Smart Cardiovascular Stent against In-Stent Restenosis

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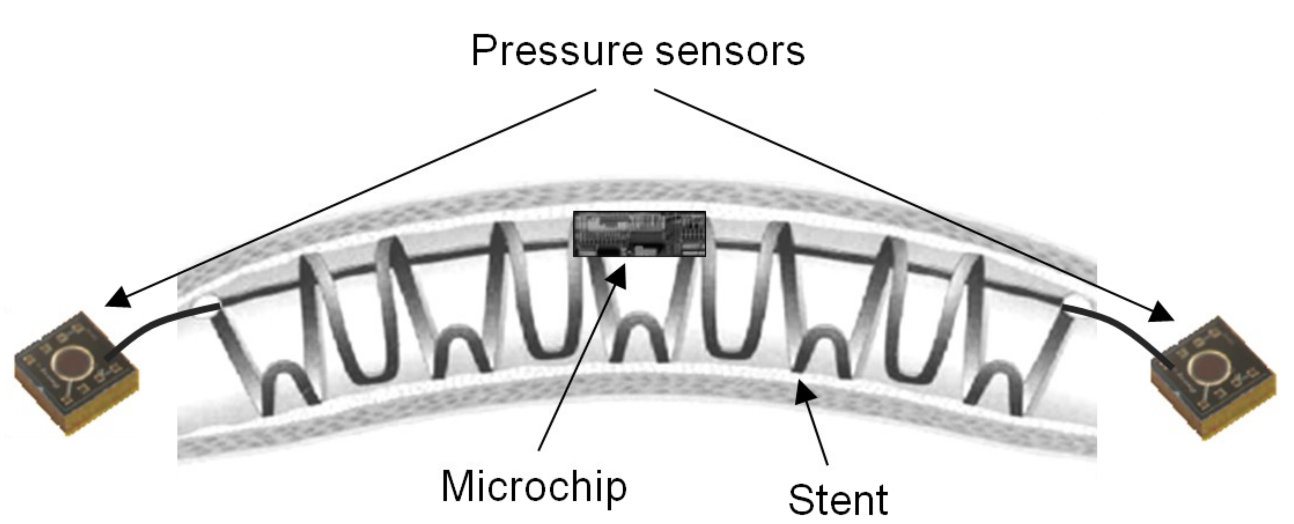
Abstract: A smart cardiovascular stent to be used as a single set of theranostics (therapeutics and diagnostics) is developed. The stent is aimed at delivering nitric oxide as a therapeutic agent and monitoring stent-induced restenosis. This novel approach is intended to reduce the risks stemmed from implanted stents and lowering manufacturing cost. The proposed stent will provide a non-invasive and continuous monitoring of restenosis caused by the stent. To assess the level of restenosis, pressure and blood flow will be monitored inside the blood vessel where the stent is placed. Existing techniques that employ catheters to measure pressure inside blood vessels are not suitable because they are too invasive, cannot monitor pressure for long periods of time and restrict the patient to be in a hospital setting.

Our approach consists of two miniature pressure sensors and a small microchip incorporated into the stent. The pressure sensors are placed at the opposite sides of the stent. Blood flow is obtained by assessing the pressure difference at these two points. The microchip reads out the pressure sensors outputs and wirelessly transmits them to a reader outside the body. Due to size constraints and safety reasons a battery cannot be used as a power source for the microchip. Instead, power is provided from the reader via electromagnetic coupling. In order to reduce the number of components to be implanted, we are proposing to employ the stent body not only as a mechanical supporter but also as an antenna. To provide an optimal power match between the microchip and the antenna, the impedance of the stent was fully characterized. This characterization has been performed using computer simulations of five different commercially available stent designs. It was found that at the frequencies of interest (902 to 928 MHz) the impedance is highly reactive. To compensate for the reactive impedance of the antenna, a matching network was designed. A prototype microchip with different components has been designed and is currently being fabricated. Future work includes micro-assembly of a prototype stent for the collection of pressure measurements using an aortic bifurcation model. Once completed, this stent will be useful in monitoring the level of restenosis and will lower the risks presented by implantable stents.

Motivation

- Cardiovascular stents have been extensively used for the treatment of coronary heart diseases through percutaneous coronary intervention.
- The goal of the stent is to open up portions of a blood vessel that might be clogged.
- Despite their success, stents are prone to develop restenosis as tissue builds up on the stent surface.
- To combat this negative effect, stents may be coated with nitric oxide (NO).
- To assess the effectiveness of the NO coating, it is desirable to monitor the blood flow through the stent.
- One way to measure the flow or velocity of a liquid is by exploiting the Hall effect in which a magnetic field is applied perpendicular to the liquid flow and then measuring the differential voltage developed.
- We decided not to employ the Hall effect because it requires relatively large magnetic fields (around 0.25 T) and it has to be perpendicular to the flow of blood—a condition that is difficult to meet.
- Instead we will monitor blood velocity by measuring the blood pressure at two locations: upstream and downstream from the stent.
- Two miniature pressure sensors from Silicon Microstructures Inc. are placed at the both ends of the stent.
- The pressure sensors outputs are read out by a custom-designed microchip which transmits the data wirelessly to an outside reader.

Proposed Smart Stent

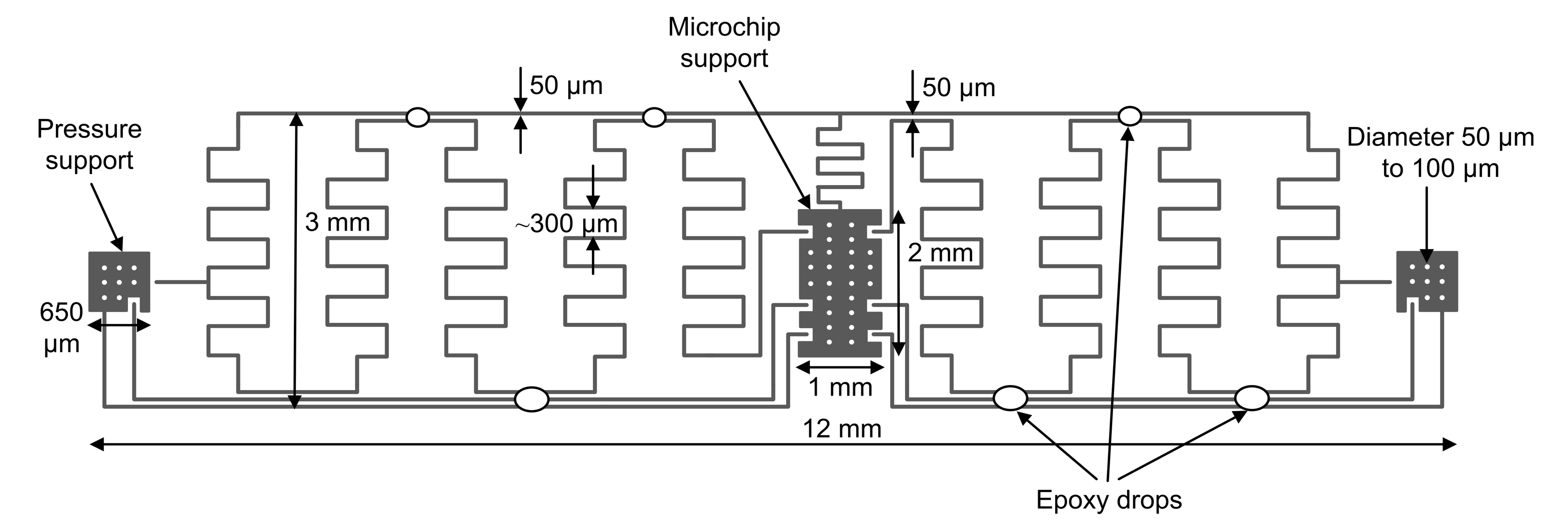


$$\Delta P = P_2 - P_1 = \alpha V + \beta V^2$$

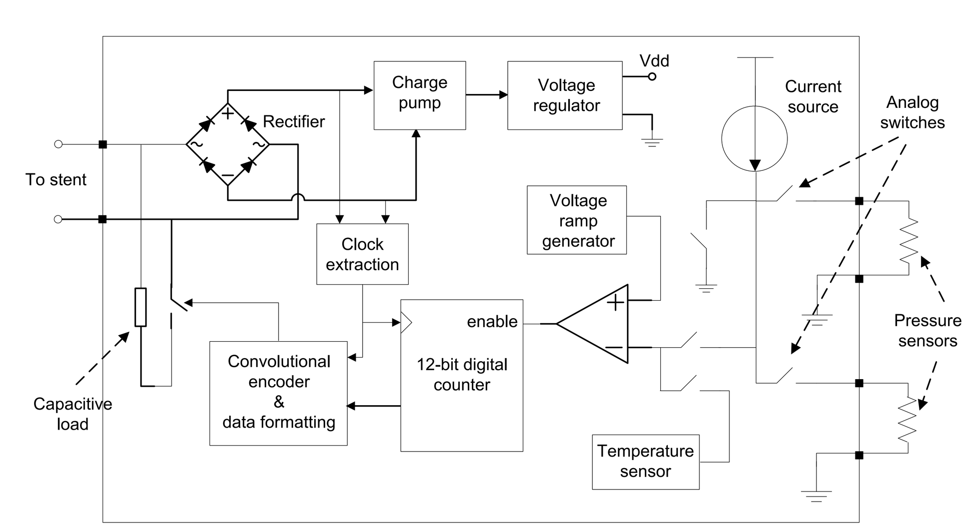
Besides its main function of providing mechanical support to the blood vessels, the stent will be employed as the antenna for wireless communications with an external reader and will provide electrical connectivity between the microchip and the pressure sensors.

Planar Stent Fabrication

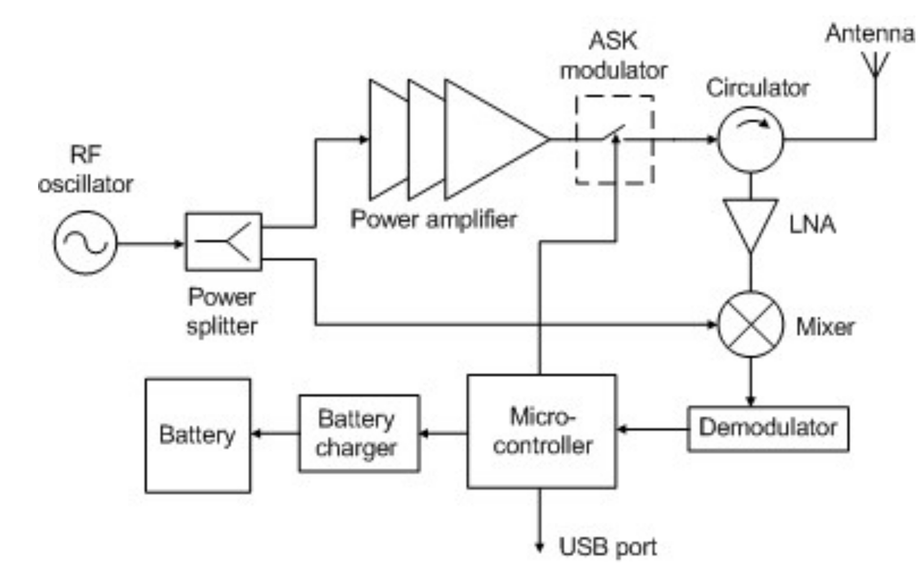
Due to the need of having to attach the microchip and the pressure sensors to the stent, a custom-shaped stent will be fabricated. We will use a planar fabrication approach due to its simplicity and because it can provide flat surfaces where the chip and the sensors can be attached.



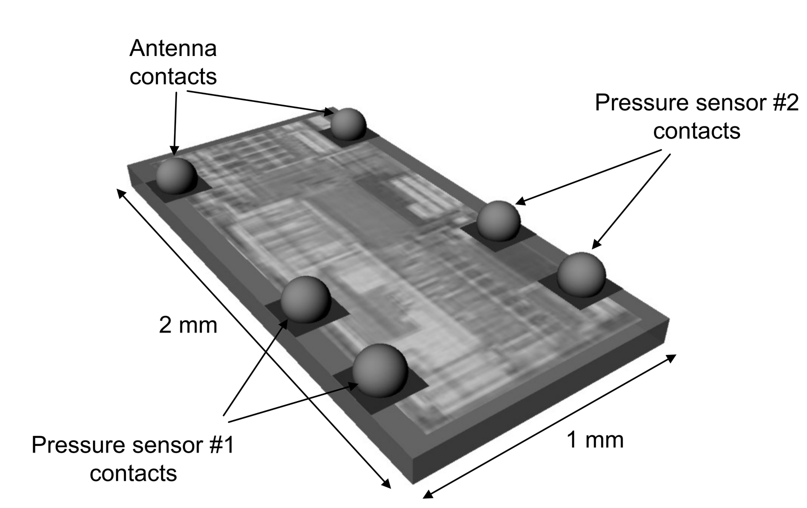
Microchip Block Diagram

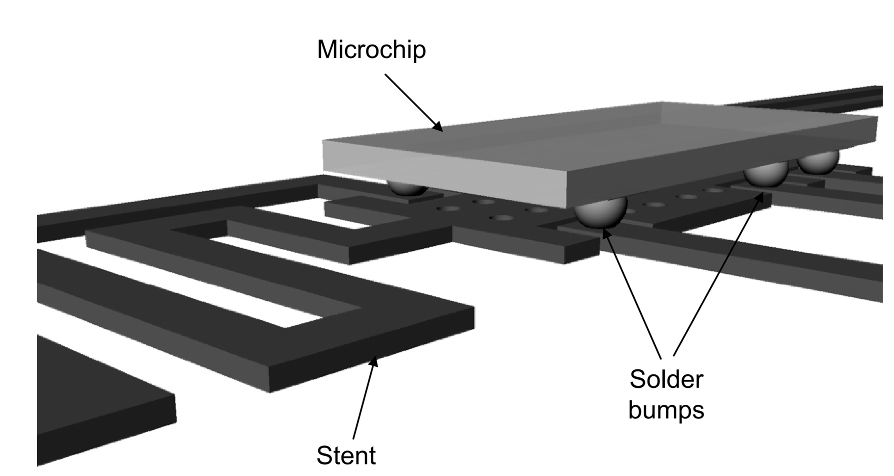


Reader Block Diagram



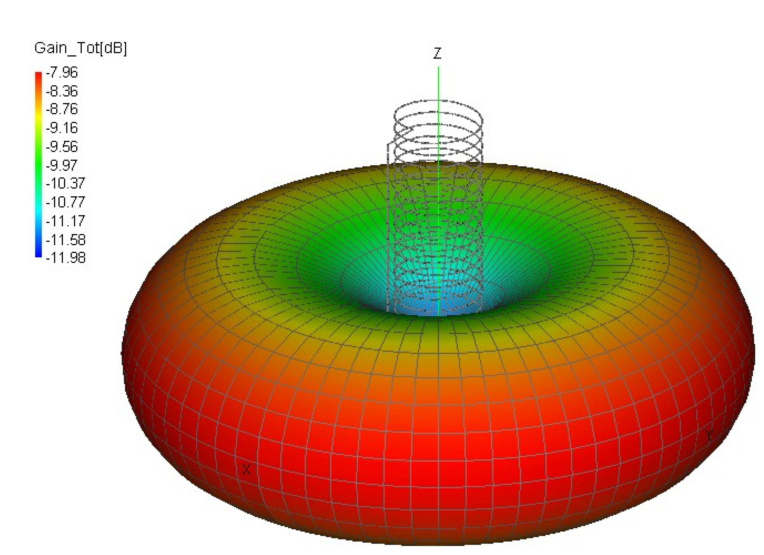
The microchip consists of voltage rectifier, a charge pump or voltage multiplier, and a voltage regulator. These three circuits convert the oscillating voltage developed at the antenna terminals into a stable voltage that is large enough to power up the other electronic circuits of the microchip. The current source is a circuit that provides a constant current and when it flows through the resistance of the pressure sensors, generates a voltage proportional to the pressure. This voltage is converted to digital format by an integrating analog-to-digital converter (ADC). An integrating ADC will be employed due to its good linearity performance compared to other ADC architectures. The ADC is composed of the 12-bit digital counter and the voltage ramp generator. The analog switches enable us to employ the same ADC to convert the output of the pressure and temperature sensors with the same ADC, thus, saving circuit resources.



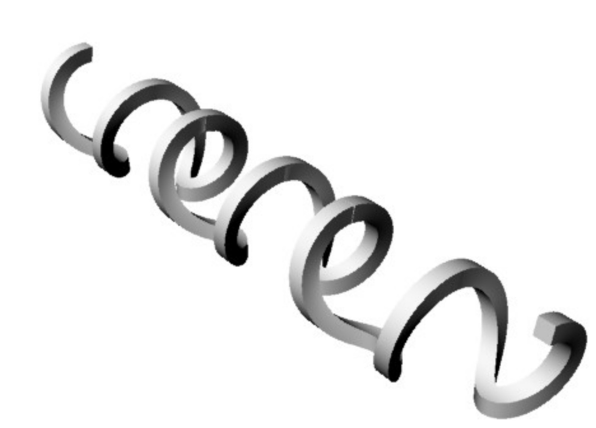


Electromagnetic Simulations of the Stent

To determine the optimal frequency and the stent shape with the best radiation properties, we are using the electromagnetic simulator Feko.



Gain pattern of a coil stent. The coil has a diameter of 1 cm and a height of 3 cm



We are currently working on the simulation on this more complex stent structure.