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Analysis of a Dielectric EAP as Smart Component for a Neonatal Respiratory Simulator

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***Abstract* — Nowadays, respiratory syndrome represents the most common neonatal pathology. Nevertheless, being respiratory assistance in newborns a great challenge for neonatologists and nurses, use of simulation-based training is quickly becoming a valid meaning of clinical education for an optimal therapy outcome. Commercially available simulators, are, however, not able to represent complex breathing patterns and to evaluate specific alterations. The purpose of this work has been to develop a smart, lightweight, compliant system with variable rigidity able to replicate the anatomical behavior of the neonatal lung, with the final aim to integrate such system into an innovative mechatronic simulator device. A smart material based-system has been proposed and validated: Dielectric Electro Active Polymers (DEAP), coupled to a purposely shaped silicone camera, has been investigated as active element for a compliance change simulator able to replicate both physiological and pathological lung properties. Two different tests have been performed by using a bi-components camera (silicone shape coupled to PolyPower film) both as an isolated system and connected to an infant ventilator. By means of a pressure sensor held on the silicon structure, pressure values have been collected and compared for active and passive PolyPower working configuration. The obtained results confirm a slight pressure decrease in active configuration, that is in agreement with the film stiffness reduction under activation and demonstrates the real potentiality of DEAP for active volume changing of the proposed system.**

I. Introduction

A) Motivations

Respiratory function is a fundamental topic in neonatology: moving from uterus to external post-natal environment requires heart and lungs correctly working since placenta gives up. Respiratory Distress Syndrome (RDS) is one of the most common neonatal pathologies (RDS occurs in about 50% of preterm infants born before than 30 weeks of gestational age) and mechanical ventilation has become the standard care in preterm infants management [1]. However, for the first time in 1967, Northway described a group of newborns suffering from BronchoPulmonary Dysplasia (BPD), which is a chronic lung disorder most common among children who were born prematurely, with low birth-weights and who received prolonged mechanical ventilation and oxygen supply to treat RDS [2]. To date, we know that BPD represents the most common severe complication in preterm infants: about 35% of neonates with a birth weight between 500 and 750 grams and 25% with a birth weight between 750 and 1000 grams develop chronic lung disease [3]. Moreover, this complication predisposes to recurrent infections, pulmonary hypertension with high mortality and poor quality of life. Reduction of the incidence and severity of BPD may be possible through a reduction of the amount of injury induced by respiratory support interventions [4]. However, nowadays, respiratory assistance in newborns remains a great challenge for neonatologists and nurses due to high inter-patient variability and the lack of specific therapeutic means: the same equipment for mechanical ventilation is used on patients affected by different pathologies and disorders, with a limited ability to tune the ventilation effect onto the different patient conditions and the different respiration functionalities.

B) The need for a neonatal respiratory simulator

Based on the above considerations, specific training of physicians and nurses on newborn ventilation is crucial for an optimal therapy outcome. Use of simulation-based training is quickly becoming a source of experiential learning in clinical education. It provides to practice safe and effective procedures and to acquire clinical skills needed for the patient care. The most common systems for medical training are passive simulators consisting in tubes, resistances and air sacs with expandable volumes, e.g. Training-test Lung Adult/Infant® (Michigan Instrument), Accu Lung® (Fluke Biomedical), Smart Lung® (Imtmedical). Such devices allow the operator to set airway resistance, pulmonary compliances and volumes, but they are unable to evaluate the dynamic interaction between the simulated air-paths and the mechanical ventilators. On the other hand, active simulators often allow to simulate only a limited set of clinical situations, due to their architecture. Usually they consist of rigid containers with plungers or compliant rubber devices equipped with springs and they are too bulky to be inserted into small phantoms. IngMar Adult/Pediatric Lung Model® and IngMar ASL 5000 Adult/Neonatal Breathing Simulator® are some examples of these devices. In addition, currently available realistic infant puppet-like simulators, such as the SimnewB (Laerdal) and the Newborn HAL®S3010 (Gaumard), replicate several vital functions and active breathing, oral/nasal intubation as well. They also allow the operator to control respiration rate and

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depth, and to observe chest rise during breathing. However, such simulators, where only a single resistance and compliance value can be set, are not able to represent complex breathing patterns and to evaluate specific alterations.

In this framework, an innovative neonatal respiratory simulator, which could be easily used for training courses to specialized staff, is necessary. An ideal simulation system, replicating the complex nature of physiological systems, should have also an anatomical resemblance for emphasizing the psychological involvement of the operator during training. Functionality, reliability and anatomical features represent the most important requirements for such simulator. The purpose of this work is to develop a smart, lightweight, compliant system with variable rigidity able to replicate the anatomical behavior of the neonatal lung, with the final aim to integrate such system into an innovative mechatronic simulator device. It is worthy mentioning that for better mimicking the physiology of the lung, the operator could be able to change the system rigidity, thus the compliance of the embedded structure, during a simulated training task. Physiological and pathological lung conditions can be simulated with different values of system compliance. The methodology investigated here exploits the DEAP (Dielectric Electro Active Polymers) technology for simulating an active element able to change the system rigidity under different ventilation and pressure conditions.

II. Materials and Methods

As regards the concept of a smart material for realizing a miniaturized simulator able to change its intrinsic compliance and then replicate the physiological and pathological behavior of a neonatal lung, we propose here a double component system including a silicone camera coupled with a commercially available DEAP material. EAP (Electro Active Polymer) technology has been known for many years; EAPs are polymers that exhibit a change in size or shape when stimulated by an electric field. They can have several configurations and composition, but they are generally divided in two main classes: Dielectric (DEAP) and Ionic. DEAPs are materials in which actuation is generated by electrostatic forces between two electrodes which squeeze the polymer arranged in between, changing the polymer rigidity (Fig. 1). DEAPs are capable of very high strains and are basically capacitors that change capacitance when a voltage is applied, by allowing the polymer to compress in thickness and expand in area due to the electric field. They are characterized by a large actuation voltage (several thousand Volts) but a very low electric power consumption [5-7].

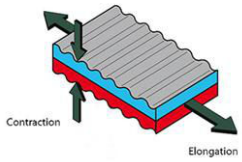

Figure 1. PolyPower DEAP technology.

Being the ultimate goal of this work a preliminary investigation of using DEAP as active element for a neonatal simulator, a commercially available DEAP material (PolyPower, Danfoss PolyPower A/S, Denmark) has been selected. PolyPower is a silicone (polydimethylsiloxane - PDMS) dielectric material with a special corrugated surface and very thin layer of metallic electrode on top of it (referred to as single layer film material). The single layer PolyPower film can be laminated into various multilayer structures: the standard structure used here is the back-to-back lamination, where two rolls of single layer film with metal electrodes are laminated together with flat back surface of first film against flat back surface of second film. The basic working principle is the same as for any other DEAP, however, due to unidirectional deformation, the elongation in the compliant direction of the PolyPower DEAP film, as shown on Fig. 1, is significantly higher than where alternative designs where the material elongates in two directions. Properties for PolyPower film are reported in Table I.

TABLE I. PolyPower properties

Attribute	Unit Of Measure	Demonstrated Performance	Expected Performance
Elongation	% at 2500V	3%	5%
Load capability (sq area)	N/cm^2 at 2500V & 5% elongation	3	5
Response time	msec	< 10	< 10

Due to its intrinsic features, PolyPower is thin and fragile, thus it has been coupled with a silicone structure that functions as retaining shell for the PolyPower film and guarantees the working stability of the system. The silicone structure, that should replicate the infant lung, has been made by moulding procedure from a dedicated casting and two different shapes (sphere and cylinder) have been tested (see Fig. 2). The spherical shape represents a simple solution for the production methods and in the same time it easily mimics the anatomical structure of a human lung. However, as described below, several working limitations led us to change from spherical to cylindrical one. Finally, the volume of the obtained structure has been chosen taking into consideration that, from literature, the residual volume of an infant affected by neonatal respiratory distress syndrome is 25ml and it represents the worst working condition for the clinical simulation. Based on this, diameters of cylindrical and spherical structure are 28mm and 36mm respectively.

In order to evaluate and measure the variation of the realized cameras stiffness due to the PoliPower effect, a pressure sensor (piezoresistive silicon pressure sensor - MS1451, Measurement Specialties, Hampton, USA) with accuracy of 0.4% FS has been held on the silicon structure and pressure values have been collected. Two different tests have been performed:

- the two silicone cameras have been isolated from the external environment and pressure values have been reported both for the bi-component camera (silicone & PolyPower) in active and passive conditions (PolyPower actuator modality on and off);

- the same camera devices have been connected with an infant ventilator (Bear Cub® 750 Ventilators, Thermo Electron Companies) in order to evaluate the system performances in real working conditions.

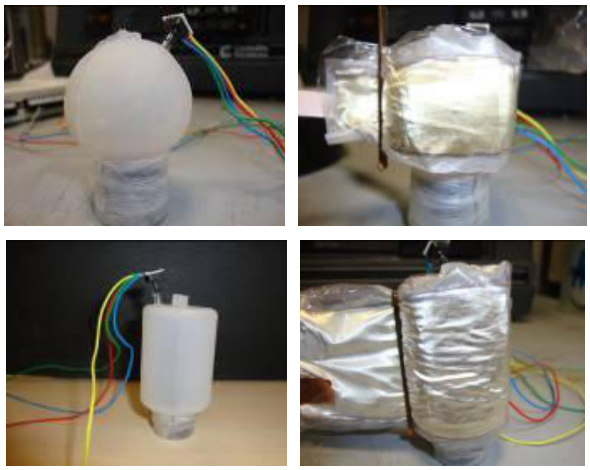

Figure 2. Spherical (up) and cylindrical (bottom) silicone structure without (on the left) and coupled (on the right) with PolyPower film. PolyPower film is enclosed on the silicone camera and fixed on it by means of a traditional spring clip.

III. Results and Discussions

As preliminary results, the characterization of the PolyPower film by means of an electromagnetic tracking system (Aurora System, Northern Digital Inc) confirms the 3% of elongation along the compliant direction of the film, when a voltage of 2500 V is applied. Based on a preliminary mechanical analysis of the system performances, stress-strain curves have been generated by means of a Instron machine (Instron 4464). The obtained results verify a decreasing trend of the film rigidity with the increase of supplied voltage. The slop values of the rigidity curves, calculated in the first section of the line where the deformation range is smaller than 5%, that represents the limit of linearity indicated by PolyPower producers, gradually decrease from 0.7MPa to 0.55MPa in a voltage range of 0-2500V (Fig. 3). The standard deviation of strain data is about 0.001, in the 0-5% of deformation range (by using 5 different test results for each activation level).

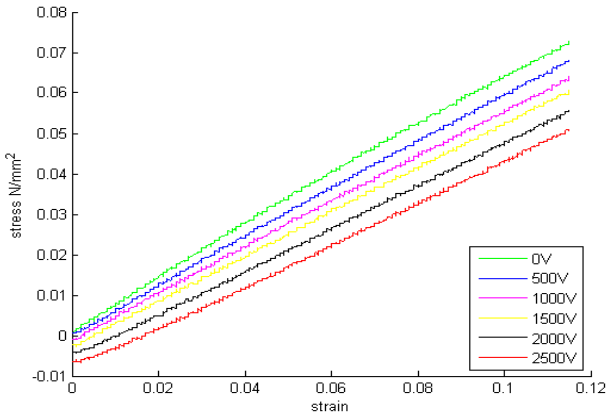

Figure 3. Stress-strain curves of PolyPower film under different voltage conditions (from 0-2500V). The offset value for high voltage is due to the lack of preload during the test.

By using the pressure sensor mounted on the silicone structure with the sensitive area inside the camera, the pressure values have been derived.

A. *PolyPower actuator in an isolated camera*

As described above, for validating the use of DEAP material as smart actuator in an active neonatal simulator, an isolated camera has been realized and pressure values have been collected and compared for active and passive PolyPower working configuration.

TABLE II. Pressure values in the Spherical Isolated camera. S=Silicone camera, S+PP=Silicone camera coupled with PolyPower film. T1..3=Test1...Test3

Pressure (cmH_2O)	**T1**	**T2**	**T3**
S	0.483	0.483	0.483
S+PP passive configuration	2.939	3.883	3.761
S+PP active* configuration	2.925	3.843	3.667

* Activation voltage of 2500 V

The activation phase of the PolyPower film in the bi-components system (S+PP) induces a slight pressure decrease, that is in line with the revealed film rigidity reduction and demonstrates the real potentiality of the DEAP material for active volume changing of the isolated camera. The limited decrease of pressure is related to the small dimensions of the polymeric film, being the camera system designed for neonatal simulator, and the low repeatability of the experimental set-up. In fact, for fixing the PolyPower film around the silicone camera, a traditional spring clip has been used, but it could be a structural limits for the PolyPower elongation: the spring clip grasped on the film could represent an obstacle for the film deformation. The same test, by using the cylindrical camera instead of the spherical one, confirmed the decreasing trend of the pressure values, but the difference between the active working condition and the passive one is larger. Such result is due to the better fit between the PolyPower film and the silicone camera shape, that allows a larger camera deformation and increases the set-up repeatability.

TABLE III. Pressure values in the Cylindrical Isolated camera. S=Silicone camera, S+PP=Silicone camera coupled with PolyPower film. T1..3=Test1...Test3

Pressure (cmH_2O)	**T1**	**T2**	**T3**
S	2.911	2.911	2.911
S+PP passive configuration	3.222	3.114	3.110
S+PP active* configuration	2.976	2.974	3.095

* Activation voltage of 2500 V

B. *Validation test with an infant ventilator*

Based on the previous results, the proposed system (silicone camera and PolyPower film, coupled together with a spring clip) has been coupled with a infant ventilator with the final aim to validate the system behavior in a real

simulated working condition. By exploiting the assist control (AC) ventilation modality, the respiratory features, e.g. frequency, Positive End-Expiratory Pressure (PEEP), inspiratory and basal flow have been set equal to 25 breaths per minute, 4 cmH_2O, 7 l/min and 4 l/min respectively. Finally, the pressure values have been carried out varying the Peak Inspiratory Pressure (PIP- the highest level of pressure applied to the lungs during inhalation) in the range 15-25 cmH_2O, that represents a realistic working condition for an infant ventilator.

TABLE IV. PRESSURE VALUES IN THE SPHERICAL CAMERA COUPLED WITH AN INFANT VENTILATOR. PIP= PEAK INSPIRATORY PRESSURE. PP=POLYPOWER. T1..3=TEST1...TEST3

Pressure (cmH_2O)	**T1**	**T2**	**T3**
PIP=15 PP passive configuration	15.768	15.324	15.571
PIP=15 PP active* configuration	15.430	15.091	15.505
PIP=20 PP passive configuration	18.584	18.732	18.648
PIP=20 PP active* configuration	18.337	18.535	17.902
PIP=25 PP passive configuration	23.870	24.405	23.474
PIP=25 PP active* configuration	24.067	23.711	24.214

* Activation voltage of 2500 V

The obtained results (Table IV) confirm the same trend of the previous test for PIP of 15 and 20 cmH_2O, thus indicating film rigidity reduction and pressure values decrease. However, this pressure reduction trend is not maintained with a fixed PIP of 25 cmH_2O. As described above, the spherical shape is easily to manage, but, in the same time, it is not easy to cover all the structure with the PolyPower film.

For overcoming this drawback, the same test has been performed with a cylindrical camera coupled with the same ventilator. The obtained results (Table V) confirm rigidity decrease and consequently pressure values reduction for 15, 20 and 25 cmH_2O.

TABLE V. PRESSURE VALUES IN THE CYLINDRICAL CAMERA COUPLED WITH AN INFANT VENTILATOR. PIP= PEAK INSPIRATORY PRESSURE. PP=POLYPOWER. T1..3=TEST1...TEST3

Pressure (cmH_2O)	**T1**	**T2**	**T3**
PIP=15 PP passive configuration	17.785	17.843	18.258
PIP=15 PP active* configuration	17.617	17.744	18.008
PIP=20 PP passive configuration	22.712	22.882	22.726
PIP=20 PP active* configuration	22.035	22.374	22.585
PIP=25 PP passive configuration	26.435	26.420	26.672
PIP=25 PP active* configuration	26.079	26.039	26.452

* Activation voltage of 2500 V

IV. CONCLUSION

Starting from the concept to design an innovative miniaturized infant simulator for respiratory care of preterm newborn, a smart material based-system has been proposed and validated. DEAP, coupled to a purposely shaped silicone camera, has been investigated as active element for a compliance change simulator able to simulate both physiological and pathological lung properties. In principle, DEAP holds great potential for widespread application fields and confirms here the possibility to realize a smart system for clinical simulation and training.

Two different tests have been performed by using a bi-components camera (silicone shape coupled to PolyPower film) both as an isolated system and connected to an infant ventilator. The obtained results confirm a slight pressure decrease in active configuration, that is in agreement with the film stiffness reduction under activation and demonstrates the real potentiality of DEAP for active volume changing of the proposed system. This quite low pressure variation results compatible with the varying compliance of neonatal lung to be reproduced in the active simulator (compliance varies from 4 to 1 ml/cmH_2O in healthy full-term newborn and infant affected by respiratory distress syndrome respectively). Additional investigations and a deeper analysis of the system potentialities are mandatory for realizing a reliable simulator device. The low system reproducibility, as described above, is due to the low stability of the system, but based on the promising results obtained here, further optimization is planned in the next future.

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