DEVELOPMENT AND VALIDATION OF A PRESSURE TRANSDUCER AND ITS ELECTRONICS FOR ESOPHAGEAL MANOMETRY

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Abstract: This paper reports the development and validation of strain gauge transducers and its readout electronics with the ultimate goal of integration in a commercial endoscopic capsule (EC). The deposition process of strain gauge transducers on a capsule surface, using microfabrication techniques, is described. An electronic circuit is designed, implemented and tested for the amplification of the transducer output signal. Electromechanical tests are performed on a cylindrical tube, which simulates the capsule weight and dimensions, and the obtained results allowed establishing a correlation between the output signal and the stress applied on an EC. These results represent an important step for the implementation of a more advanced capsule manometry system.

1 INTRODUCTION

The gold standard for the assessment of esophageal motor functions is manometry. With this technique it is possible to measure pressure changes that reflect the strength and timing of muscles contraction and relaxation. The major indications for esophageal manometry are the evaluation of dysphagia and non-cardiac chest pain. Esophageal manometry is, as well, the standard method to establish the diagnosis of: achalasia - low repetitive amplitude contractions (10-40 mmHg); diffuse esophageal spasm - uncoordinated contractions (>30 mmHg); and Nutcracker esophagus - high-amplitude peristaltic pressure waves (>180 mmHg) (Murray, 2003; Holloway, 2006; Bodger, 2006; Pandolfino, 2009).

Manometry equipment is composed by two major components: a pressure transducer and a recording system. The transducer element can be a water-perfused catheter connected to external transducers, or intraluminal solid-state strain gauge transducers. These are used to determine pressure profiles in the esophageal sphincters and body, and to convert it into an electrical signal. Although being more expensive, solid-state manometry devices present some important advantages: they have much higher frequency response characteristics, and they require less technical expertise to use (Murray, 2003; Holloway, 2006; Bodger, 2006).

Solid-state strain gauges are based on the piezoresistive effect, i.e. there is a change of electrical resistance upon mechanical deformation of the surface where they are attached to. These are usually placed in a Wheatstone bridge configuration, with all resistors attached to the mechanical surface to minimize the effect of temperature. (Wolffenbuttel, 1994). The output signals of the bridge, which provide a direct measure of intraluminal pressure, are amplified before being recorded on a computer for further data processing and analysis (Murray, 2003; Bodger, 2006).

More recently, the basic format of manometric studies has been replaced by intraluminal pressure topography plots. This novel technique is known as high-resolution manometry and its concept consists in miniaturizing and increasing the number of transducers on the manometric instrument, so that it is possible to define the pressure profile as a spatial continuum (Bodger, 2006; Pandolfino, 2009).

The long term of this project is to integrate manometry functions within a commercial endoscopic capsule (EC), using solid-state strain gauge transducers. Some capsules, such as the pH and pressure capsule, have incorporated a single solid-state transducer to record mechanical events.

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However they are not yet able to record images from the gastrointestinal tract (Camilleri, 2008). With the very promising developments on the capsule locomotion and stopping mechanisms, the addition of manometry functions as a complement to existent EC imaging functions will be of great clinical utility.

Using microtechnologies it is possible to build small transducers on the capsule surface. These technologies enable implementation of many transducers that can record pressure values all around the capsule area. As a first step, the deposition process of strain gauge transducers is studied and described. Also, an electronic circuit for the readout of the transducer output signal is designed and implemented. The proper functioning of the circuit will be first tested using a commercial strain gauge transducer. The results of the system performance and amplification circuit are described.

2 EXPERIMENTAL

2.1 Fabrication of Transducer Element

The transducer element can be fabricated with thin-film deposition and patterning processes. However, some constrains were already studied and must be considered during the fabrication process: the polymer of current available EC cannot support temperatures above 120 ºC and is incompatible with chemicals (solvents) used in some photo-lithographic processes; and the curved surface of EC limits the use of rigid lithographic masks.

The fabrication of the sensing element starts with a polyimide film (5 mm in length and width, and a thickness of 25 μm). Next, a chromium layer is deposited in the polyimide film by e-beam. A photoresist mask is created by lithography processes to be used in the wet-etching of the chromium film. The polyimide film is then etched, using the chromium pattern film as mask. This patterned polyimide film is after used as shadow mask in the deposition of metal in the EC. A shadow mask process allows the fabrication of the transducer element, despite the constraints previously considered. The mask is glued to the EC surface before the deposition of a thin metal layer. Since there is only a single mask, there are no concerns regarding its alignment. The metal deposition occurs through the etched region of the polyimide mask, creating regions were metal will be deposited, and regions without metal, forming the transducer element in the EC. After the deposition, the mask is removed, exposing the transducer that should be encapsulated with a biocompatible polymer. Due to the mentioned fabrication constraints, the deposition process is being optimized for the capsule surface polymer, and is currently in progress.

2.2 Circuit Design

For the circuit design and test, one commercial solid-state strain gauge transducer was connected in a quarter Wheatstone bridge configuration (Figures 1 and 2). The transducer length and width is equal to 5 and 1.8 mm, respectively, and it has a resistance of 120 Ω ± 5%. Since our surface is not planar we will not use two gauges because it cannot be assured the same proportion of compressive and tensile stress in both transducers. Also, an *in vivo* study of Cowles et al. (1978) found that mechanical events recordings obtained from a one quarter Wheatstone bridge transducer were of the same quality as those produced by a one half bridge configuration, in terms of accuracy, sensitivity and stability.

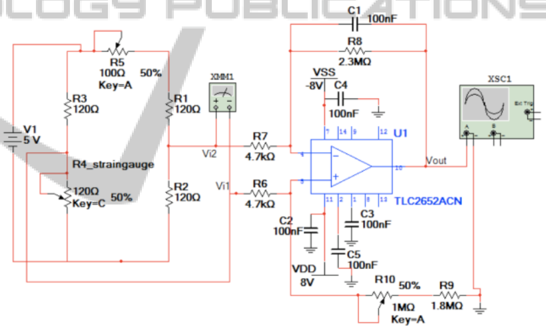

Figure 1: Layout of the system circuit with a differential amplifier, TLC2652CN, to increase the amplitude of the bridge output signal. The TLC2652CN features low offset voltage 1μV with -0.003 μV/°C, and a CMRR of 120 dB.

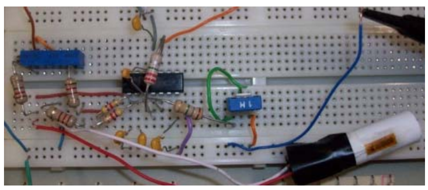

Figure 2: Implementation of the circuit on a breadboard.

The strain gauge was glued to a cylindrical tube using cyanoacrylate glue. The gauge lead out wires were then soldered to electrical wires and mounted on a breadboard, in a bridge circuit, together with three resistors - R1, R2 and R3 - of the same value (120 Ω). The multi-turn potentiometer (R5) is used to compensate the resistance tolerance of the bridge resistors. Several capacitors are used to minimize the noise introduced by the power supply.

The Wheatstone bridge output (V_{out2}) is calculated using Equation 1 (Buchla, 1992), where R is equal to 120 Ω, ΔR corresponds to the strain gauge resistance variation (directly correlated with the applied stress), and V_{ref} is equal to 5 V.

$$V_{out2} = V_{i1} - V_{i2} = V_{ref} \cdot \frac{\Delta R}{4R} \tag{1}$$

The transducer output is transmitted to an amplifier with a gain of 500. The output signal (V_{out}) from the amplifier is expressed as:

$$V_{out} = \frac{R_8}{R_7} \cdot (V_{i2} - V_{i1}) \tag{2}$$

For the circuit to work as a differential amplifier:

$$\frac{R_9}{R_6} = \frac{R_8}{R_7} \tag{3}$$

Due to the mismatched of the resistors tolerance, which in our circuit is amplified by a factor of 4, the errors that can be introduced are in the order of 20%:

$$\varepsilon_{max} \approx \frac{4p}{100} = 0.2 \tag{4}$$

where p is the resistors tolerance and ε is the fractional difference between the two ratios. To solve this mismatch we can use high precision resistors, but a more cost-effective solution for a printed circuit board is the addition of a potentiometer (R10) in series with R9, to adjust Equation 3 and balance the circuit. Therefore, we will have a fixed and a variable resistor:

$$R_{9\,fixed} = R_8 - \left(\frac{4p}{100}\right) . R_8 = 1.84M\Omega \tag{5}$$

$$R_{10\,variable} = 2.\left(\frac{4p}{100}\right) . R_8 = 0.92M\Omega \tag{6}$$

2.3 Electromechanical Characterization

The effects of applied displacement in the piezoresistive gauge, attached to a cylindrical surface, were investigated under a three point bending test. There are many techniques to assess the gauge mechanical behavior, but three point bending test has the advantage of being simple and reproducible (Schriefer, 2005). The test was performed in an AG-IS Shimadzu testing machine with a load cell of 1 KN. The cylindrical tube was positioned for transversal loading with a distance between the lower supports (L) of 10 mm.

The ultimate stress (σ, in MPa) was calculated using the force (F, in N) versus displacement curves (obtained directly from the testing machine), and the following equation:

$$\sigma = F\left(\frac{LR}{4I}\right) \tag{7}$$

where I is the second moment of area (in mm^4). For a circular cross section I is calculated as follows:

$$I = \frac{\pi R^4}{4} \tag{8}$$

in which R is the tube radius (equal to an available EC radius, 5.5mm) (Schriefer, 2005).

3 RESULTS AND DISCUSSION

In order to test the reliability and calibrate the electronic circuit with applied stress, the transducer was glued on a cylindrical tube, and a three point bending test was performed. The test was carried out to simulate the mechanical functions of the esophageal sphincters.

With the testing machine four cycles of displacement were applied with a maximum displacement of 0.02 mm. A constant speed of 0.1 mm/min was used, and the force-displacement data was collected every second (Figure 3).

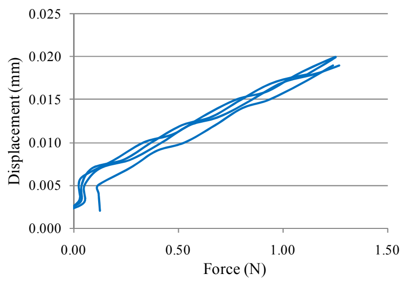

Figure 3: Representative force-displacement graph.

From the above data, the values of force at each displacement could be determined. The strain gauge transducer's resistance variation was also measured during the four cycles of displacement (Figure 4). As would be expected, the transducer's electrical resistance variation is proportional to the mechanical deformation: it reaches its maximum variation (119.518 Ω), compared to its initial value at 0 mm, when the displacement is equal to 0.02 mm.

Simultaneously, output voltages (V_{out}) were recorded using a data acquisition platform (Arduino Uno) and a LabView interface. This software platform makes it possible to process and display

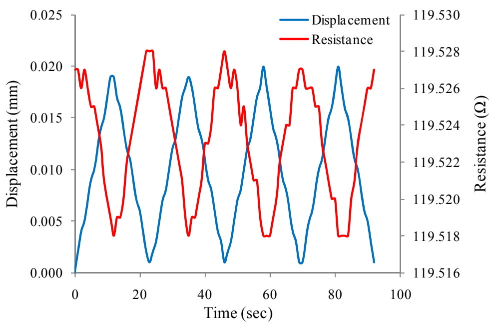

Figure 4: Transducer's resistance variation with applied displacement, for all the four cycles.

pressure-voltage data in real-time. The stress was then calculated using Equations 7 and 8, and the stress-output voltage curve was traced (Figure 5).

In Figure 5 one of the cycles is represented, and it can be concluded that the bridge output voltage is nearly proportional to the mechanical stress applied on the tube. With this result it will be possible to establish a correlation between the measured voltage and the stress induced on a capsule while travelling in the esophagus.

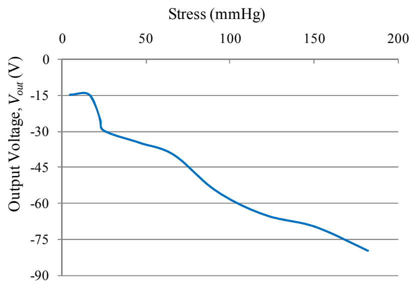

Figure 5: Representative stress-ouput voltage graph.

The main goal of the experiment was to verify this stress-voltage relation which was achieved for circuit calibration and for a further implementation in a microelectronics process, like CMOS.

4 CONCLUSIONS

There is a great interest in developing gastrointestinal manometry systems using solid-state strain gauge transducers. Manometry techniques, using long catheters have the potential to be replaced by more comfortable and simple procedures using endoscopic capsules. We report the design and performance of a strain gauge transducer and its readout circuit, calibrated for the measurement of the induced stress on endoscopic capsules. The initial results obtained make it possible to go a few steps further in system miniaturization and integration and represent a very important step for the development of a more advanced capsule manometry system. In the future, we aim to improve and integrate all the readout circuit within a CMOS chip. Moreover, we want to optimize the transducer deposition process, overcoming the constraints related with the capsule polymeric material.

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