DEVELOPMENT AND EVALUATION OF A COMPLIANCE-INDEPENDENT PRESSURE TRANSDUCER FOR BIOMEDICAL APPLICATIONS

Nancy J. Paris-Seeley, Douglas P. Romilly, James A. McEwen*
Department of Mechanical Engineering, University of British Columbia,
*Western Clinical Engineering Ltd., Vancouver, B.C., Canada

ABSTRACT

The measurement of pressure at a device/tissue interface is desirable in many biomedical engineering applications such as tourniquets and mammography in order to optimize the design or performance of the device. Testing of a selection of existing interface transducers has demonstrated that many are dependent on device and tissue compliance. Such a transducer is only useful in an application where it has been calibrated for specific device/tissue compliance combinations. To overcome this limitation the authors have developed an interface pressure transducer whose output signal is not affected by changes in interface compliance. This enables the transducer to quantitatively measure pressure in many applications without the need to calibrate the transducer for varying compliance conditions. The signal from such a transducer could be incorporated into a control system to measure and control the pressure applied by a mammography machine to the breast.

INTRODUCTION

Many biomedical applications involve the application of pressure from a biomedical device to a body part. Examples include mammography, surgical retraction, and tourniquet applications. In most of these applications, the measurement of pressure at the device tissue interface is required to either optimize the performance of the device (i.e. control applied pressure) or to optimize the design of the device. Figure 1 shows a schematic of a typical measurement environment for transducer application.

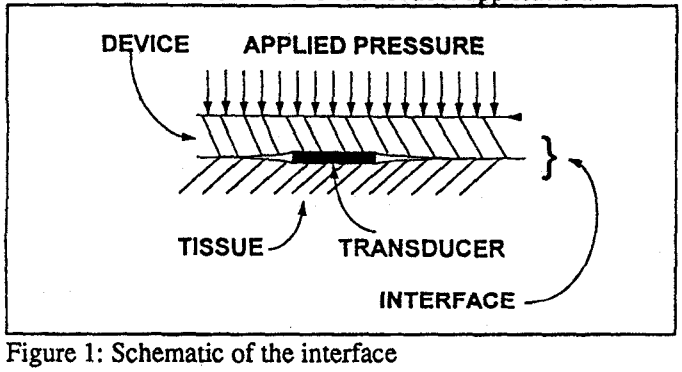

Figure 1: Schematic of the interface

A recent review of the literature demonstrates that a large variety of interface pressure measurement techniques have been previously used making it difficult to compare the quantitative results from different types of transducers, even within one application area [1-4]. A need, therefore, exists for the development of a general purpose interface pressure transducer that can be employed in a variety of applications whose results can be reliably duplicated and compared.

METHODS

Specifications

The authors have defined optimal specifications for an interface pressure transducer for biomedical applications. The following is a partial list of the specifications that have been defined:

i) output independent of tissue or device compliance;
ii)+/-2mmHg error, minimum hysteresis between measurements over 1 hr time period of +/-2mmHg;
iii) conforms to body curvature in two dimensions having radii down to 2 cm;
iv) measures normal forces only (decoupling between normal and tangential forces);
v) pressure measurement of peak pressure averaged over a measurement area of no more than 1 cm diameter;
vi) overall package dimensions dependent on application however thickness should be 1/10th of width;
vii) a reusable transducer should have a cost of manufacture of less than $50 each; if disposable components are employed their replacement cost should be less than $1;
viii) transducer design must permit its calibration by a clinical user in target applications.

Once defined, a project was undertaken to develop an interface pressure transducer with the required specifications.

Transducers

A variety of prototype and commercially available transducers were developed or obtained for evaluation. These technologies have been categorized as follows:

i) force sensitive resistive material (obtained)
ii) capacitive type (obtained)
iii) electro-hydraulic bag (developed)
iv) constant pneumatic flow valve (developed)
v) strain gauge on diaphragm (obtained)

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vi) strain gauge on diaphragm with back pressure or balanced diaphragm transducer (BDT) (developed)

Calibration System

To test the transducers and evaluate the effect of interface compliance on output, a calibration system was designed and manufactured which simulated an interface environment based on a similar system described by Ferguson-Pell[5]. The system consists of a pressure chamber, sealing ring, membrane material, and a base plate. For evaluation purposes each transducer was situated between the base plate and the membrane material and a pressure was applied through the membrane material.

Testing

The testing procedure involved single measurements at various pressure intervals to obtain a calibration curve. Pressure was increased in intervals from 0 mmHg to a maximum of 450 mmHg, held for 15 minutes, and decreased in the same intervals back to 0 mmHg. In this way hysteresis and drift were also evaluated The membrane material was varied to assess the affect of compliance changes on the transducer output.

RESULTS

The evaluation of the transducer types (i-vi) provided the following results:

i) the force sensitive resistive material transducers had approximately 20% hysteresis and drift;

ii) transducers (ii) to (v) had outputs that were not independent of the material compliance against which they acted;

iii) the BDT output was found to be independent of the material compliance against which it acted. Figure 2 shows the transducer output using a 2 mm thick latex membrane material (high compliance material HCM) and a 7 mm thick urethane gel membrane material (low compliance material LCM).

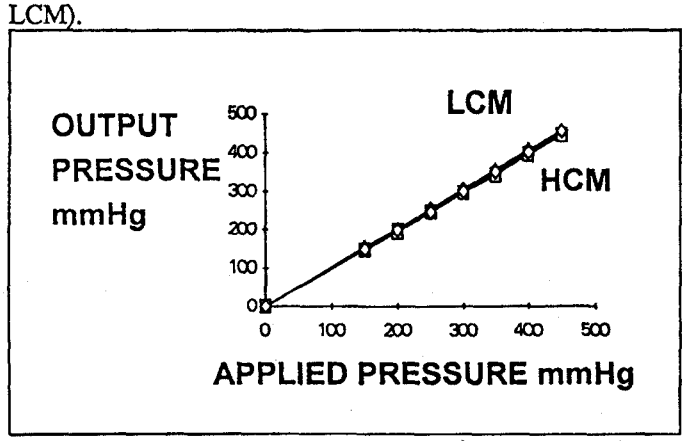

Figure 2: Balanced diaphragm transducer output

DISCUSSION

An essential characteristic of a multi-application interface pressure transducer is to accurately measure the applied pressure independent of the interface compliance. By eliminating the deflection of the diaphragm by employing back pressure, we have effectively produced a transducer that responds to applied pressure independent of material compliance (see Figure 3).

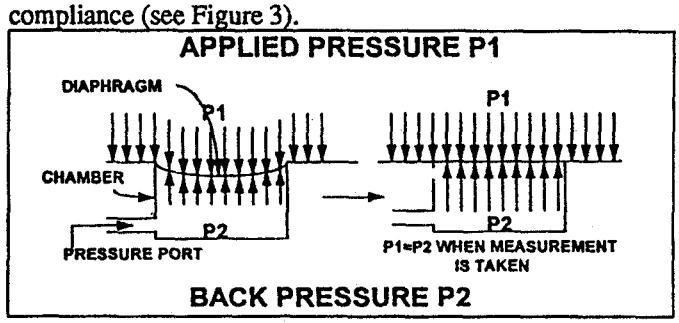

Figure 3: Compliance independent transducer

CONCLUSIONS

The authors are currently developing a second generation prototype of the BDT that will fulfill the remaining specifications and be packaged for use in tourniquet and surgical retraction trials. As well, an auto-regulation system is being developed such that the signal from the strain gauge will be used to regulate the pressure in the chamber to maintain the diaphragm's initial unloaded position. After clinical trials the authors will be looking at the feasibility of incorporating the transducer into a control system such that the signal from the transducer will be used to control the pressure being applied by a surgical retractor.

ACKNOWLEDGMENTS

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