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Flexible sensor for blood pressure measurement

A.T. Sepúlveda, A.J. Pontes, J.C. Viana, R. Guzman de Villoria, F. Fachin, B.L. Wardle and L.A. Rocha, *Member, IEEE*

***Abstract*—A new approach for the design and fabrication of a highly flexible blood pressure sensor is introduced in this paper. The goal is to measure the pressure within an aneurysm sac for post-endovascular aneurysms repair (EVAR) surveillance. Biocompatible polydimethylsiloxane (PDMS) membranes with embedded aligned carbon nanotubes (CNTs) are used to build the conductive elements of the pressure sensitive capacitor and the inductor for telemetry. Inductive coupling will be used to measure the internal capacitive variations. Fabricated test sensors validate the approach and demonstrate that CNTs/PDMS technology can be used to build highly flexible pressure sensors.**

I. Introduction

THE advances in microsystems technologies (MST) are providing new opportunities for a range of biological and medical applications [1]. Pressure sensors are an example of first use of microsystems and are one of the most successfully commercialized devices. Lately, they are being proposed for continuous blood pressure monitoring in disease prevention, diagnosis and treatment [2-3].

The field of implantable microdevices is very promising [2], and pressure sensors for blood pressure measurement are one of the devices with more research activity, mainly due to the need for continuous pressure monitoring in patients with congestive heart failure, as an earlier diagnostic method for some risk patients and for post-endovascular aneurysm repair (post-EVAR) surveillance [2-3]. In EVAR, a catheter delivery system is used to introduce a stent-graft on the affected region of the aorta (aneurysm), shielding the aneurysm walls from the blood pressure.

Currently, it is already possible to find in the market long-term pressure sensors for the monitoring of blood pressure within the aneurysm sac after the treatment of abdominal aortic aneurysms (AAAs). The *Impressure AAA Sensor* (Remon Medical Technologies, Israel) and *EndoSure Wireless Pressure Sensor* (CardioMems, USA) are two devices with sensing capabilities that enable the measurement of both systolic and diastolic pressures within the residual aneurysms sac and have been evaluated for AAAs. However, these devices still present some communication difficulties and the results are not always accurate, causing false-positive findings [4].

The work presented here aims at a new solution for the blood pressure measurement after EVAR. The sensor system uses inductive-coupling to deliver energy and communicate with the capacitive sensor, which is based on aligned-CNTs embedded in a flexible substrate of PDMS. This approach enables the sensor to be integrated in the stent-graft, improving current methods to deliver the sensors within the aneurysm sac. In addition, due to the sensor flexibility and low profile, several sensors can be integrated in the stent-graft allowing for a more accurate measurement of the pressure variations inside the aneurysm sac (something that is currently not possible). The research work presented here only addresses the development and characterization of the pressure sensor. Details about the inductive coupling can be found in [5].

II. Flexible Pressure Sensor Model

The pressure sensor proposed here will be integrated in a stent-graft, and therefore, due to the EVAR procedure the main requirements are related to the device thickness (very thin) and flexibility (in order to fit within the catheter). Fulfilling these attributes enables the attachment of the sensor to the stent-graft and deployment of both stent-graft and sensor in a single step.

After EVAR procedure, the aneurysm sac becomes depressurized with the pressure inside the sac decreasing to a few mmHg (typically 12% of the luminal pressure according to [6]). Therefore, determining the luminal pressure value (ranges typically between 50-160 mmHg) through the measurement of the aneurysm sac pressure requires the sensor to measure pressures in a range of 6-26 mmHg with a resolution of 0.1mmHg. Furthermore, a high dynamic range is required in order to detect endoleaks.

The common configurations of capacitive pressure sensors are based on square-plate (diaphragm) electrodes separated by a dielectric (frequently of air) of separation d_0 at pressure P_0. Changes on the outside pressure (P_{out}) will deform the square plates and consequently will generate a capacitive change. Figure 1 shows a schematic of a two square-plate

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A.T. Sepúlveda, A.J. Pontes, J.C. Viana and L.A. Rocha are with Institute for Polymers and Nanocomposites/I3N, University of Minho, 4800-058 Guimarães, Portugal (phone: +351 966302318; fax: +351 253510339; e-mail: xanasepulveda@dep.uminho.pt).

F. Fachin R. Guzman de Villoria, and B.L. Wardle are with the Department of Aeronautics and Astronautics, Massachusetts Institute of Technology, Cambridge, MA 02139, USA. (e-mail: rguzman@mit.edu).

(side length of $2a$) pressure sensor. The behavior of the sensor is defined by its electromechanical response.

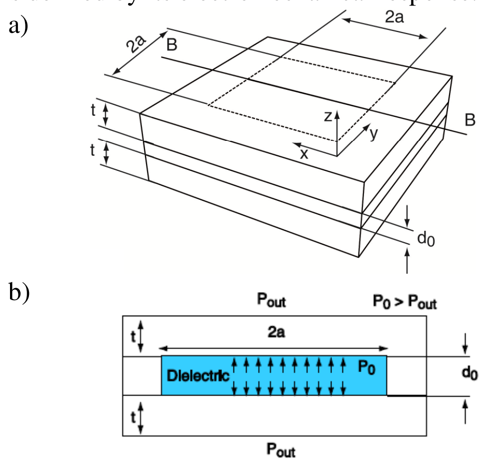

Fig. 1. Schematic of the square (side length = 2a) pressure sensor. a) 3D view and b) section cut B-B.

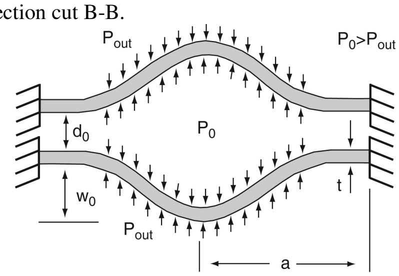

Fig. 2. Cross section of a generic deflectable diaphragm.

A cross section of the generic square double diaphragm is shown in Fig. 2 (section cut B-B from Fig. 1), considering only the mechanical domain. The diaphragm has clamped edges, where $2a$ is the side length, t is the thickness and w_0 the deflection. The angle deflection, φ, for a clamped diaphragm under a uniform load (such as pressure), is equal to zero at the center and at the edge of the diaphragm. For these defined boundary conditions, the deflection of an isotropic square diaphragm under a pressure load can be modeled by [7] (considering both bending and stretching effects):

$$P_0 - P_{out} = \left(Et^4 / \left(1-\upsilon^4\right) a^4\right)\left(4.20\left(w_0/t\right) + 1.58\left(w_0^3/t^3\right)\right) \quad (1)$$

where υ is the Poisson's ratio, E is the Young´s modulus and $\Delta P = P_0 - P_{out}$ is the pressure load.

Equation (1) allows computing the deflection at the center of the diaphragm for a given pressure load but, due to the gap variation, the deflection along the diaphragm is still needed to model the capacitive changes. The deflection of the whole diaphragm is usually described using trial functions [8], due to the complexity of the mechanical deflection calculation. Two different trial functions, (2) and (3) have been used to model the diaphragm deflection, both of which satisfy the boundary conditions.

$$w(x,y) = w_0\left[\left(\cos\left(\pi x/2a\right)\right)\left(\cos\left(\pi y/2a\right)\right)\right] \quad (2)$$

$$w(x,y) = w_0\left[\sin\left(\arccos\left(2x/a\right)\right)\sin\left(\arccos\left(2y/a\right)\right)\right] \quad (3)$$

Pressure changes generated by mechanical deflections will cause, consequently, changes of the capacitor response (electrostatic domain). A capacitor is defined as being an electronic component with two electrodes, separated by a dielectric. In the absence of any displacement and for the simple case of a parallel plate capacitor, the model for the capacitive transducer is (neglecting fringe fields):

$$C = \varepsilon_0 \varepsilon_r \left(w_c l_c / d_0\right), \quad (4)$$

where ε_0 is the permittivity of free space ($8.8546x10^{-12}$ *F/m*), ε_r is the relative permittivity, w_c and l_c are, respectively, the width and length of the capacitor electrodes (in this case $2a$), and d_0 is the gap between the electrodes. The double-plate capacitive sensor described here uses diaphragm electrodes with a complex bending profile. The calculation of the total capacitance requires the integration over the effective area of the electrodes.

$$C = \int_0^{2a}\int_0^{2a} \varepsilon_0 \varepsilon_r / \left[d_0 + 2w(x,y)\right] dxdy \quad (5)$$

where $w(x,y)$ is the distance between electrodes due to the diaphragm bending at position x,y. The integration of (5) is solved here numerically, allowing the calculation of the capacitance for a given pressure change.

III. Fabrication Process

The target application requires the capacitive sensor to be extremely flexible, foldable and characterized by a very small profile. Biocompatibility and simplicity of the technology is also required. Silicon based micro technologies are commonly used in implantable medical devices [2]. However, due to the application specifications, a new fabrication process targeting the main requirements is being developed. The proposed fabrication process includes aligned carbon nanotubes (CNTs) to build the conductive elements (inductor and capacitor), embedded in a flexible substrate of polydimethylsiloxane (PDMS). PDMS is generally characterized as being a transparent, nontoxic and biocompatible silicone elastomer.

A schematic of the fabrication process of the pressure sensor is presented in Fig. 3. PDMS flexible membranes were obtained using acrylic moulds, produced by CNC milling (Fig. 3a). The main advantages of this technique are the low involved costs and the fast production times. However, it is related with poor dimensional control (it is difficult to achieve dimensions less than 50 μm), in which more conventional micromachining technologies can achieve the required tolerances.

The electrical components are based on aligned-CNTs, as presented in Fig. 3b. To grow forests or "carpets" of vertically aligned-CNTs the chemical vapor deposition

(CVD) method [9] was used. The aligned CNT growth process involves the use of a silicon substrate with patterned Fe/Al_2O_3 catalyst, placed in a horizontal quartz tube furnace at atmospheric pressure at 750 ºC using ethylene feedstock [9]. The following step is schematically represented in Fig. 3c, which consists of embedding the polymeric matrix (PDMS) into the aligned CNTs. The substrate is positioned against the moulds and the PDMS is introduced in the cavities through a hole to create an aligned-CNT/PDMS nanocomposite, as previously described for epoxies using capillarity-assisted wetting [10], followed by the curing of the elastomer.

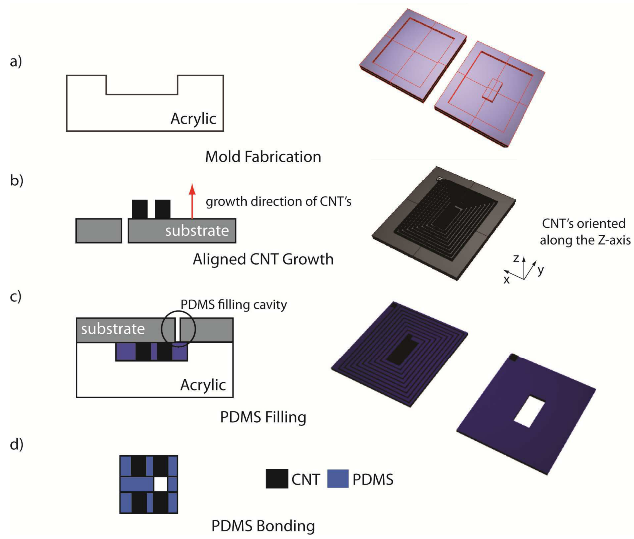

Fig. 3. Fabrication process flow for the development of a flexible pressure sensor with aligned-CNTs/PDMS nanocomposites.

The pressure sensor is composed of three layers, where the inductor and the electrodes are defined by the top and bottom layers, and the dielectric (air) is between. Figure 3d shows the configuration, which requires the bonding of PDMS membranes. PDMS adhesive techniques have been tested and Eddings *et al.* [11] present a highest reported bond strength based on five different bonding techniques for both partial curing and uncured PDMS. The last approach was used to build the sensor successfully in our work (Fig. 4).

IV. MATERIAL PROPERTIES

The impregnation of the CNTs in the PDMS matrix, as well as the respective mechanical and electrical properties (required for the sensor design and its response), is the most important step of the fabrication process. The aligned CNTs are oriented in the out-of-plane (normal to the wafer plane) direction when grown, which can be assumed that the polymer nanocomposite is transversely isotropic (isotropic in the plane of the sensor). In addition, due to the CNTs orientation, the modulus improvement is expected to be minimal as the long axis of the CNTs are oriented perpendicular to the loading direction, such that the PDMS polymer controls the response. Research work on nanocomposites has shown considerable modulus increase, due to the alignment in the CNTs axis direction in polymer (PDMS) [12] and epoxy [13], but little reinforcement effect is expected (based on micromechanics) in the transverse direction as used in our work.

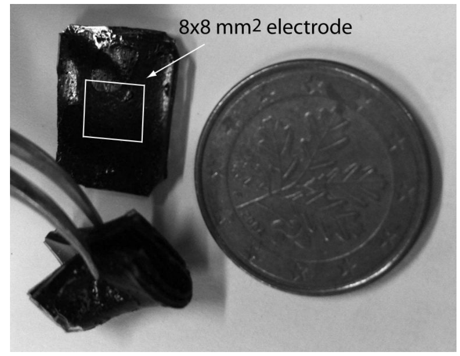

Fig. 4. CNTs/PDMS flexible pressure sensors.

Measurements of a set of polymer nanocomposites samples (PDMS membranes with embedded CNTs) using the Van der Paw method show an electrical conductivity of 0.35 $S.m^{-1}$ with a standard deviation of 0.37 $S.m^{-1}$. Other samples were subject to mechanical tests in order to obtain elastic modulus values (with the CNTs oriented perpendicular to the loading direction). The CNTs/PDMS membranes, molded into rectangular shapes with dimensions of 32x14x0.4 mm^3 (LxWxH, respectively), present an elastic modulus of about 2.4 MPa in the plane of the membrane. These values are just preliminary and further analyses are required to validate the mechanical properties.

V. EXPERIMENTAL SENSOR MEASUREMENTS

Fabricated CNTs/PDMS prototype flexible pressure sensors were tested in a vacuum chamber. The tested sensors have a mechanical thickness of 675µm (425µm of CNTs/PDMS composite plus 250µm of pure PDMS – used for uncured PDMS bonding) and a dielectric air thickness of 250µm (in fact the total dielectric gap is 750µm, resulting from the pure PDMS layers used for bonding) which result in a sensor with a total thickness of 1.6 mm (675µm+250µm+675µm). The area of the electrodes is 8x8 mm^2 (WxL). In spite of the low sensor resolution, since the geometry was not optimized (the devices are at a proof-of-concept stage), the sensor was mounted inside a controlled pressure chamber (the dielectric is hermetically sealed at ambient pressure) in order to measure the capacitive changes (a LCR meter was used to measure the flexible capacitor changes). Results are presented in Fig. 5. Existing sensors geometry is not optimized for the required post-EVAR surveillance specifications (external pressure, P, ranging from 26 to 6 mmHg) and therefore the tests were performed at much higher pressures (P ranging from 750 to 225 mmHg).

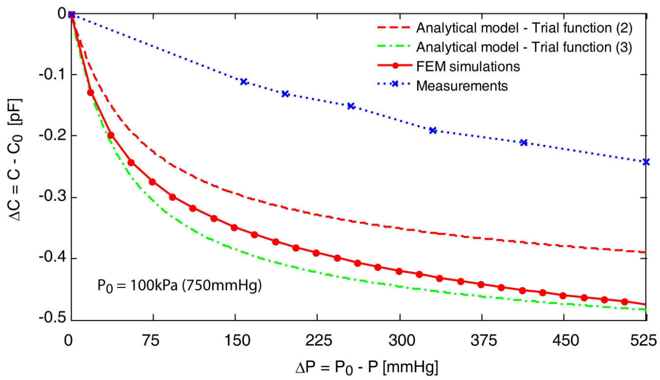

Fig. 5. Capacitive changes vs. pressure assuming ambient pressure inside the dielectric.

VI. Discussion

The capacitive sensor experimental results (Fig. 5) were compared with the described sensor analytical model and a FEM (Finite Element Modeling) sensor model. In both models an isotropic Young's Modulus and poison's ratio of 2.4 MPa and 0.48, respectively, were used for the nanocomposite mechanical layer (for simplification).

Analysis of the results show that the analytical and FEM models compare relatively well, although is clear that the trial function is an important parameter for the model. The experimental results are in reasonable agreement for high pressure differences (in terms of rate of change), but the differences are significant for pressures around the ambient pressure. Several reasons may contribute to these differences: lack of accurate material properties, geometry asymmetries created during the fabrication process (most of the process is being done manually and therefore prone to dimensional variations from the designed ones), and uncertainty regarding the actual pressure inside the hermetically sealed cavity. In fact, since the final bonding process requires a curing at 80ºC during 30 minutes (done in an oven) it is likely that the pressure inside the air cavity is not at ambient pressure.

Figure 6 compares the experimental results with the analytical and FEM models considering a pressure of 105kPa (787 mmHg) inside the dielectric cavity. With these assumptions the experimental results are in better agreement with the models indicating that most likely the pressure inside the dielectric is higher than ambient pressure.

VII. Conclusions

A newly developed technology based on CNTs has proven successful in the development of flexible pressure sensors that may enable the next generation of implantable sensors for post-EVAR surveillance. While results for the sensor are not preformed at the desired pressures for the application specifications, the low Young's Modulus characteristics of the nanocomposite layers and the fabrication process characteristics enable the design of pressure sensors that can target the post-EVAR surveillance specifications.

Future work includes an improved design of the sensors to meet the target application specification and a detailed analysis of the CNTs/PDMS mechanical properties.

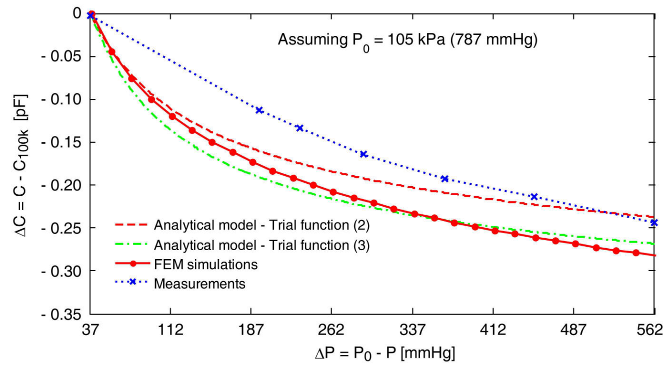

Fig. 6. Capacitive changes vs. pressure assuming 105kPa (787 mmHg) inside the dielectric.

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