comprised of 50 µm-wide involute beams, with a bridge to a longitudinal beam at the center of the device. The involute bands form two separate inductors, whereas the beam is a common electrical node. At each end of the device the bands terminate in a section that forms a ring. This provides enhanced mechanical rigidity in pre-expansion state as it is assembled around the angioplasty balloon. It also provides improved radial stiffness after expansion. Capacitive pressure sensors are connected across the common line and a lead that is connected to the ring, thereby implementing two L-C tanks when complete.

When a liquid flows through a channel, there is a pressure drop between two separate locations that depends on the flow rate. A general expression for this drop for steady-state flow is [7]:

$$P_2 - P_1 = R_a V + R_b V^2 \qquad (1)$$

where P_1 and P_2 are pressures at downstream and upstream locations respectively, V is area-averaged flow velocity in an unobstructed vessel, and R_a and R_b are coefficients that depend on obstacle geometry and fluid properties. The first term is associated with a loss due to viscous shearing stress, and the second is due to geometry variation inside a channel, which includes re-deposited plaque or excess tissue grown over a stent. As the obstacles grow, the non-linear term dominates. The dual-inductor design is intended to implement sensing based on this relationship.

During the deployment of a stent, the structure is pushed against the walls of a blood vessel, and it is necessary to protect the micromachined pressure sensors from physical damage or unpredictable characteristic changes because of the application of the radial force. Having platforms for the sensors in the stentenna structure not only achieves rigid bonding but also helps to protect the sensors from bending forces. Several preliminary experiments were conducted with dummy samples that were pressurized by a balloon inside a 3-mm i.d. silicone mock artery, which was designed to evaluate vascular implants and had compliance similar to human artery (Dynatek-Dalta, Inc., MO). They showed, in fact, that the sensors had no damage and were still functioning even after full expansion to 3.5-mm diameter. However, in order to circumvent any

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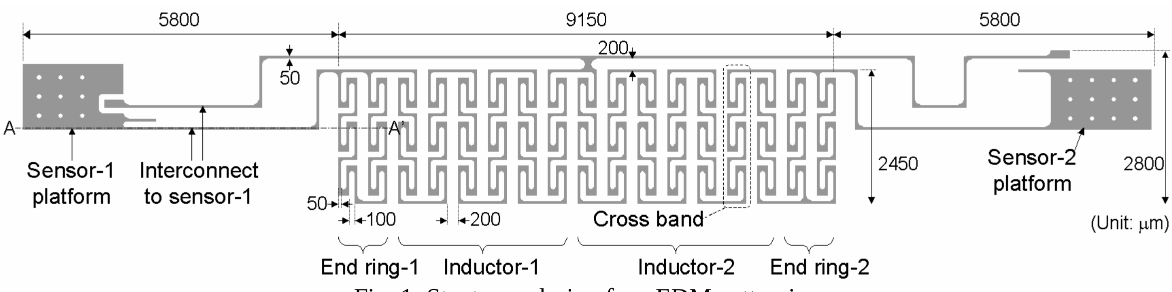

Fig. 1: Stentenna design for μEDM patterning

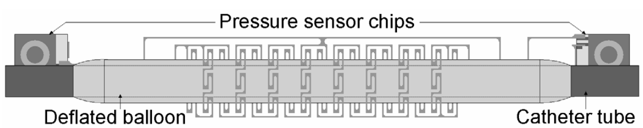

Fig. 2: A stentenna integrated with two sensor chips is mounted on a deflated angioplasty balloon.

potential failures, as shown in Fig. 2, the stent was designed to locate the sensors outside of the balloon, that had 16-mm length in this case. This large separation also helped to increase the first term in eq. (1).

The micromachined pressure sensor consists of a vacuum-sealed cavity capped by a 3.7-μm thick p^{++} Si circular diaphragm with the 1-mm diameter and 5-μm gap [1]. The diaphragm had a 10-μm thick boss for better linearity and an oxide layer on the backside for electrical protection in case of a contact between the diaphragm and a bottom electrode. The sensors were fabricated on 500-μm thick glass substrates by a silicon-on-glass dissolved wafer process. The glass substrate of a pressure sensor that is placed at upstream of flow was thinned by wet etching down to 100 μm in order to achieve smoother flow and reduce force applied to the sensor that causes bending of the longitudinal beams which hold the sensor.

Packaging is another essential component of the effort. Although passive stents that use steel do not require any insulation, in this case the stent plays an electrical role as well. In addition the assembly includes micromachined pressure sensors. Thus, the two primary goals include biological and electrical protection. The former involves in biocompatibilities of surface materials to tissues and blood. The latter involves two types of insulation; (1) between cross bands after expansion that could contact each other due to non-uniform expansion of the balloon, and (2) between the whole device and a surrounding fluid, i.e., blood, which is electrically conductive. Parylene-C was chosen for achieving these requirements because it has suitable characteristics. It provides a thin, uniform and conformal coating that is non-conductive, chemically inert, and biocompatible. It also has a proven history for applications for biomedical devices including cardiac stents [8].

Figure 3 shows the process flow for the device in a cross-sectional view at A-A' in Fig. 1. First, the pattern is created by μEDM of a 50-μm thick #304 stainless steel sheet (step-a). The machined structure remains connected to the original sheet at this point for ease of handling during following steps. Pressure sensors fabricated on a 500-μm thick glass substrate are diced to $1.4\times1.8\text{mm}^2$ chips in advance. Two sensors are attached to platforms which are linked at the ends of the longitudinal beams extended from the rings (step-b). The bonding is performed with enamel, which offers good adhesion and mechanical strength, and it is also easily applied and cured rapidly. Perforations in the platforms serve as escape paths for excess enamel. The sensors are then electrically connected to the leads with a conductive adhesive (step-c). The device is next coated with 0.5-μm thick parylene everywhere for electrical insulation (step-d). All surfaces of the device are coated. The device is then mechanically released from the sheet (step-e). Finally, additional epoxy is applied to perimeter of the sensors for enhancing the bonding strength. Figure 4 shows a fabricated device prior to the final application of epoxy.

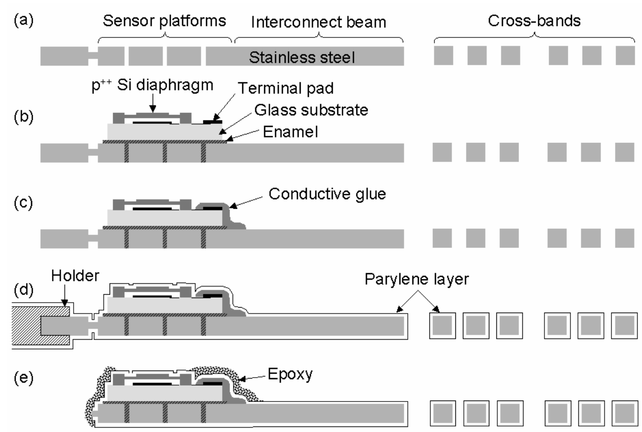

Fig. 3: Fabrication flow: (a) μEDM stainless steel foil; (b) glue down sensor chips; (c) electrically connect to terminal pads of the sensors; (d) deposit passivation layer; and (e) release device and apply epoxy perimeter of the sensor.

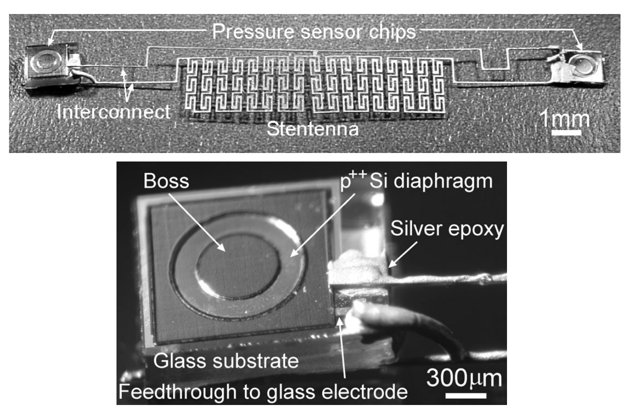

Fig. 4: (a: upper) Stentenna cut from stainless steel foil with two pressure sensors mounted on the far-end platforms; (b: lower) close-up of a sensor chip.

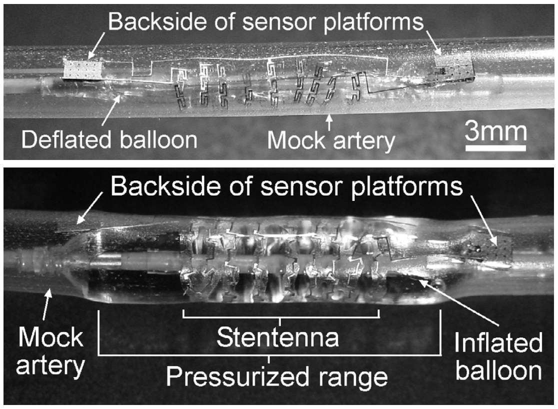

Fig. 5: (a: upper) A device inserted in a silicone mock artery with a balloon; (b: lower) the device expanded by inflating the balloon.

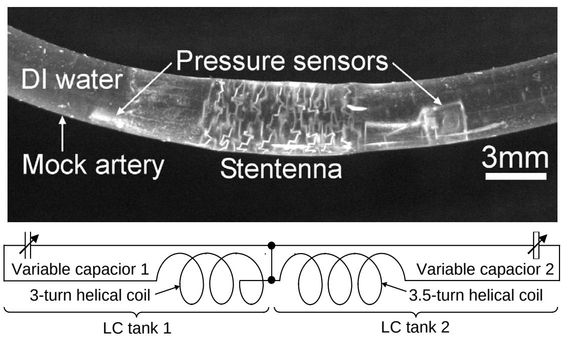

Fig. 6: (a: upper) A deployed device with balloon removed; (b: lower) the equivalent circuit after expansion completed.

The device is mounted on a deflated angioplasty balloon such that the bands alternate above and below the balloon as shown in Fig. 2. Figure 5a shows the device and balloon inserted into a mock artery. The inflation of balloon causes the artery, which has 0.25-mm thick walls, to expand from 3.0mm to 3.5mm i.d. (Fig. 5b). It can be seen in Fig. 5b that during this inflation process, the two sensors are located just off the pressurized range, reducing physical impact to both the sensors and the blood vessel. Upon inflation, the deployed stentenna is permanently deformed from planar to helical shape, which consists of two separate coils with 3 and 3.5 turns in this case (Fig. 6).

III. EXPERIMENTAL RESULTS

Figure 7 shows the fluidic test set-up used to evaluate the device in Fig. 6. A pump/flow-controller regulates the flow (of DI water), and a separate meter (Validyne PS309) measures the pressure drop along the 8 cm-long artery. To simulate blockage due to plaque, a dielectric rod with 1.5-mm diameter is positioned inside the stentenna. Input impedance and phase of an external coil are monitored with a HP4195 spectrum analyzer. The stentenna inductance is approximately 110 nH in total (>5x better than [6]). The pressure sensors have a measured response of ≈6 fF/Torr (Fig. 8a), which reduces to ≈2 fF/Torr with a 1.3-μm thick parylene coating. Sensor-1 which had lower capacitance is coupled to the 3-turn inductor, and sensor-2 is paired with the 3.5-turn inductor, so that these L-C tanks have different resonant frequencies.

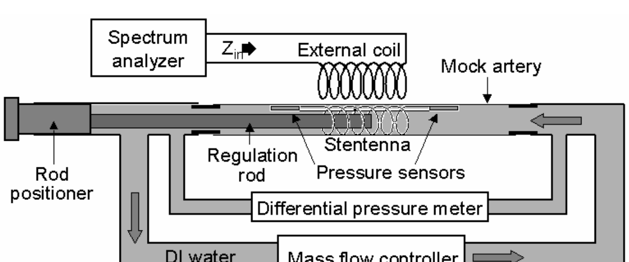

Fig: 7: A set-up for wireless pressure/flow sensing

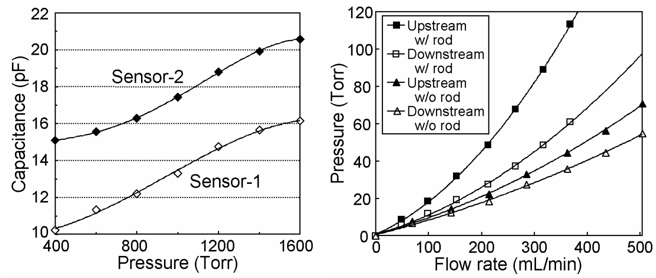

Fig. 8: (a: left) Measured response of uncoated capacitive pressure sensors used in wireless measurement; (b: right) measured gauge pressure vs. flow rate with and without the regulation rod.

Figure 8b shows gauge pressure at upstream and downstream locations as a function of flow rate, which is measured with the setup of Fig. 7. The plot also shows its dependence on the obstruction. As can be seen in Fig. 8b, the pressure response with the regulation rod indicates quadratic dependence on flow rate, which is consistent to eq. (1). Non-linearity in the curve for unblocked flow (i.e., no rod) comes from resistance of the device itself.

An impedance peak nominally at 239.1 MHz in a 4-mm diameter external coil with inductance of 610 nH is shifted down by increasing flow rate as shown in Fig. 9a. Figure 9b plots this frequency-shift and the corresponding differential pressure drop with 9-31 KHz reduction per mL/min. increase in the flow range over 370 mL/min. (Typical coronary artery flow is 100-200mL/min.) The pressure response observed is 57.4 KHz/Torr (at gauge pressure of 113 Torr), corresponding sensitivity is 273 ppm/Torr, which is >100x higher than [6]. A phase peak shown in Fig. 10a, which occurs nominally near 350 MHz with a different external coil, drops in frequency by 152-569 KHz per mL/min. increase in flow (Fig. 10b). In the

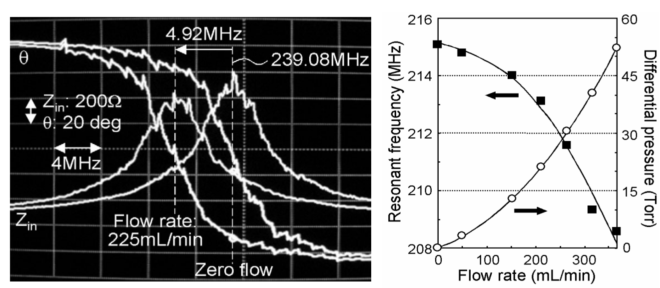

Fig. 9: (a: left) Measured amplitude of input impedance Z_{in} in an external coil shifted near 239 MHz due to flow change; (b: right) the measured resonant frequency and differential pressure vs. flow rate.

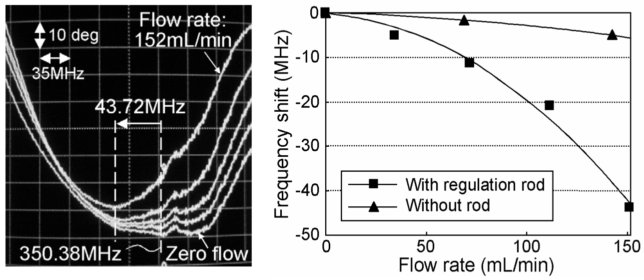

Fig. 10: (a: left) Measured phase peak shifts near 350 MHz due to flow change; (b: right) the measured peak frequency shift as a function of flow rate and its dependence on presence of the obstruction.

absence of the regulation rod, the shift is only 25-42 KHz per mL/min. As expected, the absence of this blockage has a marked impact.

The experimental results were evaluated using SPICE™ circuit simulations. Figure 11a shows an equivalent circuit model used to simulate the wireless set-up in Fig. 7. In this model, L_{EX}, L_{S1}, L_{S2}, k, C_{S1}, and C_{S2} respectively denote inductance of an external coil (identical to that used in Fig. 9), inductance for the downstream inductor, that for the upstream inductor, coupling coefficient between external and stentenna inductors, capacitance of sensor-1 at atmospheric pressure, and that of sensor-2. Other elements are measured or fitted parasitics. The model uses capacitances for 0.5-μm parylene coated sensors (see Fig. 11a) and these response (≈4fF/Torr) that are estimated from the preliminary 1.3-μm coating result with considering difference in stiffness of the layers. To observe the individual contribution of each L-C tank, C_{S1} and C_{S2} are varied to emulate responses of the pressure sensors to change in flow caused by the regulation rod. These are obtained from Fig. 8, under the following conditions: (1) downstream pressure is changed while upstream pressure is kept steady; (2) the converse condition; and (3) both pressures are changed. The result in Fig. 11b indicates a more distinct change in frequency between two L-C tanks than observed experimentally (Fig. 8b). This is a consequence of the simplicity of the simulated model and the uncertainty of the variables selected for it. Figure 11b also shows that the overall frequency shift with both capacitors active is approximately additive of the individual responses.

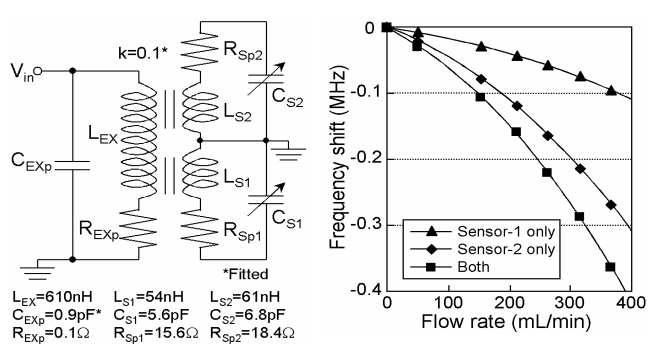

Fig. 11: (a: left) SPICE model for the microsensor system; (b: right) simulation result obtained from relationship between measured capacitance and flow rate in Fig. 8 which both are correlated by pressure.

IV. DISCUSSION

When a device is implanted into an arterial vessel, the back pressure will depend on location as well as physical condition of the patients. The differential measurement of two resonant peaks associated with separate LC-tanks at different locations can overcome the limitations of single-point measurements. The dual-inductor configuration can offer the measurement by its design. Toward this end, increase of quality factor of the LC-tank can be an asset. In addition, better coupling between external and internal inductors deserves future investigation.

V. CONCLUSION

A wireless implantable system for sensing flow and pressure inside a blood vessel has been studied. A 110-nH dual-inductor stentenna with 20-mm length, 3.5-mm diameter, and 50-μm thickness was integrated with two micromachined capacitive pressure sensors with dimension of 1.4x1.8x0.5 mm^3 and sensitivity of 6 fF/Torr. The whole device was designed to be compatible with standard stenting tools and procedures, and it was successfully deployed inside a mock artery by the inflation of an angioplasty balloon. Telemetry tests revealed capability for flow sensing and high pressure sensitivity with >100x improvement over past efforts. The design and fabrication of the stentenna based on use of planar stainless steel foil and batch-compatible μEDM technology will permit easier incorporation of other planar-based technologies for further improvement of the performance.

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