

Development of a Micromachined Pressure Transducer for Biomedical Device/Tissue Interfaces

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Abstract

In many medical situations, the need for measuring the pressure applied to a tissue quickly and accurately is crucial. Most conventional devices do not measure the actual pressure applied to the tissue because they do not compensate for the tissue or device compliance characteristics and need to be calibrated for each measurement environment. Neuromuscular damage may occur if too much pressure is applied to a tissue for an extended period of time in applications such as tourniquet systems [1]. Incorrect diagnosis may occur if too little pressure is applied in applications such as mammography units [2]. A compliance-independent pressure transducer has other biomedical applications in surgical retraction devices and prosthetic sockets. To eliminate the compliance problem, a pressure transducer was developed using bulk micromachining technology.

Background

It is often important to determine the pressure between a human tissue and medical device. Examples include mammography, surgical retraction, tourniquet systems, prosthetic sockets, and wheelchairs [3]. An extensive literature survey and review of pressure transducers on the market done by WCE (Western Clinical Engineering Ltd.) has shown that conventional transducer are very specific to their particular measuring environment and that there are no current standards for methods used in measuring pressure at device/tissue interfaces [3]. Since the tissue under measurement and biomedical device have varying compliance characteristics, the measured pressure is often not representative of the actual pressure at the interface. The following are some factors contributing to inaccurate measurements in compliance-dependent transducers [4]:

- a) the curvature of the tissue
- b) the amount of muscle or fat content
- c) the roughness of the tissue surface
- d) environmental factors (temperature, humidity, chemicals, etc.)

- e) the size and shape of the contact area if the device
- f) the thickness of the device
- g) the flexibility of the device
- h) the hysteresis of the device
- i) off-axis stresses

Development Process

The initial phase of the project included defining the requirements for a compliance-independent pressure transducer.

Specifications

The following is a list of requirements for a compliance-independent pressure transducer:

- a) maximum hysteresis between measurements over 1 hour of +/- 2 mmHg
- b) easily calibrated by the user
- c) temperature compensated for operational and sterilization temperatures
- d) not affected by humidity or chemicals common to sterilization or application environment
- e) not affected by off-axis forces, only those normal to the transducer
- f) functional under pressure range of 0-500 mmHg
- g) pressure sensing area of 1 cm²
- h) device thickness of no more than 1 mm
- i) as radiotransparent as possible
- j) comply with applicable health and safety regulations
- k) have an obvious indication of when operation fails and pose no risk to the user or patient

Functional Description

The transducer consisted of a membrane etched out of silicon. Piezoresistive elements were designed in a Wheatstone bridge configuration on the membrane [5, 6]. When the membrane is flat, the bridge is balanced. When a pressure is applied at the device/tissue interface, the membrane will flex, thereby changing the output voltage

(two resistors are under compression while the other two are under tension). The amount that the output changes is compliance-dependent. When pressure is applied to the transducer, compliance effects can be eliminated if the membrane is kept flat during pressure measurement. To maintain a flat surface, a chamber underneath the membrane must be repressurized. The pressure required to repressurize the chamber and return the membrane to its initial state (level to the surrounding surface) corresponds to the actual pressure at the device/tissue interface and is independent of the compliance characteristics of the tissue or device. Fig. 1 shows a cross sectional view of the three possible states of the pressure transducer.

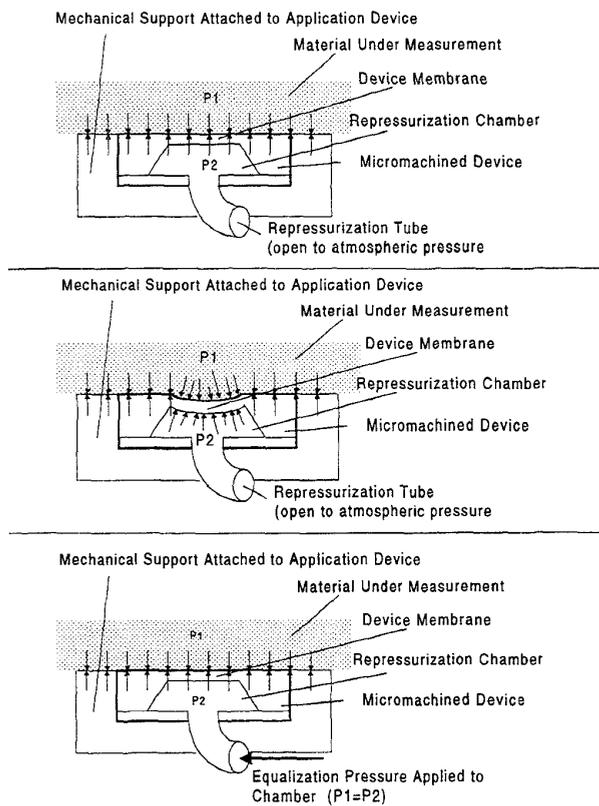


Figure 1. Mechanical Operation of Compliance-Independent Pressure Transducer

Fabrication Technique

The following summarizes the procedure used when fabricating the micromachined transducer:

- oxidize a 4" silicon wafer
- pattern the front side of wafer with dimensions of cavity using photolithography
- chemically etch the pattern in the silicon dioxide layer and create cavity using anisotropic chemical etching of silicon
- pattern the back side of wafer with dimensions of the resistor configuration and chemically etch the silicon dioxide layer
- dope (diffuse) the exposed areas with boron and remove remaining silicon dioxide layer
- deposit and pattern a layer of aluminum (for electrical contact) on back side

The sensing area of the membrane is approximately 3.5 mm x 3.5 mm (although smaller devices were also fabricated) with a membrane thickness of approximately 20 μm .

Two generations of packaging the transducer were completed. The first generation included wire bonding the micromachined chip to a regular DIP package and creating a repressurization channel externally. The second consisted of a plexiglass base with an embedded repressurization channel and made electrical contact to the outside through thin wires. The second generation of packaging eliminates the protruding and sensitive wire bonds allowing the chip to lie flush with the sensing area. Fig. 2 shows a cross sectional view of the first generation of packaging, while fig. 3 and fig. 4 show photographs of the transducer packaged using the plexiglass base.

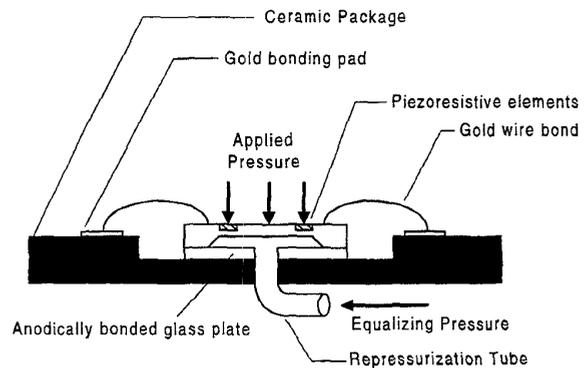


Figure 2. Cross Section of 1st Generation Transducer with DIP Packaging

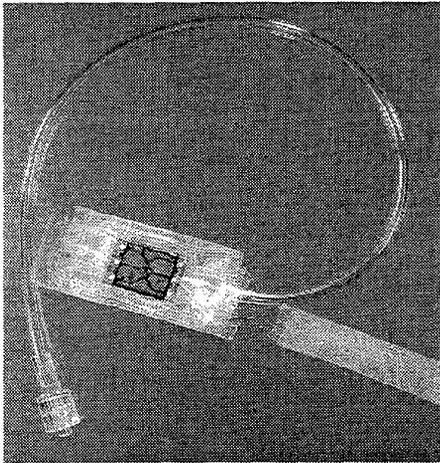


Figure 3. Front View of 2nd Generation Transducer with Plexiglass Based Packaging

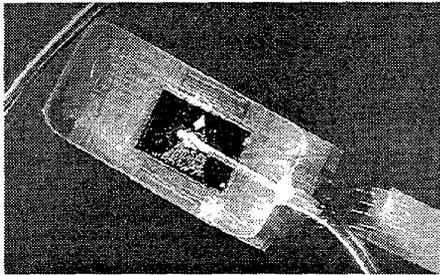


Figure 4. Back View of 2nd Generation Transducer Packaging (showing repressurization channel)

Calibration System

A calibration system was devised by WCE to simulate a tissue surface and is shown in fig. 5. The system consists of a sealed pressure chamber and latex sheet (tissue surface). The pressure transducer can be placed between the latex sheet and base plate with the sensing area in direct contact with the latex sheet and the system provides pressure to the transducer via the latex sheet. The apparatus also allows for testing the transducer with materials having various compliance characteristics.

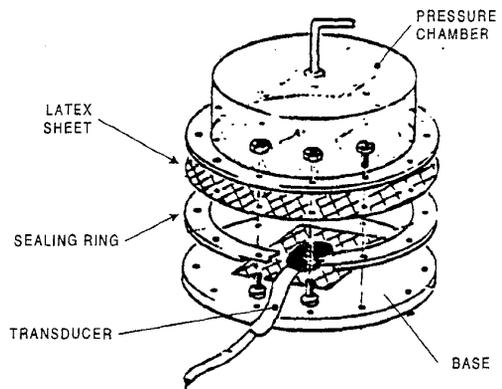


Figure 5. Calibration System

Testing

To calibrate the transducer, the output voltage was measured during the following procedure:

- increase the applied pressure from 0-500 mmHg in increments of 25-50 mmHg
- keep pressure constant at 500 mmHg for 15 minutes
- decrease the applied pressure from 500 mmHg down to 0 mmHg in increments of 25 or 50 mmHg

This calibration allows pressure-voltage characterization and testing for hysteresis and drift.

Results and Discussion

The packaged pressure transducers were tested by applying both direct air pressure and air pressure via the latex sheet using the calibration apparatus. The first generation of packaged transducers behaved quite linearly with a dynamic range of 30 mV when air pressure was applied to the top of the membrane as can be seen in fig. 6 (the same is true when air pressure was applied from the bottom).

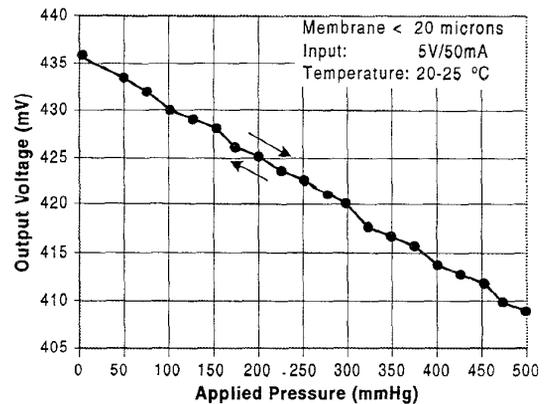


Figure 6. Applied Air Pressure from Top vs. Output Voltage of Pressure Transducer (1st generation)

When the first generation of devices were exposed to pressure applied via the latex sheet, the transducer behaved quite linearly at high pressures with a small amount of drift. However, the latex did not seem to make contact to the transducer surface at lower pressures due to the nonuniform profile of the surface of the device, so the output remained unresponsive as can be seen in fig. 7.

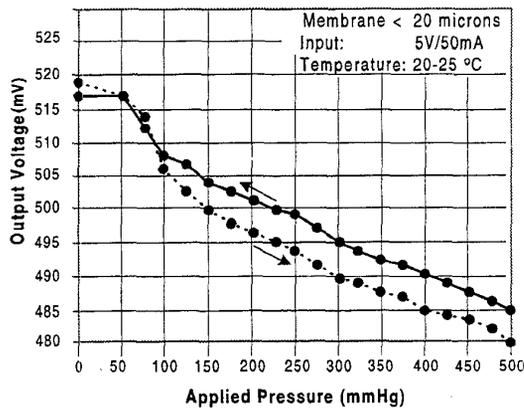


Figure 7. Applied Latex Pressure vs. Output Voltage of Pressure Transducer (1st generation)

The second generation of micromachined pressure transducer yielded approximately the same results as the previous generation when air pressure was directly applied. However, the transducers have yet to be tested using the latex sheet.

Conclusion

Although work still needs to be done in the development of a micromachined pressure transducer for biomedical device/tissue interfaces, micromachining is a viable method of producing this type of transducer. Silicon has a much larger gauge factor (in the range of 10-200) than most metallic foil strain gauges (in the range of 1-10); therefore, silicon is more sensitive to smaller strains. Silicon is a nearly perfect mechanical material resulting in minimum mechanical hysteresis. Micromachined strain gauges can also be miniaturized readily and do not require as many discrete components as other strain gauge transducers. Silicon pressure transducers allow on-chip circuit integration (for temperature compensation) and lend themselves to high volume, low cost production.

Acknowledgments

The authors gratefully acknowledge the contributions of the researchers in the Micromachining Group at Simon Fraser University and the engineers at Western Clinical Engineering Ltd. for their technical advice and expertise.

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