Dynamic Characteristic of the Pleural Cavity Pressure Sensor

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Abstract: We are developing an implantable sensor to measure the interface pressure in the pleural cavity. A 3D printing process was used to evaluate different shapes and materials for the transducer part. The better compromise resulted in a disk-shaped, 10 cm diameter, printed with biocompatible TPU (Thermoplastic polyurethane) filaments with a hardness 92A, offering the best compromise in terms of static sensitivity. We now investigate the dynamic characteristics of our sensor.

1 INTRODUCTION

The first functional model of breathing was developed in 1674 by John Mayow (J. R. Partington, 1956), reproducing the inhalation mechanism. It was made with a balloon inserted into a transparent bigger one. The inner balloon was opened to ambient pressure, so that when outer balloon expanded, the inner balloon was undergoing passive expansion, and thus air started flowing inside the inner balloon.

Graham (Evarts Ambrose Graham, n. d.; Aboud, F. C, Vergheze, and A. C., Evarts Ambrose Graham, 2002) was the first to observe the negative pressure inside the intrapleural cavity - located between the lungs and chest - and to explain its contribution to respiratory mechanics. Actually, lungs follow the periodic movements of the chest thanks to this existing negative pressure inside the intrapleural cavity (Ppl). The Ppl is approximately -0.6 cmHg during inhale and -0.25 cmHg during exhale.

In some conditions, the intrapleural pressure Ppl is measured to access parameters like the Pressure-Time Product (PT product), the Work of Breathing (WOB) or the transpulmonary pressure, which are essential in selecting ventilation strategy and in preventing patients from lung overdistention.

The intraesophageal pressure (Pes) is currently preferred to the direct pleural manometry (Milic-Emili, et al., 1964). It is uncomfortable to the patient, who must swallow the balloon with catheter, but is less dangerous. Still, this method suffers limitations. In particular it is difficult to control the correct placement of the balloon at the esophageal site without imagery guidance. Furthermore, it was recently demonstrated that the intrapleural and esophageal pressures, are not correlated in some body orientations (N. Terzi, S., etal., n.d.; C. Guerin, et. al., 2021).

Therefore, we investigated the development of an interface pressure sensor to allow the direct measurement of Ppl inside the pleural cavity. We earlier described the design of our intrapleural pressure sensor (T. Mimra, et al., 2022), the clinical evaluation of our first prototype (N. Terzi, S., et al., n.d.), then the production of a 3D-printed model (FDM) with various shapes and materials. The better compromise resulted in a disk shape, 10 cm diameter, printed with biocompatible TPU (Thermoplastic polyurethane) filaments with a hardness 92A and offering the best compromise in terms of static sensitivity. We now investigate the dynamic characteristics of our sensor.

2 THE 3D-PRINTED INTRAPLEURAL PRESSURE SENSOR

2.1 Balloon Designs

Our sensor is mainly composed of a balloon (Figure 1, 2), to be inserted into the pleural cavity.

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Figure 1: Our first triangle balloon. We notice the Luer Lock fitting (on top) and the handle (right down).

From the first clinical experimentations, we understood that we must pay attention to the shape of the balloon in order to prevent from internal tissue injuries at insertion and during operations. The surgeons prefer a form factor thin enough to be installed inside the pleural cavity but large enough to be easily manipulated. Therefore, we proposed a thickness of 5 mm within a 3D frame 10 cm by 10 cm, which fits in the intrapleural cavity while offering a maximum mechanical transfer surface and easy handheld. We envisaged various shapes – square, triangular and disk – (Figure 1, 2).

Figure 2: The disk balloon (right) has a diameter of 10 cm, the square balloon (left) has a side of 10 cm.

Furthermore, the material of the balloon must meet the constraints for biocompatibility (no material release) and waterproofing. Other operational aspects concern the mechanical compatibility with the standard Luer Lock fitting, and the provision of a handle to facilitate the surgeon task when placing the balloon into the pleural cavity.

The balloon is currently connected to a commercial pressure sensor (MLT1199 BP Transducer, ADinstruments) through a 1-meter long tubing. The signal of the pressure sensor further feeds a data-acquisition system (PowerLab 4/26, ADinstruments), for filtering and digital conversion. The digital signal is processed with a specific instrumentation software (LabChart7, AD Instruments).

2.2 Balloon Materials

Materials selected for printing the balloons must be biocompatible and flexible enough to conform with the inner cavity. Materials for 3D FDM printing are called filaments and resins are used for SLA 3D printing. The hardness of the flexible filaments is the shore, ranging from 10 for soft materials up till 100 for extra hard one. We fabricated 28 balloons with various shapes and various (7) materials selected for their biocompatibility (Table 1),

Table 1: Hardeness of filaments used for FDM and resins for SLA.

Material	Marking	Shore	Commercial Name
FDM printing			
Thermoplastic Polyurethane	TPU	92A	Ultimaker TPU 95A
Thermoplastic Elastomer	TPE	95A	Gembird TPE flexible
Polypropylene	PP	32D	Ultimaker PP 32D
Polylactic Acid	PLA	rigid	Prusament PLA
PolyEthylene Terephthalate Glycol	PETG	rigid	Prusament PETG
SLA printing			
Photopolymer resin TPU	TPU resin	85 - 90 A	eSUN LCD UV 405nm TPU-Like Resin
Photopolymer resin	-Rigid Resin	rigid	ANYCUBIC 405nm UV Sensitive Resin

3 TESTS AND RESULTS

In this section, we present the results of our tests for the 3 shapes of balloons printed in TPU92A (Thermoplastic polyurethane) and in TPE95A (Thermoplastic elastomer).

3.1 Percussive Response Tests

The balloon, filled with water, is placed under a tube guide (diameter 5cm, length 70 cm) in which a roll-shaped weight of 500 g is lowered from a height of 50 cm, thus producing a percussion at impact on the surface of the balloon (Figure 3).

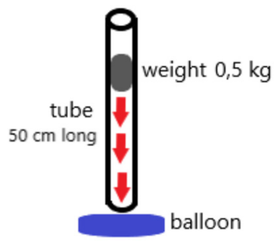

Figure 3: The experimental set-up for the dynamic percussive response.

The transient signal output of the pressure sensor after impact (Figure 4), is recorded in order to compute the time constant of the sensor.

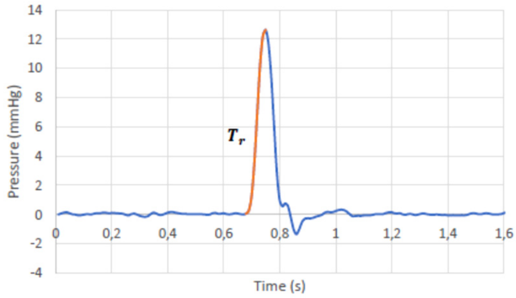

Figure 4: Typical transient response after a percussion.

Considering the transfer function of the sensor being of a first-order type, the temporal response time (Tr) at 63% of the final (end) response, corresponds to the time constant of the First-Order model, and thus to the equivalent cut-off frequency (Fr) following equation:

$$F_R = \frac{1}{2 \cdot \pi \cdot \left(\frac{T_r}{100} \cdot 63\right)}$$

The dynamic tests are repeated 10 times for each device for averaging the time response at 63% and to derive the mean equivalent cutoff frequency (Table 2).

Table 2: The equivalent cut-off frequency (Hz) of the Ppl sensor, for various shapes and materials.

	PETG	PLA	PP	Resin	TPE 95A	TPU 92A	TPU Resin
Triangle	2.3	3.2	6.2	4.3	26.6	60.6	36.2
Square	2.8	2.4	5.0	4.2	28.8	39.8	47.2
Disk	2.2	2.6	3.6	4.5	27.9	44.0	47.2

Any shape printed from TPU92A and TPU resin offers a satisfying bandwidth. The normal respiration rate being 0.2 to 0.34 Hz, the sampling frequency domain will be 34 Hz if considering a convenient oversampling ratio of 100.

3.2 Frequency Response Tests

In this test, we now evaluate the frequency response of the Ppl sensor to a periodic respiratory stimulation. The respiration is simulated with an artificial lung connected to a medical ventilator (Monnal T50, Air Liquide; Figure 5).

Figure 5: The measuring balloon is inserted inside the artificial lung.

Controlled respiration was measured by a flow sensor (ML 311, ADinstruments), connected to the ventilator tube, for comparing recorded curve of the ventilator and curve of the measuring balloon. The pressure was recorded from the pressure sensor (MLT1199 BP Transducer, ADinstruments). This test was performed with following balloons: all measuring balloons made from TPU 92A, triangle balloon made from PP and rigid resin, disk balloon made from TPU resin, PETG and TPE, squared balloon made from PLA (Figure 6).

The experiment lasted 60 seconds, the number of breaths which were recorded depended on the set frequency of the ventilator. Respiration frequency of the medical ventilator was set to 10 inhales per minute, which corresponds to 0,16 Hz (Figure 7).

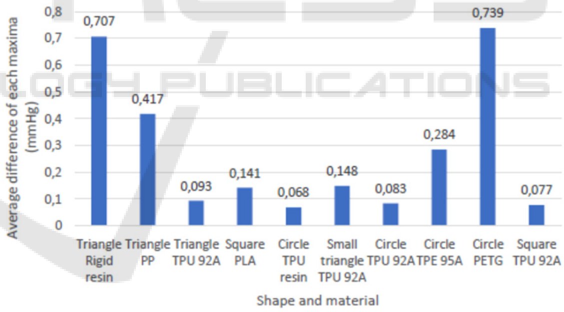

Figure 6: Average difference of each maxima with respiratory frequency 10 breaths per minute, for different shape and material.

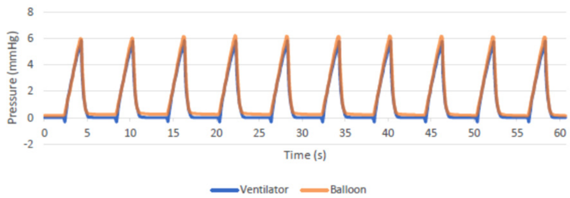

Figure 7: Respiration curve of the disk balloon made from TPU resin (best of frequency 10 breaths per minute).

The best measuring balloons at this breathing rate are the disk balloons made from TPU resin, also disk and square balloons from TPU 92A (Table 3).

Table 3: Correlation between pressure in balloon and ventilation flow at a breathing frequency 0.16 Hz (9.6/mn).

Correlation	Material	Shape
0,93	Disk	TPU 92A
0,96	Square	TPU 92A
0,89	Triangle	TPU 92A
0,87	Disk	TPE 95A
1,00	Disk	TPU resin
0,87	Square	PLA
0,86	Triangle	PP
0,84	Triangle	Rigid resin
0,86	Disk	PETG

4 CONCLUSION

The current measurement method of the intrapleural pressure (Ppl) from the esophageal site overestimates Ppl. In addition, it is uncomfortable for the patient whose exposure must be limited to a few minutes.

It therefore sounds a promising idea to investigate the realization of a sensor which could be implanted directly in the pleural cavity, for a couple of days or week, in order to access anytime the true value of the Ppl and therefore address its long-term variations.

We proposed a device, in the form of a small disk (10 cm diameter) or a triangle (side 10 cm) printed with biocompatible TPU92A or TPU resin. It is filled with air but a fluid filled will also transmit the pressure. The device exhibits good static and dynamic characteristics. We demonstrated, on an artificial lung, that it can track correctly the respiration at standard frequencies.

Our next task will be to test it under real conditions (in vivo animals), to confirm its promising qualities.

Future developments will focus on the integration of a wireless pressure sensor so as to make the system autonomous after implantation. A MEMS microsystem – integrating a pressure sensor, a microcontroller, and a wireless communication – will be placed inside the balloon to collect directly the inside pressure and to transmit it outside the body, for instance with passive RFID.

Before to be implemented in the thoracic cavity, the safety and the impact on patient should be evaluated through a clinical survey.

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