

A novel disposable sensor for measure intra-abdominal pressure

Nuevo sensor desechable para medir la presión intraabdominal

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Abstract

Background: Measurement of intra-abdominal pressure (IAP) is realized with the Kron's method. However, this technique has drawbacks like an infusion of water into the bladder of the patient. **Objective:** The prove a new novel disposable sensor in the way to measure the IAP (DSIAP) this one addresses some limitations of the Kron method. **Materials and methods:** The DSIAP was tested in vitro and clinical settings. The proposed technique was compared with Kron's method through Pearson correlation and Bland-Altman analysis. For in vitro tests, 159 measurements were taken performed by simulating the IAP in the bladder. For the clinical test, 20 pairs of measurements were made in patients with routine IAP monitoring in the intensive care unit. **Results:** In vitro measurements showed a strong correlation between the DSIAP and the reference ($r = 0.99$, p -value $< 2.2 \times 10^{-16}$). The bias and 95% confidence intervals were 0.135 and -0.821 - 1.091 cmH₂O, respectively. Measurements in patients with DSIAP versus Kron's method shown a very good correlation ($r = 0.973$, p -value $< 5.46 \times 10^{-13}$), while the bias and confidence intervals were 0.018 and -3.461 - 3.496 mmHg, respectively. **Conclusions:** The results suggest that the proposed DSIAP showed a profile similar to pressure transducers already in clinical use while overcoming some limitations of the former.

Key Words: Disposable sensor. Intra-abdominal pressure. Pressure transducer. Kron's method.

Resumen

Antecedentes: La medición de la presión intraabdominal (PIA) generalmente se realiza con el método de Kron, a pesar de presentar inconvenientes como la infusión de agua en la vejiga del paciente. **Objetivo:** Introducir un nuevo sensor desechable para medir la PIA (SDPIA) que aborda algunas limitaciones del método de Kron. **Método:** Se probó el SDPIA en pruebas in vitro y clínicas. La técnica se contrastó con el método de Kron empleando la correlación de Pearson y el análisis de Bland-Altman. Para las pruebas in vitro se realizaron 159 mediciones simulando la PIA en la vejiga. Para las pruebas clínicas se realizaron 20 mediciones en pacientes con monitorización rutinaria de la PIA en la unidad de cuidados intensivos. **Resultados:** En las mediciones in vitro se encontró una alta correlación ($r = 0.99$; $p < 2.2 \times 10^{-16}$). El sesgo para la diferencia entre los dos métodos de medición fue de 0.135 cmH₂O, con un intervalo de confianza del 95% de -0.821 a 1.091 cmH₂O. En las mediciones clínicas también se encontró una alta

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correlación ($r = 0.973$; $p < 5.46 \times 10^{-13}$) para la diferencia entre los dos métodos de medición de 0.18, con un intervalo de confianza del 95% de -3.302 a 3.650 mmHg. **Conclusiones:** Los resultados sugieren que el SDPIA propuesto muestra un desempeño similar al de los transductores de presión actualmente en uso clínico, mientras sobrelleva algunas limitaciones de estos últimos.

Palabras Clave: Sensor desechable. Presión intraabdominal. Transductor de presión. Método de Kron.

Introduction

Measurement of intra-abdominal pressure (IAP) is commonly performed in post-operative and critically ill patients^{1,2}, as an increase in IAP could derive in intra-abdominal hypertension, abdominal compartment syndrome, and failure in another body organs³⁻⁵. Hence, an opportune monitoring of IAP allows a prompt diagnosis and adequate treatment of such patients⁶. There currently exists a variety of techniques for measuring of IAP, both directly and indirectly through the urinary bladder, inferior vena cava, stomach, or vesicle⁷⁻¹⁵. A review of the principles, advantages, and disadvantages of the diversity of techniques for the measurement of IAP is beyond the scope of this article and reader is encouraged to read reference¹⁶. Although there is no gold standard, the Kron's method, based on measuring the intravesical pressure, is widely used in clinical practice for measuring the IAP; it has the inconveniences of water infusion toward the bladder, long measuring time for each data point as well as long waiting time in between consecutive measurements. Hence, there is still a need for improvements in the techniques for measuring IAP, for example, to minimize or reduce contamination of the instruments with patient's urine which results in high measurement costs.

Nowadays, it is undeniable that healthcare costs are relevant for patients but also for healthcare professionals, administrators and government officials. In developing countries, such as Mexico and some others in Latin America, this topic is of paramount importance because we keep dependence on medical supplies imports, the ever-escalating costs will not end and will keep impacting the availability of supplies in our health-care systems. Accordingly, novel initiatives focused on reducing the costs of substituting imports with products generated by local research and development are welcome. Substitution of imported medical devices through local technological innovation represents a viable and desired alternative because it not only diminishes health-care costs but also generates employment. Accordingly, a reduction in costs associated with the measurement of IAP would be beneficial in undeveloped countries.

The main contribution of this study is to introduce a different medical mechanical pressure transducer based on a disposable membrane which represents a physical barrier between the patient's urine and measurement instruments. The transducer was validated *in vitro* tests by comparing it with a water column, graded in cmH₂O that simulated the IAP, as previously reported¹⁷, as well as with direct IAP measurements from patients in the intensive care unit (ICU). Human tests were performed by comparing the pressure transducer device versus the Kron's method taken as reference.

Materials and methods

The novel transducer has a hermetic chamber and two valves to achieve pressure measurements (Fig. 1). When the catheter connection valve (A) is plugged, the liquid or gas enters the transduction chamber (B), where the transducer sends air with a pressure proportional to the gas or liquid entering the measuring valve (C), where an electronic pressure measurement device displays the measured pressure in mmHg or cmH₂O. The transducer chamber of the proposed pressure transducer was designed using SolidWorks computer-assisted design software (Waltham, MA, USA) and fabricated using the fused filament deposition printing technique which is a rapid and low-cost three-dimensional (3D) printing technique, based on depositing successive layers of melted printing material to conform a 3D object. The printing material was acrylonitrile butadiene styrene (ABS) plastic and the cost of the ABS plastic employed was < 2 dollars. The transducer chamber was divided into two subchambers separated by a thin Nylon membrane that allows the transduction of IAP to the sensor and avoids contamination of the instrument with the patient's urine.

In vitro test simulating IAP measurements

Using as a simulator of the bladder, a serum bag filled with distilled water was used, and a uniform pressure was exerted on the bag in random form over a range from 5.3 to 33.4 cmH₂O by tightening up the screws

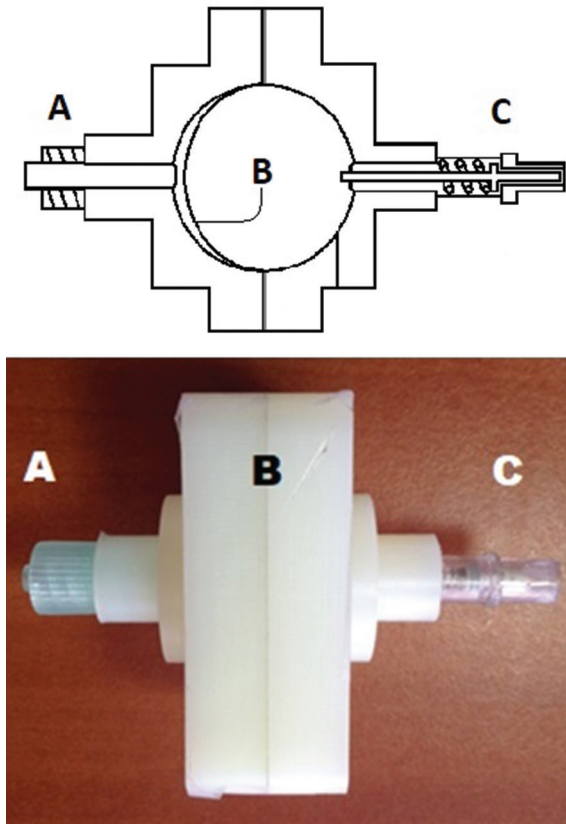


Figure 1. Schematic of the disposable transducer. **A:** connecting valve to catheter. **B:** transduction chamber. **C:** air pressure measuring valve. Bottom: actual view of the disposable transducer.

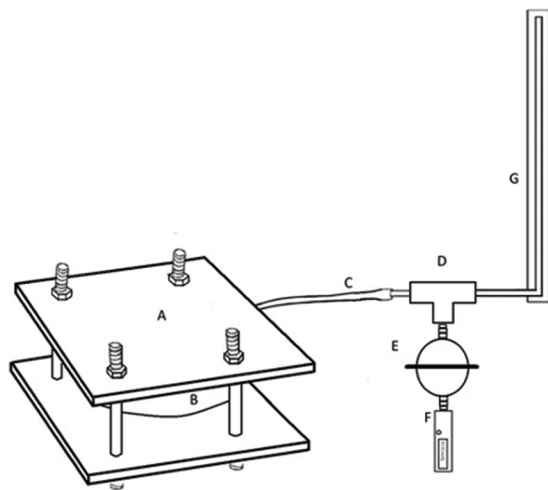


Figure 2. Schematic of in vitro simulated intra-abdominal pressure experiment. **A:** press. **B:** water bag. **C:** catheter. **D:** three-way stop-cock valve connector. **E:** mechanical pressure transducer with a proximal and a distal valve. **F:** pressure measurer/calibrator. **G:** H_2O water column graded manometer.

located on the four corners of a mechanical press. Simultaneous measurements were performed with the disposable pressure transducer and a standard water column manometer graded in cmH_2O , Figure 2.

A total of 159 pairs of measurements were performed at different pressures ranges: one-hundred and two pairs of measurements between 0.0 and 21.0 cmH_2O (0-15 mmHg), thirty-one pairs between 21.1 and 27.0 cmH_2O (16-20 mmHg), and the remaining twenty-six pairs between 27.1 and 34.0 cmH_2O (21-25 mmHg). All measurements were performed at a temperature between 20 and 25° C. Data for the pressure transducer were distributed as shown in the stem and leaf plot below, where the decimal point is one digit(s) to the right of the | symbol:

```

- 5 | 9
- 6 | 1 1 2 6
- 7 | 1 3 3 8 9
- 8 | 0 1 6 8 9 9
- 9 | 0 0 1 3 5 6 7 7 8 9 9 9
- 10 | 1 1 3 5 7 8 9
- 11 | 0 1 1 2 5 6 7 7 8
- 12 | 1 2 2 3 5 6 8 8
- 13 | 1 2 3 4 6 8 9
- 14 | 0 0 8 9
- 15 | 1 2 2 8
- 16 | 2 3 3 3 4 8
- 17 | 0 3 3 5 5 6 6 8 9
- 18 | 0 2 2 5 6 7 8 8 8
- 19 | 1 4 4 5 8
- 20 | 2 2 3 4 5 7
- 21 | 2 7
- 22 | 0 2 2 2 2 8
- 23 | 0 0 2 4 6 8 9 9
- 24 | 1 7 8
- 25 | 3 6 6 6 8 9
- 26 | 3 4 5 6 9
- 27 | 0 3 3 8 9
- 28 | 1 2 3 4 5 8 9
- 29 | 5 6
- 30 | 2 7 8 9
- 31 | 1 3 4 7
- 32 | 2 3 3
- 33 | 4 6.

```

Clinical tests

SUBJECTS

The research protocol was submitted to the research committee of Hospital Juárez de México, the study was approved and assigned the registration number HJM 0609/19-I. The studied sample consisted of 20 measurements performed on patients with routine monitoring of IAP admitted to the intensive care



Figure 3. Measure of intra-abdominal pressure in a patient using the proposed disposable transducer.

unit; those identified with ≥ 10 mmHg were selected for the study. Informed consent was granted by a family member. Patients age ranged from 19 to 56 years (41 ± 14 years), weight 94 ± 19 kg, and height 1.65 ± 0.05 m.

DATA ACQUISITION

The measurements were made in patients through the indirect method of Kron's, which is the most used method and regarded as the standard to measure the IAP due to its low cost and its worldwide acceptance. The Kron's method involves placing a Foley urinary catheter through the urethra until it lodges in the bladder in patients placed in the dorsal decubitus position. Three three-way valves (Luer Lock) are placed in the urine drain line, where a bag of saline solution is connected to the first Luer Lock valve and an H_2O column graduated in cmH_2O is connected to the second valve. Particularly, in this work, in the third Luer Lock valve was connected to the new pressure transducer device to make sequential measurements of IAP with both methods. Then, the valves are placed in position to allow the urine draining to the bladder and when the urine stops coming out, the urine drainage duct is blocked in such a way that 25 ml of saline can be infused into the bladder to measure with the H_2O column. For the data acquisition, an inspiratory pause was placed on the ventilator and the transducers were placed at the level of the median axillary line or the symphysis pubis as "a reference to 0 cmH_2O " and the saline was allowed to flow through their respective Luer Lock valves to the connected transducer and the data were acquired. Finally, the Luer Lock valves were placed in the position to drainage

of urine. Figure 3 shows an example of the experimental setup during the data acquisition in a patient.

Measurement results were distributed for the pressure transducer device, as shown in the stem and leaf plot below, where the decimal point is one digit(s) to the right of the | symbol:

```
- 0 | 2 3 4 5 5 7 7 7 8 9
- 1 | 0 0 3 3 3 3 4 9
- 2 | 1 7
```

As can be seen, 11 pairs of measurements were acquired on the pressure range from 0 to 10 mmHg (0-13.595 cmH_2O), seven on the range from 10 to 20 mmHg (13.60-27.19 cmH_2O), and two on the range from 20 to 30 mmHg (27.19-40.79 cmH_2O). These last three patients were sent to the operating room to decompression surgery after measurements were retested. All measurements were performed at a temperature between 20 and 25° C.

Statistical tests

Statistical analysis was performed using the software R (Core Team 2016, R Foundation for Statistical Computing, Vienna, Austria). Statistical tests performed for both experiments were as follows: (a) correlation analysis, (b) linear regression analysis, and (c) Bland-Altman analysis, to determine the existing relationship between the water column manometer graded in H_2O and the disposable pressure transducer device.

Results

In vitro measurements simulating IAP

Correlation analysis between the pressure transducer device and the water column manometer

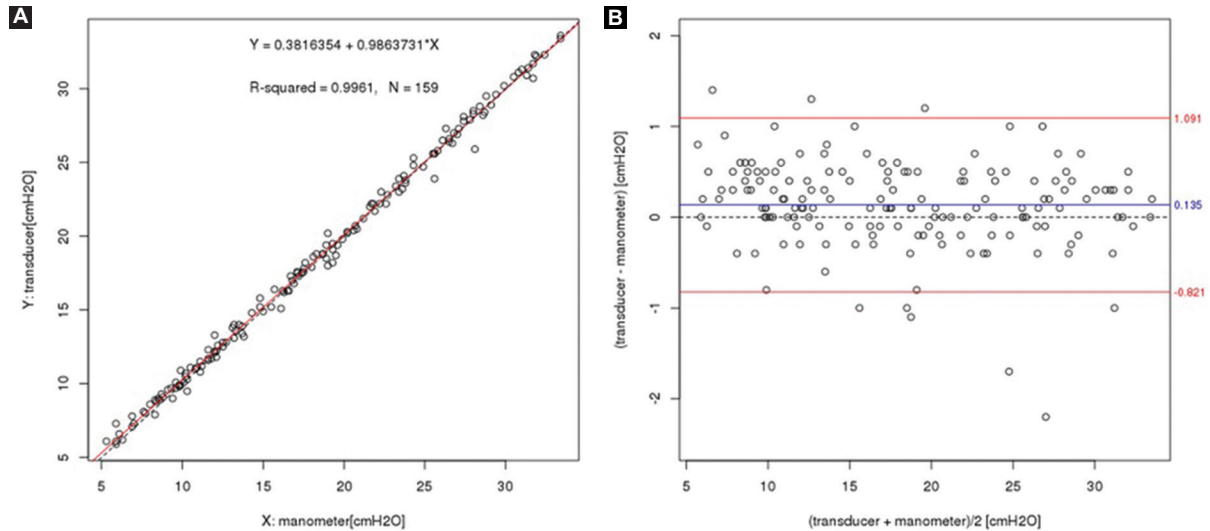


Figure 4. *In vitro* measurements of intra-abdominal pressure using the proposed pressure transducer and the water column manometer of H₂O as reference (n = 159). **A:** regression curve; red line indicates the regression line and the dashed line indicates the identity line. **B:** Bland–Altman plot: Solid horizontal blue line and solid horizontal red lines indicate the bias and 95% limits of agreement, respectively.

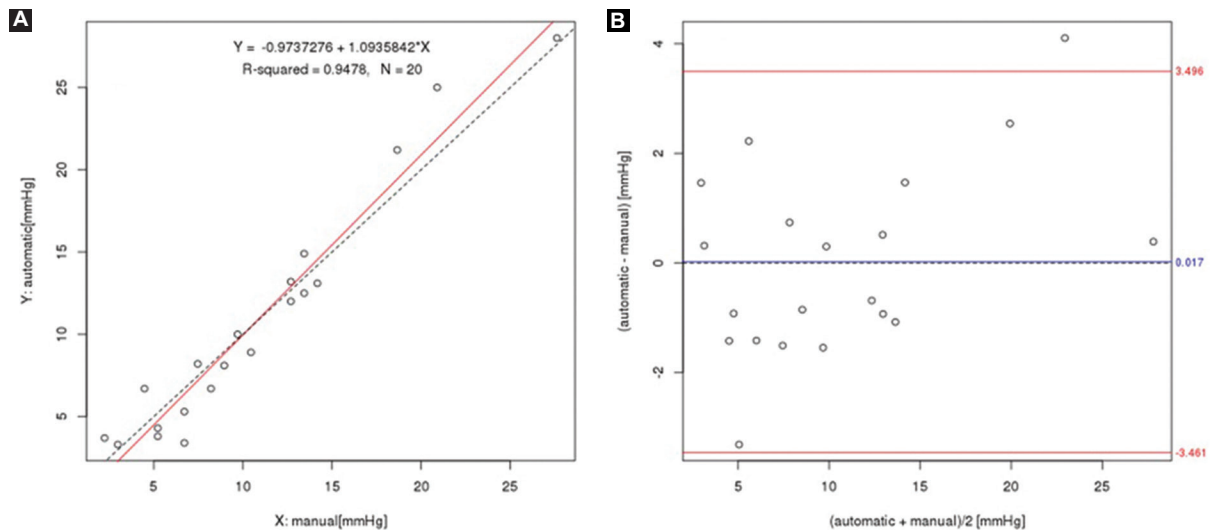


Figure 5. Measurements of intra-abdominal pressure in patients with abdominal complications using the proposed pressure transducer (manual) and the reference device (automatic) (n = 20). **A:** regression curve; red line indicates the regression line and the dashed line indicates the identity line. **B:** Bland–Altman plot: Solid horizontal blue line and solid horizontal red lines indicate the bias and 95% limits of agreement, respectively.

graded in H₂O showed a Pearson's product-moment correlation $r = 0.9980317$, with a 95% confidence interval equal to 0.9973070 and 0.9985615, and p -value $< 2.2 \times 10^{-16}$. The fitted line obtained through linear regression analysis was $\text{transducer H}_2\text{O} = 0.9863731 \cdot \text{manometer H}_2\text{O} + 0.3816354$, with $r^2 = 0.9961$, and p -value $< 2.2 \times 10^{-16}$. Figure 4A presents the linear regression results for the *in vitro* experiment. From Bland–Altman analysis, we found that the proposed pressure transducer produced a bias of 0.135 cmH₂O (p -value = 0.0006132) and a standard deviation of 0.488 cmH₂O. Accordingly, the 95% confidence interval was -0.821 – 1.091 cmH₂O.

The maximum error was 2.2 cmH₂O. Figure 4B shows the corresponding Bland–Altman plot for the *in vitro* experiment.

Clinical tests for measuring of IAP

In measurements from patients, we found an absolute error equal to 1.39 ± 1.00 mmHg, which corresponds to a relative error equal to $18.31 \pm 16.27\%$ when normalized to reference measurements. The coefficient of variation was computed by dividing the standard deviation of the absolute error by its mean and was found to be equal to 0.72.

Table 1. Biometrics and performance of the proposed pressure sensor (PIA manual) and the comparison to the reference (PIA automatic) for each of n = 20 patients

Patient No.	Age (years)	Weight (kg)	Height (m)	Body mass index (kg/m ²)	PIA automatic (mmHg)	PIA manual (mmHg)	Absolute error (mmHg)	Relative error (%)
1	47	120	1.65	44.08	14.90	13.43	1.47	10.92
2	19	52.4	1.56	21.53	13.10	14.18	1.08	7.61
3	19	52.4	1.56	21.53	12.00	12.69	0.69	5.41
4	47	120	1.65	44.08	21.20	18.66	2.54	13.63
5	47	120	1.65	44.08	5.30	6.72	1.42	21.09
6	47	120	1.65	44.08	3.80	5.22	1.42	27.26
7	56	66	1.62	25.15	3.70	2.24	1.46	65.27
8	36	96.3	1.68	34.12	6.70	8.21	1.51	18.38
9	36	96.3	1.68	34.12	3.40	6.72	3.32	49.38
10	36	96.3	1.68	34.12	8.90	10.45	1.55	14.81
11	25	93.6	1.6	36.56	12.50	13.43	0.93	6.94
12	25	93.6	1.6	36.56	10.00	9.70	0.30	3.08
13	25	93.6	1.6	36.56	8.20	7.46	0.74	9.88
14	25	93.6	1.6	36.56	4.30	5.22	0.92	17.69
15	55	93.4	1.7	32.32	3.30	2.99	0.31	10.55
16	55	93.4	1.7	32.32	8.10	8.96	0.86	9.55
17	55	93.4	1.7	32.32	13.20	12.69	0.51	4.05
18	55	93.4	1.7	32.32	25.00	20.90	4.10	19.64
19	55	93.4	1.7	32.32	28.00	27.61	0.39	1.41
20	55	93.4	1.7	32.32	6.70	4.48	2.22	49.63
Mean	41.00	93.73	1.65	34.35	10.62	10.60	1.39	18.31
SD	13.79	19.15	0.05	6.63	7.15	6.37	1.00	17.27

SD: standard deviation.

We found a Pearson's product-moment correlation $r = 0.9735539$, with 95% confidence interval equal to 0.9329757 and 0.9896960, and $p\text{-value} < 5.46 \times 10^{-13}$. The corresponding linear model found through linear regression analysis between the proposed pressure transducer (manual) and the reference device (automatic) for IAP was $\text{piaAutomaticmmHg} = 1.10991 * \text{piaManualmmHg} - 0.97373$, with $r^2 = 0.9449$, and $p\text{-value} < 5.46 \times 10^{-13}$. Figure 5A presents the corresponding regression results for the experiments with patients. When Bland–Altman was applied, we found that the proposed pressure transducer produced a bias of 0.17 mmHg ($p\text{-value} = 0.6661$) and a standard deviation of 1.773549 mmHg resulting in 95% limits of agreement equal to -3.302 and 3.645 mmHg. The maximum error found was equal to 4.411 mmHg. The

Bland–Altman analysis corresponding to the highest measurements from patients is shown in Figure 5B.

Finally, a summary of the performance of the disposable pressure transducer device when compared to the Kron's protocol for IAP measurements is presented for each patient in table 1 in terms of the absolute and relative errors.

Discussion

Evaluation of novel measurement instruments requires to quantify their performance through their characteristics that specify how good their measurements are¹⁸. In this study, we evaluated such characteristics for a novel disposable pressure transducer device. The relationship between the proposed

pressure transducer and the water column was found to be strongly linear through the Pearson correlation coefficient ($r = 0.9980317$ and $r = 0.9735539$, for the *in vitro* and clinical measurements, respectively). Due to the high linear correlation in both experiments, Bland–Altman analysis was employed to verify the data distribution across the measuring range. Bias was found in both experiments, the *in vitro* experiment was statistically significant (p -value = 0.0006), but the patients experiment was not (p -value = 0.6661).

In the linear regression analysis, in both experiments, the slope of the regression line (m), defining the sensibility of the instrument, was very close to 1 ($m = 0.986373$ and $m = 1.10991$). For the *in vitro* and clinical measurements, the values reflect the values measured with the proposed pressure transducer are almost the same those measured with the water column. While the y -intercept (b) was close to 0 ($b = 0.381635$ and $b = -0.97373$, for *in vitro* and clinical measurements, respectively), this indicates that the value added in the whole range inherent to the proposed disposable transducer is almost 0. Accordingly, the measurements performed with the proposed pressure transducer are almost the same than those made with the water column, which corresponds to a desirable characteristic in the novel measurement instrument. It is worth mentioning that some instruments currently available in the market for pressure measurement have reported *in vitro* experimental results with a higher zero deviation range than the one found in our pressure transducer device in this study^{16,19}, but we think they do not offer any clinical advantage.

A characteristic that can affect a measurement, or a set of measurements, is the cost of the device. Elevated costs of medical devices in health-care centers around the world, particularly in their critical areas, demand to find more affordable and efficient solutions continuously. Such solutions would allow redirecting economic resources toward innovation in infrastructure, processes, and materials indispensable to offer high-quality medical care at lower costs. As a consequence of high resources consumption, the treatment of critically ill patients in the intensive care units represents a considerable portion the health-care expenditures, which already account for 1% of the gross domestic product in the United States of America^{20,21}. In Mexico, the cost of the device of the Kron's method is between US\$ 1.71 and US\$ 2.85, while the cost of this new device to clients will be around US\$ 1.15 with the advantage of avoiding urine contamination. This

result represents approximately half of price the Kron's method. Therefore, a lower cost production of a pressure measurement device, as the one proposed in this study, as well as its portability in all acute care areas of health-care centers, especially those without monitors available, constitute a qualitative and competitive advantage concerning costs.

Conclusions

In the present work, a new novel disposable sensor was tested to measure IAP in humans. Both *in-vitro* and clinical tests were performed. Based on the provided results, we found that the proposed disposable sensor seems promising for its use in clinical applications. We consider that this and similar efforts contribute to the development of low cost solutions that would be beneficial in countries like Mexico.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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