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Capacitive Sensing for Monitoring Stent Patency in the Central Airway

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***Abstract*— Central airway obstruction (CAO) is a respiratory disorder characterized by the blockage of the trachea and/or the main bronchi that can be life-threatening. Airway stenting is a palliative procedure for CAO commonly used given its efficacy. However, mucus impaction, secretion retention, and granulation tissue growth are known complications that can counteract the stent's benefits. To prevent these situations, patients are routinely brought into the hospital to check stent patency, incurring a burden for the patient and the health care system, unnecessarily when no problems are found. In this paper, we introduce a capacitive sensor embedded in a stent that can detect solid and colloidal obstructions in the stent, as such obstructions alter the capacitor's dielectric relative permittivity. In the case of colloidal obstructions (e.g., mucus), volumes as low as 0.1 ml can be detected. Given the small form factor of the sensor, it could be adapted to a variety of stent types without changing the standard bronchoscopy insertion method. The proposed system is a step forward in the development of smart airway stents that overcome the limitations of current stenting technology.**

***Clinical Relevance*— This establishes the foundation for smart stent technology to monitor stent patency as an alternative to rutinary bronchoscopies.**

I. Introduction

The rise of personalized medicine represents an important shift in health care by providing tailored attention to patients for improved health outcomes [1]. Continuous data streams from wearable and implantable devices present physicians and health experts with time-resolved information—specific to the patient—for more accurate diagnostics and interventions [2, 3]. Respiratory medicine has seen the benefits of these technologies: early diagnostics enable doctors to treat patients in otherwise life-threatening situations. Such is the case of central airway obstruction (CAO), where the collapse of the central airways leads to difficulty breathing and poor oxygenation of the body. The causes of CAO can be benign or malignant (e.g., lung cancer), but in both cases, airway stenting has shown to be an effective therapy [4]. However, while stent implantation is relatively safe, the presence of a stent can cause complications. Retention of secretions, mucoid impaction and granulation formation are common complications associated with airway stenting [5].

This research aims to address these limitations by providing a surveillance method based on capacitive sensing that detects obstructions in the stent. By detecting obstructions, a smart stent could alert doctors and/or patients about potential complications, thereby cutting down on unnecessary bronchoscopies. Capacitive sensors can be fully sealed into the sidewalls of a stent, so they can be installed using traditional methods. This backward compatibility, combined with their low cost of manufacturing, offers the potential of rapid adoption in the clinic.

Realizing this airway stent monitoring sensor included the following contributions: 1) A sensor architecture for airway stents that detects obstructions based on their impact on the capacitor's dielectric relative permittivity and total sensor capacitance. 2) A capacitance model for when a non-uniform medium is present (e.g., partial obstruction). 3) Experimental validation of sensor performance with a variety of solid and colloidal obstructions.

The rest of the paper is organized as follows: Section II discusses related work regarding wearable and implantable devices for respiratory health, advances in stent technology, and capacitive sensing for fluid measurements. Section III presents the implementation of the sensing system including the sensor fabrication and modeling, and the integration of the functional electronics. Section IV details the experimental methods and discusses the results as part of the validation of the proposed sensing system. Section V summarizes the contributions of this work and outlines the future plan for the continuation of the research to enable the development of smart airway stents.

II. Related Work

Wearable technology in the context of respiratory health can be categorized into four different areas: pulse oximetry, pulmonary ventilation, activity tracking, and air quality monitoring [6]. Pulmonary ventilation refers to the product of respiratory rate and tidal volume, two indicators of CAO distress. For example, a two-electrode capacitive sensor was integrated into clothing in order to measure respiratory rate [7]. The electrodes were placed in the abdominal area and in the back. The changes in air volume during inhalation and

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exhalation produced a change in the permittivity of the medium between the electrodes and therefore a change in the capacitance. Through this method, the respiratory rate was directly inferred, and with further analysis, the air volume was also estimated. Another chest-mounted device used a novel material based on silver nanoparticles that changed its resistive properties when stretched [8]. Using this principle, the respiratory rate was determined by evaluating the changes in resistance of the device. Chu et al. [9] developed a sensor that was able to measure respiratory rate and also tidal volume. The sensor had a form factor similar to a band-aid and was meant to be disposable. It relied on a similar principle as other sensors that measure the thoracic displacement using strain gauges [8]. A very different approach was taken by Sharma et al. [10] who created a wearable that uses radio-frequency (RF) to measure respiratory rate, respiratory volume, and heart rate. The device uses a near-field coherent sensing principle: it transmits a low-power RF signal into the body, then evaluates the signal's coupling to the internal dielectric motion of the heart and lungs.

While respiratory rate and tidal volume information are important for diagnosing CAO, they are not sufficient for detecting complications after stenting is implemented as the therapy of choice. To address this issue, researchers have considered follow-up bronchoscopies for early detection and prevention of stent-associated complications [11]. They concluded that surveillance bronchoscopy within 4 to 6 weeks after stenting has the potential to detect complications early, regardless of symptomatic status. Bronchoscopies are physically and economically burdensome, so improving stenting technology may offer better outcomes for patients. Stent improvements have been limited and currently focus on structural strength and personalization through 3D printing and drug-eluted stents [12, 13].

The use of semi-cylindrical capacitive sensors for fluid measurement has been briefly explored but only in non-medical applications. Chiang and Huang [14] used this principle to evaluate flow rate in a pipe. The two electrodes were wrapped around the pipe and used a capacitance-to-voltage converter to evaluate flow rates. They concluded that flow rate was directly proportional to the output voltage of the circuit. A similar sensor was demoed as a way of measuring the liquid level in a storage tank [15]. Both applications rely on the change in the capacitance of the medium between the two plates.

III. System Implementation

The capacitive sensing system is designed to detect any obstruction that may occur in an implanted airway stent due to the accumulation of secretions, the presence of any other foreign object that may reach the central airways where the stent is located, or the generation of granulation tissue.

A. Capacitive Sensor Fabrication

The capacitive sensor is composed of two half-cylindrical copper electrodes on a Kapton substrate and an elastomer tube. At first, two 0.05 mm thick copper films with one adhesive side were laid on a 0.05 mm thick Kapton film, with a 0.6 mm gap between the two electrodes, as shown in Figure 1(a). The width of the copper films is 13.5 mm. The length for both the copper films and the Kapton film is 32 mm. There is a 2-millimeter margin left on both longitudinal directions of the Kapton film. The combined films were then rolled into a cylinder, as indicated in Figure 1(b). The overlapped Kapton layer was fixed with superglue, which seals the sensor from possible liquid penetration. To cast the outside silicone tube, elastomer (Dragon Skin™ 10 NV) was poured into a 3D printed mold. Figure 1(c) shows an exploded view of the sensor mold casting. After curing, the sensor was removed from the mold, and two openings were bored into the sidewalls to expose the electrodes for wire soldering. The outside diameter of the sensor was determined by the mold to be 15 mm.

B. Capacitive Sensor Modeling

To model our sensor, we considered two methods. First, we followed others who used conformal mapping to determine the effects of the sensor's geometry on the capacitance when a uniform dielectric is present [16]. The technique converts

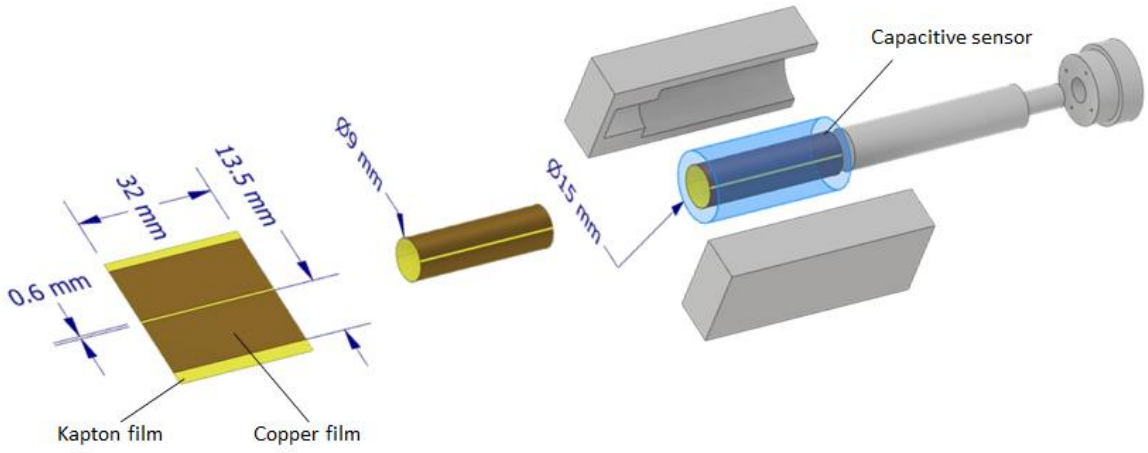

Figure 1. Fabrication process of the capacitive sensor. (a) Copper films are laid on a Kapton film; (b) The films are rolled into a cylinder; (c) Exploded view of sensor mold casting.

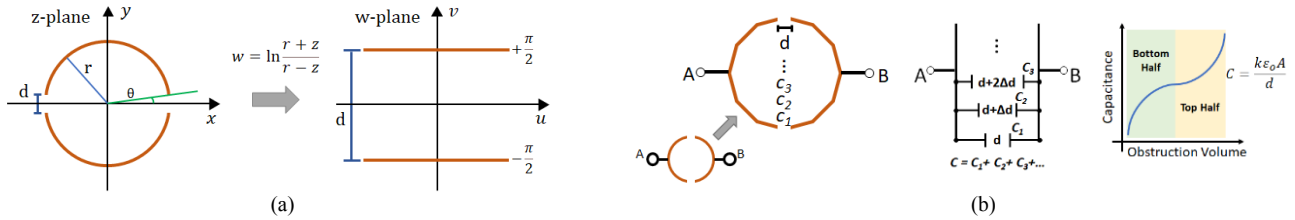

Figure 2. Semi-cylindrical capacitive sensor modeling. a) Analytical model using a conformal transformation to evaluate the effects of the stent geometry in the total capacitance, b) Numerical approximation model as a summation of smaller capacitors in parallel to assess different levels of obstruction.

coordinates in the z-plane (a physical complex plane fixed to the cross-sectional area of the sensor) to the w-plane (an abstract complex plane used for calculating capacitance) by using a transformation defined as

$$w = \ln\frac{r+z}{r-z}, \tag{1}$$

where r is the radius of the cylinder, z is a complex function in the z-plane defined as $z = x + iy$, and w is a complex function defined as $w = u + iv$. From this expression, we find that u and v can be expressed as $v = \pi/2$ and $u = \ln[\sin\theta/(1-\cos\theta)]$, where θ represents the angle between the x axis in the z-plane and the edge of the plate of the capacitor. Finally, using the parallel-plate equation for capacitance as a function of area and distance, and the expressions for u and v, the analytical solution for the capacitance of the semi-cylindrical capacitor can be written as

$$C = \frac{kh\varepsilon_0}{\pi}\ln\left[\frac{\sin\theta}{1-\cos\theta}\right], \tag{2}$$

where k is the relative permittivity of the medium, h is the length of the cylinder, and ε_0 is the permittivity of free space.

The second technique we used was a discrete approximation that considers the capacitive sensor as an array of $2n$ parallel-plate capacitors with the same area and whose distance between plates changes in increments of Δd. This can be expressed as

$$C = C_1 + C_2 + C_3 + \cdots + C_{2n}, \tag{3}$$

$$C = \frac{k\varepsilon_0 A}{d} + \frac{k\varepsilon_0 A}{d+\Delta d} + \cdots + \frac{k\varepsilon_0 A}{d+(n-1)\Delta d} + \frac{k\varepsilon_0 A}{d+(n-1)\Delta d} + \frac{k\varepsilon_0 A}{d+(n-2)\Delta d} + \cdots + \frac{k\varepsilon_0 A}{d}, \tag{4}$$

where k is the relative permittivity of the medium, ε_0 is the permittivity of free space, A is the area of the capacitor, and d is the distance between the edges of the two plates of the capacitive sensor. Through this approximation, we were able to gain intuition of the behavior of the capacitance when a non-uniform medium is present (e.g., partial obstruction). The two approaches are illustrated in Figure 2.

C. Functional Electronics

The developed capacitive sensor is interfaced with a low voltage signal conditioner from Renesas Electronics that incorporates a capacitance-to-digital converter (CDC) with an on-chip digital signal processor (DSP) for sensor compensation of offset, sensitivity, and temperature drift. The CDC has a maximum resolution of 14 bits and under this configuration the maximum sampling rate is effectively 54 Hz. The maximum input capacitance accepted by the circuit is 260 pF and it presents a sensitivity of 125 aF/LSB. The sensing input of the signal conditioner circuit can be configured as single-ended or differential. Additionally, the chip has a digital output communication block that can use an SPI or I2C protocol to communicate with a microcontroller for further processing. In our system, the microcontroller (ATMEGA1281, Microchip Technology) configures the CDC, samples the data, and transmits it via USB to a computer. The system is powered from the USB port using the 5V supply. The voltage is then down-converted and regulated to 3V to power the microcontroller and the signal conditioner. A block diagram of the full sensing system is presented in Figure 3.

IV. Experiments and Validation

To validate our design, we first measured the capacitance of the sensor with no obstruction using a capacitance meter (M6013). The capacitance was determined to be 3.15 pF, which was used as our reference value. The following experiment was to verify the functional electronics comparing the capacitance read by the CDC to the reference value from the capacitance meter. The CDC was configured with a 14-bit resolution and a 0 pF to 10.1 pF range. The sampled capacitance value of the sensor with no obstructions was 3.162 pF, resulting in a difference of about 0.01 pF with respect to the reference value. With an established baseline, we evaluated the response of the system in the presence of solid obstructions of different materials, emulating the case of granulation tissue most commonly found in metallic stents. The materials used were wood, hard plastic, coated chromium-vanadium steel, recycled paper, normal paper, soft vinyl, and a hybrid material composed of metal, plastic and an air core. To standardize the testing procedure, cylinders of each material with 6 mm radius and 40 mm height were fabricated and inserted into the sensor. For the measurements, the system was maintained with the same configuration of bit resolution and range as for the baseline experiment. To avoid any error associated with damage to the sensor or alteration of the testing environment,

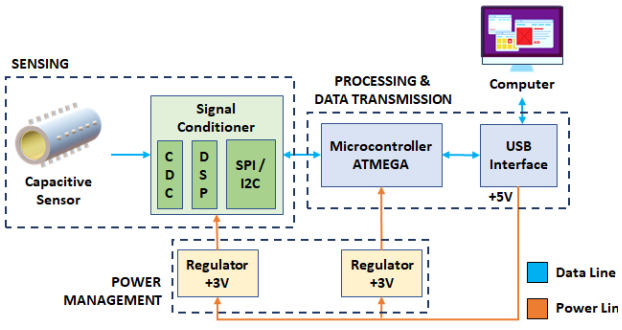

Figure 3. Architecture of the proposed capacitive sensing system.

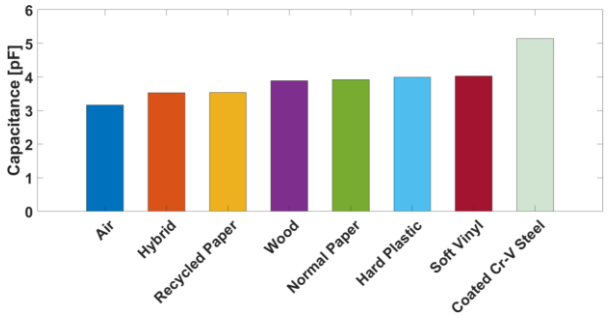

Figure 4. Capacitance measurement for different solid obstructions.

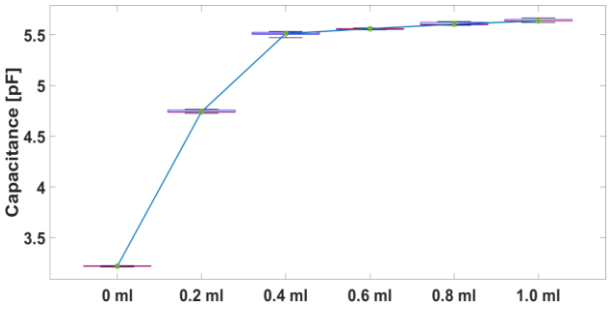

Figure 5. Capacitance evaluation for colloidal obstructions.

the capacitance value without and with the obstruction was re-recorded every time a new cylinder was inserted. As shown in Figure 4, the sensor was able to accurately differentiate the obstructions as a result of the high resolution of the system.

To assess the performance of the sensor regarding retention of secretions in stents, we used a colloidal substance made of water and several sodium compounds resembling mucus. The sensor has a volume capacity just above 2 ml, so we created five samples of the colloidal substance from 0.2 ml to 1 ml using a graduated pipette. The 1 ml upper limit was chosen because it represents a heavily obstructed stent (50% blockage). The samples were contained in thin straws for ease of testing, and the effect of the straws in the capacitance was determined to be negligible at 0.06 pF. A similar testing procedure as with the solid obstructions was followed and the capacitance values for each case were recorded. The experiment was conducted ten times for each sample to test the repeatability of the sensor.

As shown in Figure 5, the system had enough resolution to capture changes produced by small amounts of the colloidal substance. This result suggests that capacitive sensing could help in early diagnostics of retention of secretions and in-time interventions, and the high repeatability displayed during testing shows the robustness of the sensor. Furthermore, the shape of the curve intuitively follows the behavior described by the numerical approximation model presented in Section III.b. The biggest changes in capacitance can be seen between the smaller samples, where the colloidal substance sits closer to the edges of the capacitor and the device is more sensitive. As the volume increases, the area covered by the obstructions are farther from the capacitor edges (i.e., in the middle of the stent), and the changes in capacitance are smaller. Until this point, the behavior of the change in capacitance can be described as logarithmic. Given the symmetry of the device, if we were to measure the capacitance for the case where the obstruction volume is bigger than 50%, the capacitance changes would remain smaller with volumes near the middle region and would drastically increase as they approach the 100% volume capacity. In this case, the behavior can be described as exponential as shown in Figure 2(b).

While the results of the experimentation are promising and validate the design of our sensor, it is important to acknowledge that the current version of the sensing system is not viable for deployment in humans. Form factor, power delivery and biocompatibility are challenges that need to be addressed to accomplish a fully integrated implantable device. With flexible and biocompatible electronics [17] and solid-state micro-batteries [18], new smart stents could provide long-term patency monitoring and alert patients and physicians before serious complications occur.

V. Conclusion and Future Work

This work was motivated by the limitations of current stenting technology for early diagnosis of stenting complications and the associated burden on patients having to go through routine bronchoscopies. We designed and implemented a capacitive sensing system that detects when early stages of obstruction occur due to retention of secretions or granulation tissue. The system effectively captures changes in the environment inside the stent by measuring the effect of different obstructions on capacitance as a consequence of the changes in the permittivity of the medium. The sensor itself is embedded in the stent, and although this work adopted a silicon stent, it could be adapted to other types of stents without changing their form factor. Additionally, we derived an analytical model that allows us to analyze the effects of stent geometry in the sensor capacitance, and an approximation model that provides insight in cases of partial obstruction. Our system offers a foundation for capacitance-based smart stents that detect abnormalities and notify patients and physicians accordingly. Future work will focus on miniaturization, integration of the functional electronics into the stent, and power management optimizations.

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