MICRO HYDRAULIC PRESSURE SENSING STENT

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ABSTRACT

This paper reports both the novel configuration and the operation principle of a pressure sensing stent (medical mesh tube) that (1) completely incorporates a micro pressure sensor into the stent wire structure and (2) achieves 75 times amplification in output signals of capacitive sensing via micro-scale hydraulic movement. A fabrication method was developed for wafer-level manufacture of the 'on-wire' pressure sensors, by grafting and processing multiple wires onto a silicon wafer. The fabricated pressure sensor on a stent successfully (1) detected the full cardiovascular pressure range of 60~260mmHg with a resolution of 0.24µm/mmHg; (2) produced 114fF of capacitive signal outputs, which is x75 times amplified compared to conventional measurement without hydraulic mechanism; and (3) demonstrated a frequency-based-sensing resolution of 0.4 kHz/mmHg at a resonance of 13.89MHz. The fabricated on-wire sensor held a tiny footprint of 8000×100µm^2, engraved on a 260µm-diameter copper wire, still enabling measureable outputs.

KEYWORDS

Stent, capacitive pressure sensor, implantable device.

INTRODUCTION

Despite the wide medical practice, a stent, which is used to expand the narrowing arteries when inserted, frequently suffers from the needs for periodic post-surgery monitoring of the arteries because of the restenosis (re-narrowing, of an artery by plaque). Such a periodic monitoring requires invasive surgery every time in order to temporarily insert a pressure sensor into the body and monitor any pressure changes caused by the re-narrowing of arteries, resulting in significant time, efforts, financial burdens and discomforts for patients.

In order to reduce such a periodic surgery, several groups have developed pressure-monitoring stents, which can be mainly categorized into two groups: a hybrid stent combined with additional IC/sensor chips [1] and a single stent that is capable of pressure sensing via EM-resonance or X-ray interference [2-3]. However, previous pressure-monitoring stents exhibited practical limitations such as insertion difficulty due to the existence of a discrete sensor chip, low accuracy due to weak signal, or potentially hazardous effects of X-ray on health. Recently the use of the helical stent structure as an inductor was demonstrated [4], resulting in resonance frequency changes when the applied pressure varies the capacitance in a parallel-plate pressure sensor.

In order to address the previous limitations, we developed an on-wire pressure sensor that produces enhanced output signals. This paper reports a novel configuration and operation of a pressure-sensor-embedded-stent that (1) removes any discrete chips by constructing a pressure sensor on a wire (Fig.1) and (2) amplifies output capacitance signals via hydraulic-amplification due to enhanced advancement of fluids in a narrower chamber as well as higher dielectric constants of liquid in comparison to air (Fig.2).

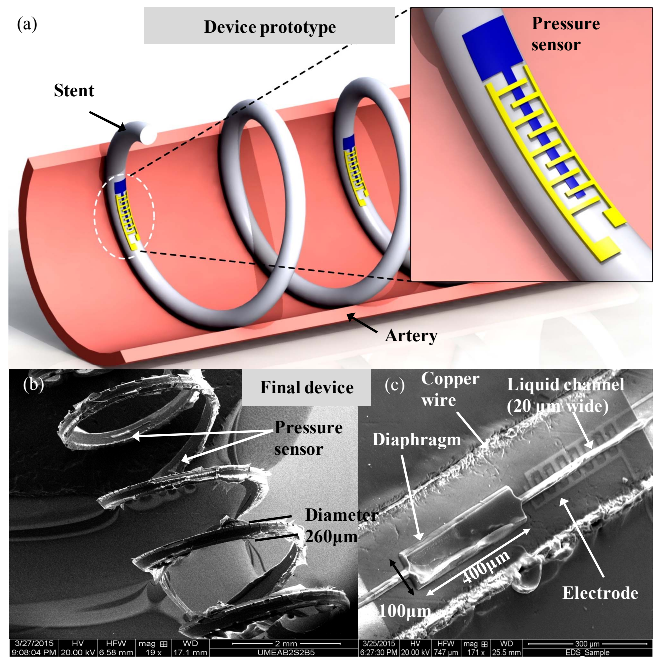

Figure 1: Device prototype: (a)showing the pressure sensor on inductive stent and any plaque formation on the artery wall can be sensed by this embedded pressure sensor; Final device: (b) showing inductor formation after device fabrication and pulling out from the wafer, (c) detail image of an individual pressure sensor embedded on Cu wire.

OPERATION PRINCIPLE

Figure 2 illustrates the operation principle of the on-wire pressure sensor that produces amplified and digitized output signals based on hydraulic motion of embedded liquid. The on-wire pressure sensor consists of a large reservoir covered with a flexible membrane and a narrow channel with a pair of interdigitated electrodes (Fig.2-a). The flexible membrane easily bends under a small pressure change due to its large area and causes a portion of the underneath liquid to move out of the reservoir. The moved liquid flows through a narrow channel. Since the width and

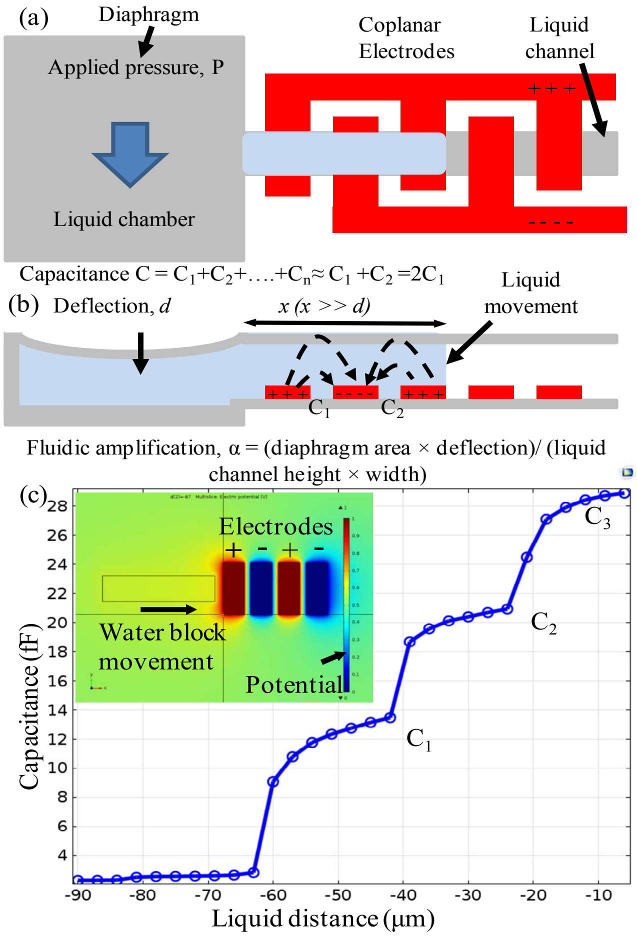

Figure 2: Operation principle (a) top view, (b) cross sectional view: explaining that the fluidic amplification from the larger diaphragm area to narrower channel area can improve the differential capacitance as one unit of C; (c) COMSOL simulation: showing digitized capacitance with respect to liquid distance.

depth of the channel are shorter than those of a reservoir, the movement of the liquid is amplified following the hydraulic ratio, producing amplified signal outputs. Such a resultant movement of the liquid causes the changes in capacitance between the pair of interdigitated electrodes due to the difference in dielectric constant between air and liquid (Fig.2-b). As the liquid passes by each gap of any two electrodes, it flips the corresponding capacitance into a higher value. Since all the capacitors are in a parallel configuration, their total capacitance is the sum of all individual capacitors, resulting in digitized outputs depending on how many electrode gaps the hydraulic liquid crosses (Fig.2-c).

FABRICATION

Wafer-level fabrication process was performed by grafting multiple wires onto a Si wafer and engraving a pressure sensor on the wires using standard microfabrication techniques, as illustrated in Fig.3. First, on a silicon wafer, multiple trenches were formed as wire holders by utilizing DRIE etching (Fig.3-1). The trenches were 300µm wide, 180µm deep, and 50-80mm long. Into each trench a Cu wire of 30 gauge or 260µm diameter was placed and then fixed utilizing glue (Fig.3-2). The wafer with glued wires was mechanically polished (MP) down to produce flat wire surface with the roughness of <1µm for high precision microfabrication (Fig.3-3). On top of the flat wire surface, both a hydraulic liquid chamber ($400\times100\times20\mu m^3$) and a channel ($8000\times20\times20\mu m^3$) were formed by engraving the Cu wire using photolithography and wet etching with a solution of 1:3 diluted nitric acid (Fig.3-4). The copper wire surface was then coated with Parylene to electrically isolate the capacitive coplanar interdigitated electrodes that were subsequently fabricated by metal sputtering and patterning (Fig.3-5,6,7). The fabricated interdigitated electrodes held a gap distance of 6.1µm between adjacent fingers (Fig.4-a,b). Both the engraved chamber and channel were filled with a sacrificial photoresist (AZ-9260) layer and then coated by a parylene layer (Fig.3-8,9). The parylene layer formed a freestanding membrane with a thickness of 1.8 µm once the sacrificial layer was removed by acetone (Fig.3-10 & fig.4-c,d). Finally, the hollow channel was filled with working media (DI water) and then sealed, forming a fully embedded pressure sensor on a wire.

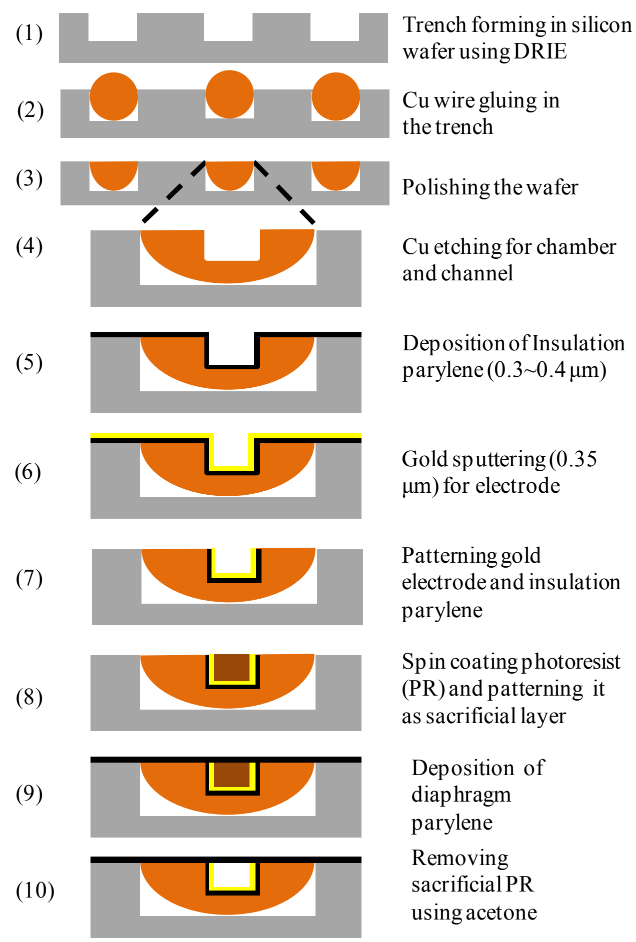

Figure 3: Fabrication process flow for embedded pressure sensor on copper wire.

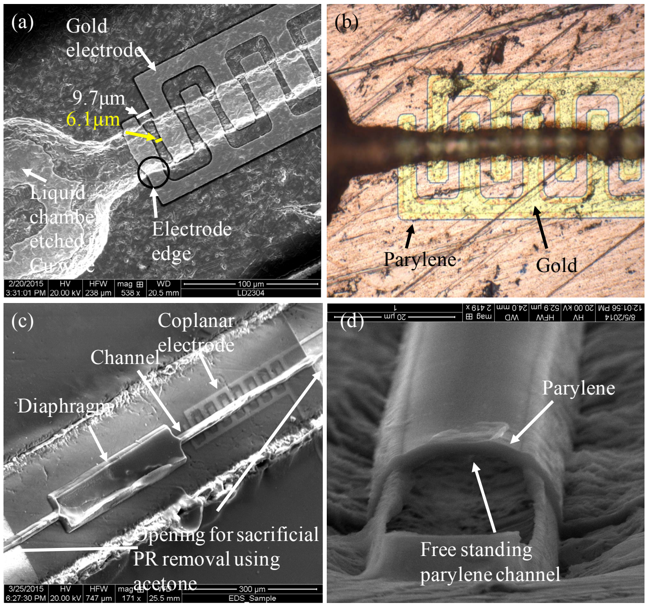

Figure 4: (a)&(b) SEM images before diaphragm formation: a chamber, an electrode and a channel. (c)&(d) SEM images after diaphragm formation: a diaphragm covers both the chamber and the channel and a freestanding parylene channel after removing sacrificial PR.

TESTING METHODOLOGY

To validate the concept of hydraulic-based pressure sensing as a stent, the fabricated device was tested under cardiovascular pressure range and the resultant signal change was monitored both optically and electrically. In both cases the device was placed in a custom-made sealed chamber. The chamber was manufactured by stacking three acrylic layers (3.18mm thick) with Buna-N (nitrile rubber) O-rings and tightening the multiple layers via mini screws. The middle layer provides the space for a pressure chamber where the fabricated stent was placed for measurement. The chamber was pressurized by supplying air flows in a pressure range between 0-1,550mmHg. The gas flow was regulated by a syringe pump (KD Scientific, KDS- 210) with a pressure resolution of 25mmHg. Under pressure increment, the movement of the liquid meniscus was monitored.

Optical Testing

To verify the device operation under cardiovascular pressure range, liquid movement under different pressure was measured optically by changing pressure from 0 mmHg to 260mmHg. At each pressure level the location of the liquid meniscus was recorded by a digital camera (Edmund Optics) through a microscope (Mitutoyo, at 5X optical zoom). In order to measure the liquid movement accurately (with 1µm accuracy of the meniscus), the images were then processed through a custom developed MATLAB program. The liquid advancement through the channel was calculated based on the meniscus at zero pressure. Based on this calculation liquid movement at different pressure level was plotted.

Electrical Testing

To confirm the optical measurement and verify the feasibility of electrical measurement, the capacitance values were monitored through the interdigitated electrodes. Additionally, the interdigitated electrodes were connected to an external inductor of 6.8µH and the variations of their resultant resonant frequency were monitored using an impedance analyzer (Agilent 4294a). The measurement was performed by sweeping the excitation frequency between 10Hz and 100MHz with a sweeping voltage of 1.1 V.

EXPERIMENTAL RESULTS

Experimental results showed that (i) the pressure sensor was able to transfer liquid through the channel, which is good enough to fabricate some electrode fingers for electrical measurement; (ii) the change of capacitance was in the detectable limit and can be detected by series resonance.

Optical Testing

Measurement results showed that the applied pressure in the full cardiovascular range of 0~260mmHg produced liquid movement through the channel 0~74µm (Fig. 5(a)) with a resolution of 0.24µm/mmHg, as shown in Fig. 5(b).

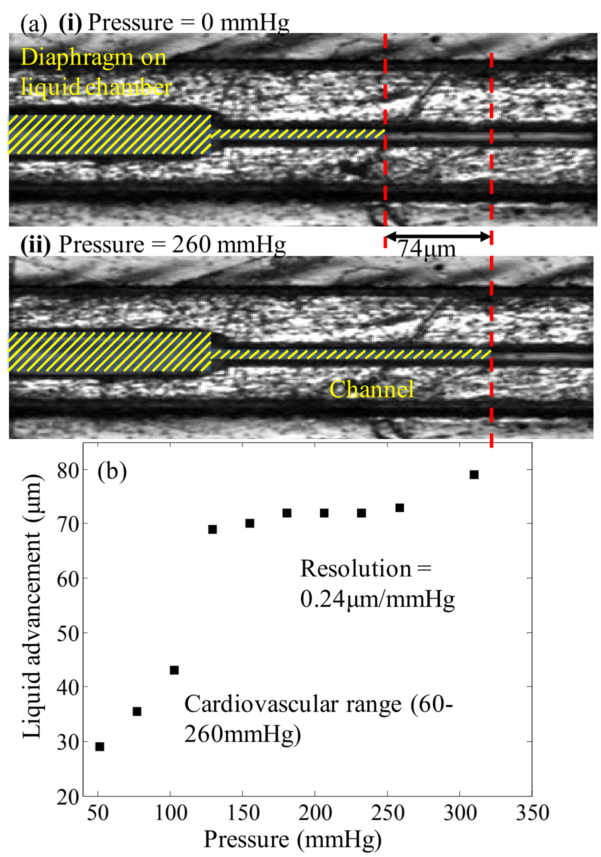

Figure 5: Optical characterization: (a) showing liquid movement of 74µm (shaded area) through the channel from (i) zero pressure to (ii) full scale pressure; (b) showing liquid moves at different pressure level within the cardiovascular range at a resolution of 0.24µm/mmHg.

Figure 5(a) also showed that the liquid meniscus initially stayed at 171μm away from the chamber (zero pressure) and at 260mmHg it reached at 245μm thus a 74μm full scale liquid displacement was measured. The pressure-displacement relationship indicated the optimal distances between adjacent electrodes as well as the number of interdigitated capacitive fingers. It is notable that the liquid movement showed non-linear correlation between the the applied pressure: a resolution of 0.36 and 0.12μm/mmHg, respectively, below and above 150mmHg. Such non-linearity arised from the inherent ineleastic material property of parylene [5].

Electrical Testing

Measurement result also showed that (1) the resonance frequency changed from 13.887MHz to 13.776MHz for corresponding pressure change from 0 to 260mmHg as shown in Fig.-6(a); and (2) the resolution of the resonance frequency change was measured as 0.4kHz/mmHg (Fig.-6(b)). The nominal resonance frequency was measured as 13.887MHz and varied between 13.776 and 13.887MHz. These resonance frequencies were located within the allowable frequency for implantable devices. Figure 6(a) also showed that the operating signal band was 111kHz thus occupied less frequency bandwidth. It also showed that the

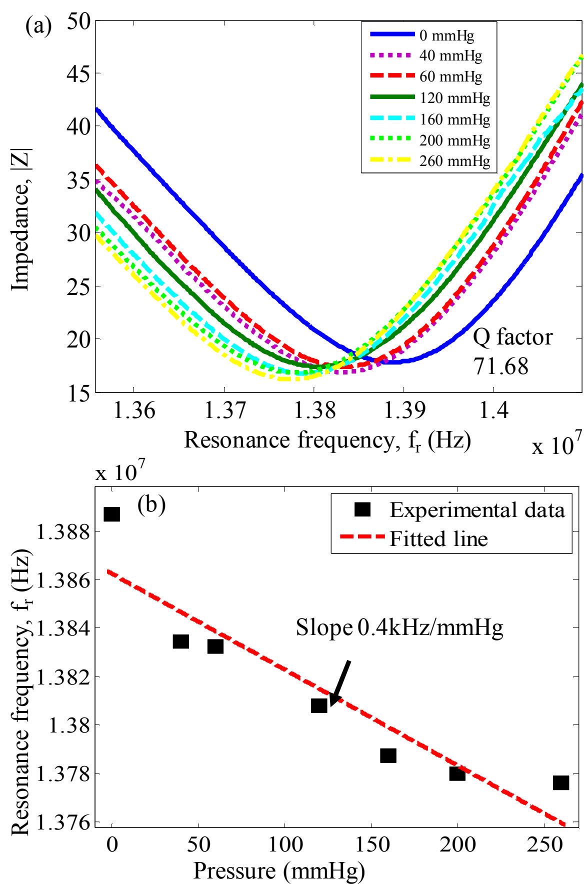

Figure 6: Electrical characterization: (a) shift in resonance frequency at different pressure, (b) resolution of the pressure sensor showing 0.4kHz/mmHg.

quality factor ($Q = f_r/\Delta f$, where f_r and Δf are resonance frequency and bandwidth respectively) of the device is 71.68, which indicated the theoretical sensing distance of more than few mm in wireless system [6].

CONCLUSION

This paper reported a pressure sensing stent that incorporated an on-wire capacitive pressure sensor to minimize difficulty in surgery and signal detection. The pressure sensing stent employed a unique on-wire configuration and hydraulic-amplification and –digitization. A fabrication method was developed for wafer-level manufacture of the 'on-wire' pressure sensors, by grafting and processing multiple wires onto a silicon wafer. The fabricated pressure sensor successfully demonstrated the detection of the full cardiovascular pressure range of 60~260mmHg with a resolution of 0.24μm/mmHg and x75 times amplified output signals compared to conventional measurement without hydraulic mechanism. The fabricated on-wire sensor held a tiny footprint of $8000 \times 100\mu m^2$, engraved on a 260μm-diameter copper wire.

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