Device for simulation of restrictive pathologies in healthy subjects with non-invasive mechanical ventilation

Dispositivo para simulación de patologías restrictivas en sujetos sanos ventilados mecánicamente de manera no invasiva

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ABSTRACT: The respiratory mechanics assessment in patients with mechanical ventilation allows to adjust the treatment in intensive care units related to the ventilatory mode and parameters of mechanical ventilator settings. However, to estimate the compliance and respiratory resistance in spontaneous ventilation is only possible with obstructive maneuvers or invasive techniques. One of the most important limitations to develop new techniques for respiratory mechanics estimation is the non-stationary characteristic of the system and the variability of parameters according to the variability of the breathing pattern. The aim of this article is to present and evaluate a device that allows artificially modify the thoracic compliance of a healthy subject, which will make possible to register in the future a useful database for the development of techniques for estimating ventilatory mechanics. The device was formed by a cuirass, a pump and a controller that allows to vary the pressure inside the cuirass, which was placed in the chest and abdomen of the volunteers to change compliance in a controlled manner. 5 volunteers participated in the performance test of the device, achieving percentage changes of 34.5 ± 9.4% respecting their resting value for a pressure of 10 cmH$_2$O and changes of 46.8 ± 5.7% for the maximum pressure of 20 cmH$_2$O. It was possible to design a device that allowed to artificially modify thoracic compliance in a comparable way for any healthy subject.

RESUMEN: La evaluación de la mecánica ventilatoria en pacientes ventilados mecánicamente permite ajustar su tratamiento en las unidades de cuidados intensivos en términos del ajuste del modo ventilatorio y sus parámetros asociados. Sin embargo, solo con maniobras obstructivas es posible estimar parámetros como la compliancia y la resistencia respiratorias en ventilación espontánea. Una de las limitaciones más importantes en el desarrollo de técnicas de estimación no obstructivas de la mecánica ventilatoria es que se trata de un sistema no estacionario y la variación de sus parámetros está sujeta a la variabilidad del patrón ventilatorio. Este artículo tiene como objetivo presentar y evaluar un dispositivo que permita modificar artificialmente la distensibilidad torácica de un sujeto sano, lo cual permitirá registrar en un futuro una base de datos útil para el desarrollo de técnicas de estimación de la mecánica ventilatoria. El dispositivo se conformó por una coraza, una bomba y un controlador que permite variar la presión al interior de la coraza, la cual fue ubicada en el pecho y abdomen de los voluntarios para cambiar la distensibilidad de manera controlada. 5 voluntarios participaron en la avaluación del dispositivo, consiguiendo cambios porcentuales de 34,5 ± 9,4% respecto a su valor en reposo para una presión de 10 cmH$_2$O y cambios de 46,8 ± 5,7% para la máxima presión de 20 cmH$_2$O. Se logró diseñar un dispositivo que permitiera modificar artificialmente la distensibilidad torácica de manera comparable para cualquier sujeto sano.

1. Introduction

In the breathing, the expiration depends on the elastic recoil forces of the pulmonary tissues associated with both lung (Cl) and chest wall (C_{cw}) compliances, forces that during inspiration must be overcome by the action of the respiratory muscles [1]. When the compliance is abnormally low, whether due to pulmonary stiffness or due to changes in the thoracic cage, more work is required to achieve a sufficient volume of air to inflate the lungs [2], which can lead to respiratory muscular dysfunction due to the increase in the work that the muscles must support after the modification of the respiratory mechanics. In advanced stages of the disease, muscular weakness leads to a reduction of lung volume and sometimes mechanical ventilation is necessary as a treatment. Therefore, accurate assessment of respiratory mechanics will contribute significantly to the treatment of mechanically ventilated patients [3, 4].

Due to the increase of respiratory diseases and related, as obesity [5–7] and thoracic injuries [8–10], to simulate and to understand the ventilatory response in the presence of restrictive thoracic loads is a current topic of study [11–13]. In order to assess the effect of restrictive thoracic loads, Chest Wall Strapping (CWS) is commonly used, which consists of applying force to the chest and abdomen with straps or girdles [11]. In the review by M. Eberlein *et al.* [11] the analogy found between patients with obesity, patients with lung transplantation and obstructive pathologies with the force exerted by CWS is presented, and the effect of this on respiratory mechanics and lung function is described, based on different studies performed on healthy subjects. In these studies, volume and air flow signals are generally obtained through pneumotachographs, plethysmographs, and spirometers, and they also estimate the transpulmonary pressure in an invasive manner using an esophageal balloon to calculate the slope of the pulmonary recoil pressure curve versus the volume, which allows to assess whether or not a reduction of respiratory compliance occurs [11]. Although, using CWS is possible to evaluate the effect of resistive loads, it is not possible to standardize the tests between one subject and another because it is not possible to guarantee the same pressure in thorax.

This article presents the development of a device that allows to apply controlled changes of pressure in the thorax and abdomen in order to simulate restrictive pathologies. In addition, to assess the performance of the device, the respiratory compliance value was calculated in healthy subjects under noninvasive mechanical ventilation applying different pressures with the device.

2. Experimentation

The design of the device used to generate changes in the compliance of the ventilatory system of healthy subjects is presented in detail below. This device, called "cuirass" consists of a chamber located on the thorax and abdomen of the volunteers and a control system that allows the adjustment of pressure inside this.

2.1 Design of the cuirass

The purpose of the cuirass is to superimpose a constant extra volume on the chest of the subject assuring that the air contained does not escape easily. The shape chosen for the cuirass corresponds to the middle section of a cylinder, which, unlike an ellipsoid, allows a greater area to be covered over the chest and abdomen. Another requirement considered for the design was the comfort for the subject, which includes the weight of the cuirass and the softness of the interface that would be in contact with the skin, all that preserving the capacity of confinement of the air.

Figure 1 shows the conceptual design of the system created in 3D CAD modeling software ANSYS SpaceClaim. The interface between the cuirass and the skin was designed with a shape such that in conjunction with the properties of the material will allow in keeping the air confined within the cuirass, therefore, when the pressure increases, a force exerted on the border is generated, increasing its adhesion to the chest. For the cuirass-skin interface material, for its hardness, flexibility and translucent color, the silicone Smooth-On: SORTA-Clear 18 was selected. On the other hand, for the dome of the cuirass, the transparent acrylic of 5 mm thickness was selected, and a double-rimmed edge in ABS was made by rapid prototyping to make the connection between the dome and the silicone border. The bond between the silicone and the ABS was made mechanically from the casting process, and thanks to the affinity between the acrylic and the ABS, a chemical bond was established by the application of methylene chloride on the surfaces in contact between the acrylic dome and the ABS rail. At the edge of ABS a pair of holes were added to each side to guide a pair of straps over the dome and around the torso that will allow the firm placement of the cuirass on the chest and abdomen of the subject.

2.2 Design of the control system

The system is composed by different pneumatic, electromechanical and electronic modules. Figure 2 shows a schematic diagram of the components. The plant that includes the cuirass and the subject, a pneumatic
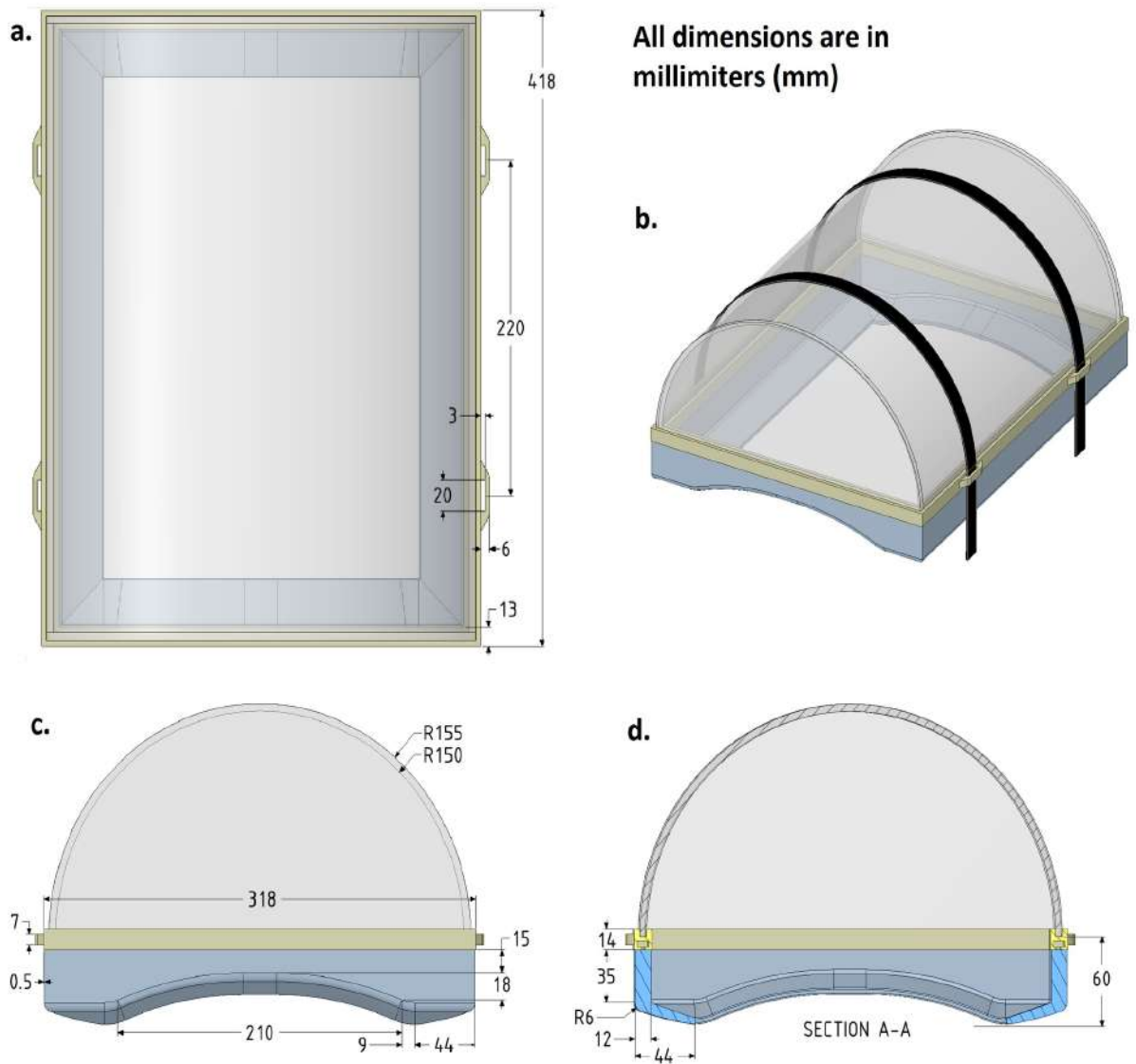
Figure 1 Views of the shape and final dimensions of the components of the cuirass. a) top view, b) three-dimensional perspective c) and d) lateral view

pump (12 V, 15 A, maximum pressure of 150 psi with an airflow of 20 L/m) that is the actuator of the system and control of the entire system that includes, a pressure sensor (MP3V5010DP, 0 to 10 Kpa) that records the pressure in the cuirass, an amplifier of the pressure signal, a FRDM-KL25Z (uC) card, a keyboard for information input and a display screen.

In this system, the variable to be controlled is the pressure inside the cuirass since of its stability depends the compliance computation. The first step was the plant identification, which was performed in open loop, filling the cuirass of air with a step function until reaching a stable operating point and recording the values of the pressure signal with one subject breathing at rest. The signal was filtered low-pass with 0.2 Hz cutoff frequency, in order to eliminate noise produced by the subject's breathing rate. With the system response data, the Matlab®pidTuner tool was used, which allowed to identify the plant and design the PID controller.

After obtaining the values of the constants Kp, Ki and Kd, corresponding to the proportional, integrative and derivative parameters of the PID controller, the control within the electronic system was implemented through by Eqs. (1), (2), (3) and (4).

$$U_n = U_{n-1} + K_0 e_n + K_1 e_{n-1} + K_2 e_{n-2} \qquad (1)$$

$$K_0 = K_p + K_i + K_d \qquad (2)$$

$$K_1 = -K_p - 2K_d \qquad (3)$$

$$K_2 = K_d \qquad (4)$$

Eq. (1) describes the output of the controller (u_n), which depends on the previous output (u_{n-1}), the current value of the error (e_n) and their previous values (e_{n-1}, e_{n-2}), which were obtained from the difference between the control target value and the sensor measurements. The coefficients (k_0, k_1, k_2) were determined from the proportional, integral and derivative parameters by Eqs (2), (3) and (4). With a sampling frequency of 10Hz, the control output, the error and the recording of the pressure signal are updated. Figure 3 shows a flowchart describing the process implemented in the microcontroller to controller action each time a new patient is instrumented with the cuirass or a different pressure is applied.

2.3 Device performance assessment

Experimental design

Following approval from the Ethics Committee of University Investigation Center (SIU by Spanish acronym) of the University of Antioquia five male subjects were enrolled in this study, age of 23±4.64 years, height of 173.8 ± 5.97 cm and weight 75.84 ± 11.96 Kg. All of them gave written informed consent. The criteria for study subjects selection were, *Inclusion:* male sex, adults and body mass index less than 30. *Exclusion:* smokers, people who have ingested alcohol 48 hours before, who use hallucinogens, people under medical treatment, with electric implanted stimulators or with thoracic trauma.

All of participants were connected to mechanical ventilator Hamilton C1 (*Hamilton Medical, Bonaduz, Switzerland*) with a noninvasive oronasal mask. The ventilator allowed the acquisition of flow, airway pressure and volume signals with a sampling frequency of 1024 Hz. During 3 minutes the subjects were ventilated in spontaneous mode, in which they were not using the device to guarantee the coupling to mechanical ventilator. After that, the cuirass was adjusted to the chest and abdomen of the subjects with a strap system, avoiding leaks as possible. Records were made with pressures of 10 and 20 cmH$_2$O during 3 minutes each.

Compliance of respiratory system

Compliance of respiratory system was calculated in both pressure levels in order to validate that pressure changes in the cuirass imply proportional compliance changes in the respiratory system. To calculate the compliance (C) the Eq. (5) was used, obtaining the variables with an occlusion maneuver at the end of inspiration (see methodology details in [14])

$$C = \frac{V_T}{P_{plat} - PEEP_t} \qquad (5)$$

Where V$_T$ is tidal volume delivered by the mechanical ventilator. PEEP$_t$ is total positive pressure at the end of expiration, which is defined as the summation of the positive end-expiratory pressure applied by the ventilator (PEEP) and the intrinsic end-expiratory pressure (PEEP$_i$) developed in patients due to dynamic hyperinflation [15] and P$_{plat}$ is the plateau pressure obtained during the occlusion maneuver.
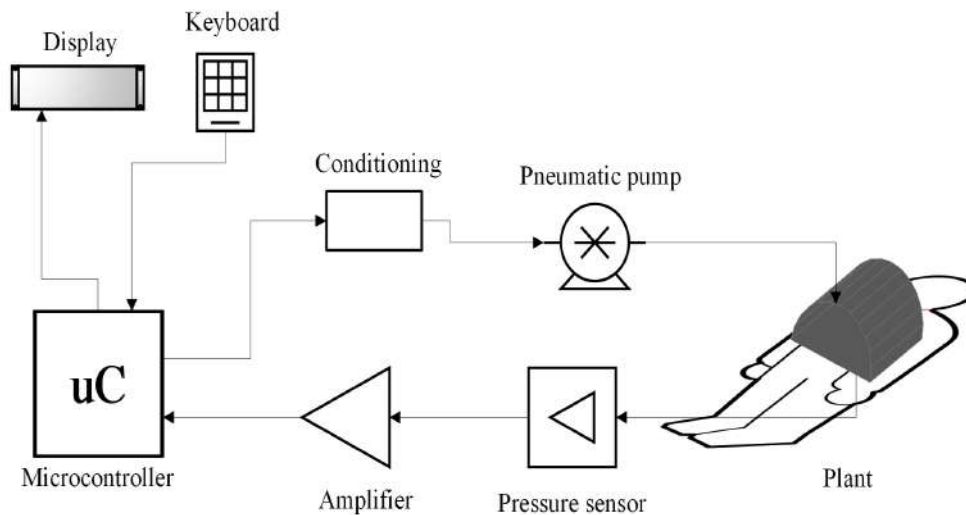
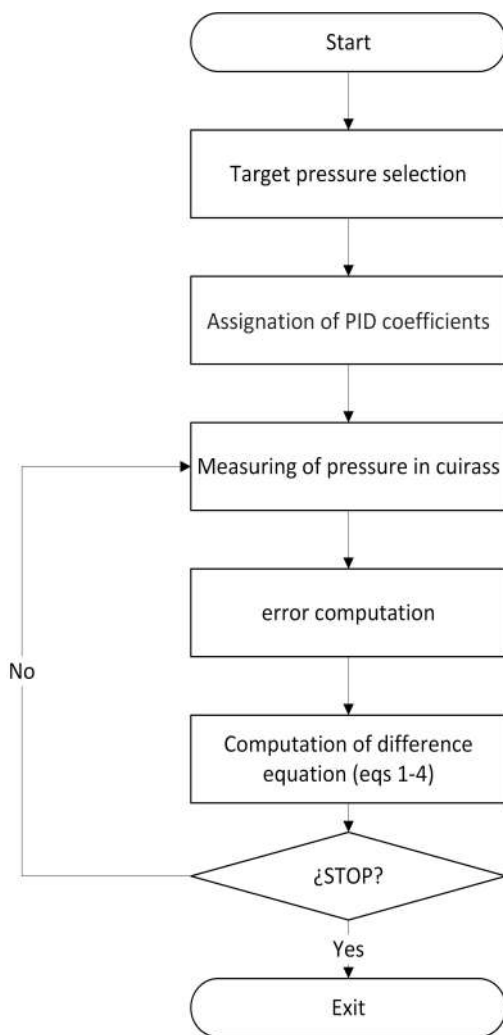**Figure 2** Schematic diagram of the control system structure

Figure 3 Flowchart describing the firmware built into the microcontroller to regulate the pressure in the cuirass

3. Results and discussion

The device for the simulation of restrictive pathologies presented in this article, consists of a control system that allows to modify and maintain a level of pressure on chest and abdomen. This pressure generates a decrease in the total compliance of the respiratory system, due to the parallel summation of the artificial compliance value created by the cuirass and the compliance of the respiratory system of the subject at rest.

The device had mainly two stages of design, the cuirass that with the subject represents the plant and the system of pressure control. Figure 4 shows the cuirass overlapped to a subject on which it had high adjustment, allowing the system to maintain the desired target pressure. However, in some cases, limitations were found in the size of the cuirass and the adjustment of the silicone to different body structures, since there were cases in which leaks due to the width of the thorax were found. These limitations could be diminished using a silicone with a greater surface area in contact with the skin achieving a tightness between the subject and the cuirass.

With the volunteer a filling of the cuirass was carried out with the maximum power of the pump, in order to identify the plant. Figure 5 shows the response to the step obtained before and after applying the filter that eliminates the noise produced by the ventilation of the subject.

With the open-loop system response and the use of the Matlab pidTuner tool, the plant was identified and the PID controller was designed with a 65.72% of fit between real response and identified plant's response. The transfer
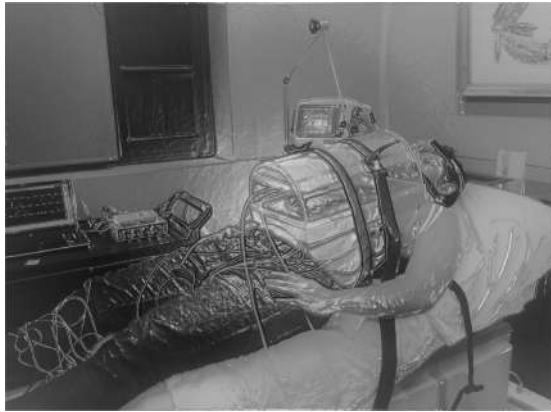
Figure 4 Photograph of the designed device superimposed over the chest and abdomen of a healthy subject under noninvasive mechanical ventilation

function of the plant is shown in Eq. (6) and the controller in Eq. 7), with Kp, Ki and Kd, equals to 0.1127, 2.054, 0.064 respectively.

$$G(s) = \frac{34.71}{(1.46s + 1)(1.30s + 1)} \qquad (6)$$

$$PID = 0.1127 + 0.064s + \frac{2.054}{s} \qquad (7)$$

In order to know the behavior and stability of the system found, the step response and the Nyquist diagram were determined to the system, which are presented in Figure 6.

As part of the evaluation of the performance of the device, two levels of pressure were exerted on the chest and abdomen of five healthy subjects, calculating for each level the total compliance of the respiratory system from Eq. 5 and comparing with the value at rest. Figure 7 presents the result obtained by the system when selecting as objective pressures 10 and 20 cmH$_2$O inside the cuirass for one subject as example of pressure control. The values of compliance for each pressure level are presented in Table 1. Taking into account that the value at rest corresponds to the compliance obtained without wearing the device and the value of 0 cmH$_2$O corresponds to the compliance obtained after adjusting the cuirass with the system of straps on the chest and abdomen of the subjects.

According to the results of Figure 6, it can be observed that the control system identified is a stable system to frequencies minor than 0.71 rad/seg. Concerning the range of unstable frequencies, the pump doesn't work to those higher frequencies, therefore, the unstable region

has not influence. In addition, the controller allowed to reduce the over-impulse of the transient response of the system. The reduction of the over-impulse can also be seen in Figure 7, not exceeding a value of 8% of the desired pressure, whereas in Figure 6 there is an over-impulse slightly greater than 50% of the desired value, which can cause problems in the ventilation of the subject.

Also, it can be observed an oscillation in both curves of the Figure 7, this oscillation is due to the breathing of the subjects, i.e. when the subjects were in an inspiration phase, the diaphragm was contracted, a vacuum in the chamber was generated and therefore a negative pressure during the rest can be observed. On the other hand, when the subjects were in an expiration phase, the diaphragm was relaxed and the pressure in the chamber raised, this is the reason why in some parts of the curves the reference pressure was overcome.

The system used to control the pressure, had a good performance, with a settling time of 6 seconds, the system guarantees a fast control pressure with a steady-state error of 2 cmH$_2$O due to the changes in the breathing of the subjects. On the other hand, the delay time was close to 0 seconds, which confirms the fast response of the system.

As can be seen in Table 1, pressure variations of the order of 10 cmH$_2$O, generate percentage changes comparable between all subjects. In the review presented by M. Eberlein *et al.* [11], are related different studies where CWS was used, identifying reductions of up to 58% in compliance values, in spite of, the same variation was not achieved for all subjects in the same experimental study. In our case, a change of 34.5 ± 9.4% was achieved at a level of 10 cmH$_2$O and a change of 46.8 ± 5.7% was achieved at the maximum pressure level (20 cmH$_2$O). In none of the cases a 10% deviation was exceeded, which suggests that the system allows to achieve a constant and relatively comparable compliance for all subjects, allowing to evaluate the ventilatory response at various levels of restriction.

4. Conclusions

In this article, we presented the design, manufacture and performance tests of a system for controlled variations of thoracic compliance, in which, unlike the systems reported in the literature, it is possible to know the change applied on the thorax. The second order structure of plant identification allowed to design and implement a controller whose performance is adjusted to the needs.

A weakness of this system is that its use is restricted to a narrow population segment and its use in obese, very thin

Figure 5 Step response of the system, in (a) the pressure obtained is presented and in (b) the filtered signal used in the identification process. A typical overshoot in systems of second order or higher can be identified
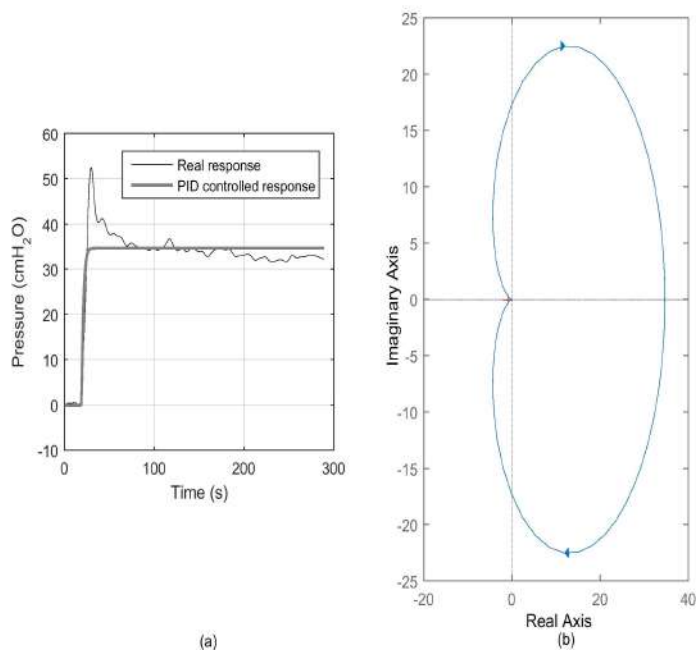
Figure 6 Identification of the plant using the pidTuner tool of Matlab. (a) the system response with the PID controller compared to the real open loop response, (b) the Nyquist diagram of the closed loop system

Table 1 Assessment of the variations of the compliance of respiratory system according to changes in the pressure in cuirass

Team sheet	Pressure	Compliance (mL/cmH$_2$O)				
		Subject 1	Subject 2	Subject 3	Subject 4	Subject 5
1	Rest	91.57	75.79	173.96	149.69	199.61
2	0 cmH$_2$O	81.55	59.50	156.04	90.95	166.05
3	10 cmH$_2$O	69.00	46.82	132.13	85.77	114.47
4	20 cmH$_2$O	56.52	42.57	84.40	73.95	99.46
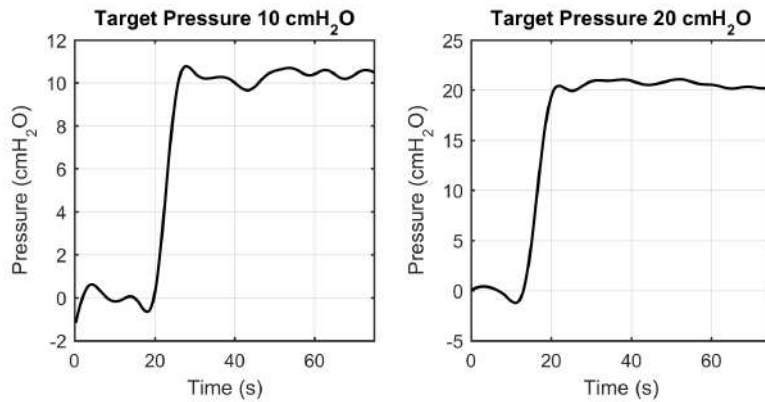
Figure 7 Pressurized system response in one volunteer with 10 and 20 cmH2O target pressure respectively. The effect of the controller on the maintenance of the pressure and on the increase of the speed of response is evidenced

or female people will require changes in dimensions or even different shapes.

The results show that this device will allow to generate artificial variations of respiratory compliance useful in the development of processing techniques that in the future will be able to estimate the pulmonary compliance of patients with restrictive and obstructive diseases.

5. References

[1] J. H. Bates, *Lung Mechanics. An Inverse Modeling Approach*, 1 st ed. New York, USA: Cambridge University Press, 2009.

[2] J. W. Kreit, "Mecánica del Sistema Respiratorio," in *Tratado de medicina crítica y terapia intensiva*, 4th ed., W. C. Schoemaker (ed). Madrid, España: Médica Panamericana, 2002, pp. 1164-1176.

[3] T. Troosters, R. Gosselink, and M. Decramer, "Respiratory muscle assessment," in *Lung Function Testing: European Respiratory Monograph*, vol.10, R. Gosselink and H. Stam (ed). Wakefield, UK: European Respiratory Society Journals, 2005, pp. 57-71.

[4] A. Carlucci, L. Pisani, P. Ceriana, A. Malovini, and S. Nava, "Patient-ventilator asynchronies: may the respiratory mechanics play a role?," *Critical Care*, vol. 17, no. 2, pp. R54, 2013.

[5] A. Lomas and L. Jara, "Manejo respiratorio perioperatorio del paciente obeso," *Rev. Esp. Patol. Torac.*, vol. 25, no. 3, pp. 201-208, 2013.

[6] Ministerio de Salud y Protección Social, *Análisis de Situación de Salud (ASIS)*, Ministerio de Salud y Protección Social, Bogotá, Colombia, 2016.

[7] OMS: Organización mundial de la salud, *Obesidad y Sobrepeso*, 2015. [Online]. Available: `http://www.who.int/mediacentre/factsheets/fs311/es/`. Accessed on: Mar. 28, 2017.

[8] C. E. Battle, H. Hutchings, and P. A. Evans, "Risk factors that predict mortality in patients with blunt chest wall trauma: A systematic review and meta-analysis," *Injury*, vol. 43, no. 1, pp. 8-17, 2012.

[9] M. F. Undirraga, D. P. Rodríguez, and P. D. Lazo, "Trauma de tórax," *Rev. Médica Clínica Las Condes*, vol. 22, no. 5, pp. 617-622, 2011.

[10] J. D. Charry *et al.*, "Índice de shock como factor predictor de mortalidad en el paciente con trauma penetrante de tórax," *Rev. Colomb. Cirugía*, vol. 30, pp. 24-28, 2015.

[11] M. Eberlein, G. A. Schmidt, and R. G. Brower, "Chest Wall Strapping. An Old Physiology Experiment with New Relevance to Small Airways Diseases," *Ann. Am. Thorac. Soc.*, vol. 11, no. 8, pp. 1258-1266, 2014.

[12] D. G. Chapman, N. Berend, K. R. Horlyck, G. G. King, and C. M. Salome, "Does increased baseline ventilation heterogeneity following chest wall strapping predispose to airway hyperresponsiveness?," *J. Appl. Physiol.*, vol. 113, no. 1, pp. 25-30, 2012.

[13] C. T. Mendonca, M. R. Schaeffer, P. Riley, and D. Jensen, "Physiological mechanisms of dyspnea during exercise with external thoracic restriction: role of increased neural respiratory drive," *J. Appl. Physiol.*, vol. 116, no. 5, pp. 570-581, 2014.

[14] I. C. Muñoz and A. M. Hernández, "Noninvasive approach to estimate ventilatory mechanics in spontaneous breathing with different PEEP and pressure support values: validation with mechanical simulation," in *VII Latin American Congress on Biomedical Engineering CLAIB*, Bucaramanga, Colombia, 2016, pp. 241-244.

[15] E. García, L. Amado, and G. M. Albaiceta, "Monitorization of respiratory mechanics in the ventilated patient," *Med. Intensiva (English Ed.)*, vol. 38, no. 1, pp. 49-55, 2014.