Development of A MEMS Based Manometric Catheter for Diagnosis of Functional Swallowing Disorders.

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Abstract. Silicon pressure sensors based on micro-electro-mechanical-systems (MEMS) technologies are gaining popularity for applications in bio-medical devices. In this study, a silicon piezo-resistive pressure sensor die is used in a feasibility study of developing a manometric catheter for functional swallowing disorders diagnosis. The function of a manometric catheter is to measure the peak and intrabolus pressures along the esophageal segment during the swallowing action. Previous manometric catheters used the water perfusion technique to measure the pressure changes. This type of catheter is reusable, large in size and the pressure reading is recorded by an external transducer. Current manometric catheters use a solid state pressure sensor on the catheter itself to measure the pressure changes. This type of catheter reduces the discomfort to the patient but it is reusable and is very expensive. We carried out several studies and experiments on the MEMS-based pressure sensor die, and the results show the MEMS-based pressure sensors have a good stability and a good linearity output response, together with the advantage of low excitation biasing voltage and extremely small size. The MEMS-based sensor is the best device to use in the new generation of manometric catheters. The concept of the new MEMS-based manometric catheter consists of a pressure sensing sensor, supporting ring, the catheter tube and a data connector. Laboratory testing shows that the new calibrated catheter is capable of measuring pressure in the range from 0 to 100mmHg and maintaining stable condition on the zero baseline setting when no pressure is applied. In-vivo tests are carried out to compare the new MEMS based catheter with the current version of catheters used in the hospital.
1. Introduction

The functional swallowing disorder also known in medical terms as dysphagia is caused by the disruption of the swallowing mechanism. This ailment endangers the children’s development process and becomes fatal in some serious scenarios. Dysphagia occurs as a result of anatomical abnormalities in the esophagus structure or in the coordination of the esophagus muscles, due to the inability for these to contract and relax [1]. The use of a manometric catheter is to measure the pressure changes occurring along the esophagus segment during the swallowing action. The recorded pressure readings are useful in diagnosing the abnormalities of the muscles and providing appropriate guidelines in the assessment of the efficiency of the therapy.

Up until now, water-perfusion manometric catheters were used in the dysphagia diagnosis. This type of diagnosis uses a catheter with several small water channels running through its length, which allow water to flow through to the opening end of the catheter. An infusion pump is used to perfuse water through the channels and out of the end of the catheter. During the swallowing action, the opening end of the catheter becomes occluded, and thus increases the pressure within the water channels. The pressure signal is then transmitted to an external transducer. The transducer converts the pressure into an electrical signal for recording. Several limitations are encountered in the water-perfusion catheter. The pressure reading is not accurate when the patient is in movement. This is due to the long distance of travel and the level position of the fluidic pressure into the sensing transducer. The response time of this type of catheter is slow, which is not suitable to measure the pharyngeal manometric readings [2]. Constant water flow in the catheter and into the pharynx close to the opening of the air-way poses a risk of water inhalation, choking, and increased discomfort.

Current solid state manometric catheters on the market are of the capacitive MEMS-based pressure-sensor type. This kind of catheter produces nonlinear output response and needs correction circuitries to compensate the output pressure readings. After compensation, this type of catheter gives accurate pressure measurement and is stable to temperature effects, and is without any baseline drifting. The drawback for this capacitive MEMS-based catheter is the cost about US$9,500-20,000 each. Therefore, the catheter is reused, which increases the maintenance cost and the risk of other diseases transmitted from one patient to another.

The objective of this study is to develop a MEMS-based manometric catheter which would eliminate the drawbacks faced by the catheter currently used in the hospital. High accuracy measurements, multi-functions, low cost, and disposability for hygienic use are the main focus in this study.

2. Methods

In the MEMS industry, silicon pressure sensors are well known devices. Capacitance and piezoresistivity are the two most common principles in the silicon pressure sensor design [3]. In this study, a piezoresistive pressure sensor is used (Silicon Microstructures Inc., Milpitas, CA). The choice of this type of pressure sensor is based on the small size of the sensor, ability to connect external signal conditioning and data logging system remotely from the sensor, and low cost [4].

2.1. Prototype Design

The prototype of the new MEMS-based manometric catheter consists of three major parts, the sensing area, the catheter tube and the external signal connector. The sensing area consists of the piezoresistive pressure sensor and a sensor carrier ring. A silicone catheter is used as the main catheter tube. A four pin female connector is used as the external signal connector.

2.1.1 The Pressure Sensor. The SM5018 silicon piezoresistive pressure sensor die is used in this study. This pressure sensor used the full Wheatstone structure to measure the applied pressure. This type of sensor is the smallest pressure sensor available from the company at the moment. The dimensions of the sensor are $0.65\text{mm} \times 0.65\text{mm} \times 0.65\text{mm}$. This sensor is capable of measuring pressures up to 30psi.
The size of the pressure sensor is critical in developing the new generation of manometric catheters. The smaller the sensor size the smaller the overall catheter thickness, which will reduce the discomfort on the patient. Not only the size of the sensor was taken into consideration in selecting the pressure sensor, but the sensor offset, total span and span temperature, pressure hysteresis, sensor sensitivity, long-term drifting, and span nonlinearity were as well important factors in choosing the right pressure sensor in this new manometric catheter development, and in that of other medical devices [5].

2.1.2 The Silicone Catheter. A silicone based catheter is used. The catheter has several lumens inside the catheter tube. The signal wires used to link the sensor and the external connector are placed inside the lumen running through from one end to the other.

2.1.3 The Sensor Carrier. A stainless steel ring is used as a sensor carrier at this stage. The ring has a cylindrical shape, measuring 2.5mm in diameter and 4mm in length. An indentation is made in the middle on top of the ring surface to serve as platform. The ring is slid into one end of the catheter tube. The pressure sensor die is placed on top the ring, so that it sit in the indentation.

2.1.4 The External Signal Connector. The electrical connections between the sensor and signal connector were formed using copper wires. The copper wires are housed inside the catheter lumen for protection. On one end the wires are bonded on top of the sensor connection pads, and on the other end they are soldered to a four-pin connector which allows quick connection to the remote signal conditioning and data logging system.

![Figure 1 The new MEMS based manometric catheter.](image)

3. Experimental Testing

3.1. Laboratory Testing
The test setup for the new MEMS-based manometric catheter consisted of a pressure jar, a constant power supply, a digital multimeter and an external connection cable. The first set of sensor response readings is obtained, where the catheter end with the pressure sensor and the sensor carrier are without any encapsulation-protection coating. The second set of readings is obtained, where encapsulation-protection coating of silicon adhesive (7-9800 Soft Skin Adhesive, Dow-Corning Corp. Hemlock, MI) is applied.

At first, the catheter is placed into a sealed jar. Then a pressure range from 0 to 120mmHg is applied with a 5V DC excitation voltage to the sensor. The sensor performance characterisation is recorded using a digital multimeter. The test is repeated several times to specify the sensor span pressure hysteresis.
3.2. In-Vivo Testing

Following the simulated laboratory testing, the prototype manometric catheter was subjected to in-vivo tests. The in-vivo test is carried out at the hospital. The prototype catheter was connected to an external signal logging amplification system and was calibrated together with the current version of the manometric catheter (Millar catheter) used in the hospital. Before catheterising, both prototype catheter and Millar catheter were subjected to specific pressure to obtain the sensor pressure response reading. During the in-vivo test, the newly developed manometric catheter prototype is catheterised into a healthy person without swallowing abnormalities together with the Millar catheter used in the hospital. The Millar catheter is used as a reference for the new prototype. The intrabolus and peak pressure occurring during the swallowing action along the esophageal is recorded during the in-vivo testing process.

4. Results and Discussion

The newly developed MEMS-based prototype manometric catheter was successfully connected to the test setup equipment in laboratory testing. The output performances of the sensors are shown in figure 2 below.

![Pressure Sensor Response](image)

Figure 2 Output responses of the MEMS pressure sensor.

From the results, the output responses of the pressure sensors were very linear with pressure. The sensor output reading of the encapsulated catheter is always higher than the catheter without encapsulation. This is so because of the pre-loaded pressure generated by the silicon adhesive material. Before the in-vivo test, both the prototype catheter and the Millar catheter are subjected to arbitrary pressure to obtain the sensor response. As shown in figure 3, the prototype catheter gave a good sensitivity. The output response is similar to the Millar catheter.

The in-vivo test results show that the prototype catheter is able to measure the peak pressure reading in the esophagus with good sensitivity. However, the intrabolus pressure reading is not in agreement with Millar’s response as shown in figure 4. We believe this is due to the orientation position of the prototype pressure sensor in the esophagus. Furthermore, in the initial state, the prototype catheter exhibits a baseline drift effect. After several experimental investigations, we put down to loose connections to the pads. We also realised that a signal conditioning system was needed to compensate the baseline drift phenomenon [6].

Overall a good correlation between the prototype and the Millar catheter for recording the esophageal and pharyngeal peak pressures are obtained.
5. Conclusion
The MEMS-based manometric catheter is successfully fabricated and encapsulated. The performance of the MEMS based pressure sensor with linear output response is a positive step towards the goal of implementing a new and low cost medical device in the diagnosis of dysphagia. The offset, baseline drift, and temperature effects of the sensor need to be compensated in future developments. Signal conditioning, which includes a filtering system, signal amplification, and baseline adjustments is an essential feature to be implemented into the output data logging devices. After signal conditioning and compensation process, the catheter is expected to record the intrabolus pressure more accurately and in agreement with the Millar catheter. Overall laboratory and in-vivo test results demonstrated the feasibility of development of a low cost, miniature, and disposable new piezoresistive MEMS-based manometric catheter.

Figure 3 Comparison between the new prototype and Millar catheter.

Figure 4 Correlation between Millar’s and the prototype’s catheter response for both intrabolus and peak pressure readings.

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