Mitral valve repair based on physical characterization of coaptation forces

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Conflict of interest statement

- Daniel Grinberg
  - No conflict of interest
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- Alexis BRUHAT
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- Anthony COSTA
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meeting presentation**:** mitral conclave

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World count: 734

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Abbreviations :

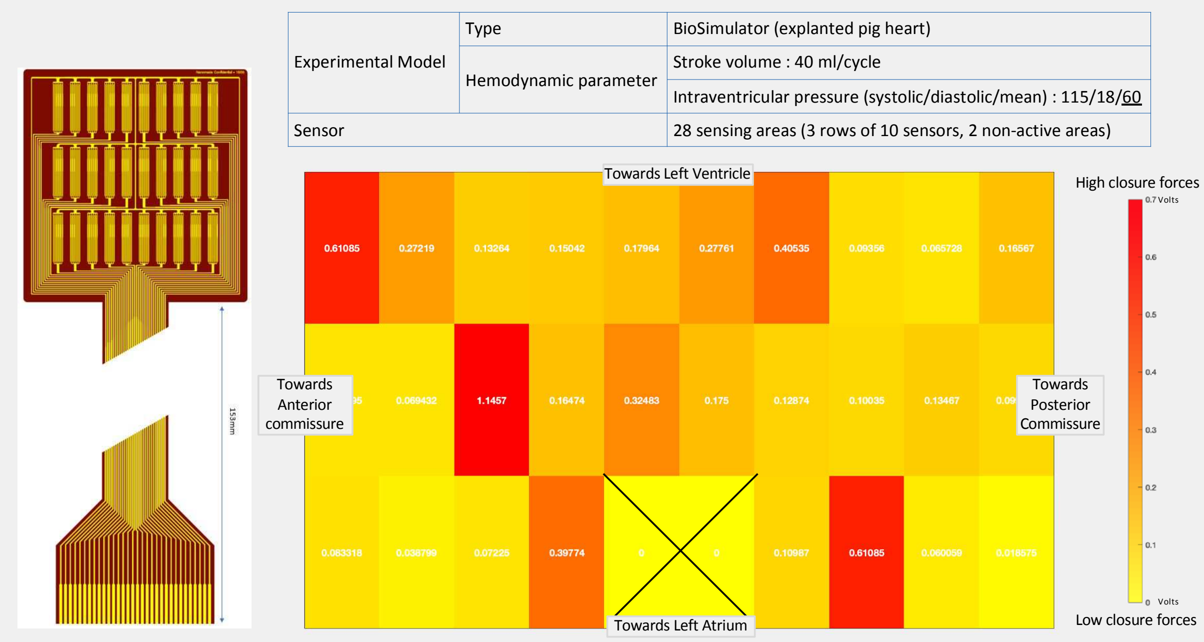
MVr - mitral valve repair
PMR - primary mitral regurgitation
MR- Mitral Regurgitation
FFT - Fast Fourier Transform

CENTRAL MESSAGE

Technological breakthrough allows surgeons to obtain a precise coaptation characterization of the mitral valve (measurement of surface and mapping of coaptation forces), in order to assist surgeons during mitral valve repair.

CENTRAL PICTURE (GRAPHICAL ABSTRACT)

Measurement of coaptation forces and mapping of these forces in *ex vivo* beating hearts



TEXT:

Open heart mitral valve repair (MVr) is the gold standard treatment for severe primary mitral regurgitation (PMR). Several approaches have been described to intraoperatively mimic ventricular systole like the “saline test” and the “ink test”[1]. Such methods provide only a morphologic and approximate assessment. Thus, MVr success today still primarily depends on the expertise of the individual surgeon. Consequently, major heterogeneities are observed globally on the rate of MVr repair, surgical techniques, and outcomes. In Western countries, only two in three PMR patients benefit from MVr, while the others are treated with an implanted prosthesis that is associated with worse outcomes[2]. Furthermore, depending on the series, up to 25 percent of patients develop recurrent Mitral Regurgitation (MR) after a MVr[3]. Among these patients a large majority have no MR at the discharge, highlighting the insufficient power of the echocardiography to predict mid-term repair failure[4]. New tools are required to better understand the coaptation behavior and to assist surgeons in order to increase the repair rate and long-term repair success.

The restoration of a large surface of coaptation is one of the key principles of mitral reconstruction and a high coaptation height is correlated with lower postoperative residual MR. In a previous work, we developed an innovative technique to measure the tension applied on chordae during transapical beating-heart implantations of neochordae[5]. Our results revealed a decrease in subvalvular apparatus stress when strong and homogeneous coaptation was restored. Up to now, coaptation forces have been poorly characterized due to challenges in materials and device design (e.g., compactness, flexibility, sensing accuracy), as well as its deployment in complex clinical environments (e.g., beating heart, coaptation zone.

In the present work, we have developed a device enabling precise physical and quantitative characterization of the coaptation (e.g., mapping coaptation forces [perpendicular forces, one leaflet against the other] and measurement of coaptation surface).

The tool is composed of three principal parts:

- A piezoresistive pressure sensor including 28 strain gages made from resistive ink printed on a flexible polyimide substrate. Its design (total area of 5.8 cm^2 and 150 mm thick comprised of 28 individual 2mm^2 sensing elements) provides easy insertion between the two leaflets without changing the natural 3-dimensional coaptation shape, due to the low thickness and stiffness of the sensing element. During the measurement period the sensor sits in the mitral valve orifice and
- A support device (holder) enables facile maintenance of the sensor in the mitral valve and removal after measurement.
- An acquisition system leads to record and analyze data in real-time. The time domain of 28 signals is then post-treated based a Fast Fourier Transform (FFT). Frequency analysis of all data is performed in different conditions of mitral valves (i.e. normal or prolapse).

The device is specifically designed for application to MVr procedures. It is inserted inside of the heart through the left atriotomy (repair access) during the procedure and positioned between the two leaflets. The device can be kept in the heart when the atriotomy is closed making continuous force measurements in a beating-heart state possible, and removed before the closure of chest without risk of air embolism.

The prototype has been iteratively tested on three porcine *ex vivo* total heart models activated by an apical pump (e.g. BioSimulator, Figure 1, video). Initial results achieved precise surface mapping of mitral coaptation forces (Figure 2). The coaptation signal was first recorded in a normal valve and then in an induced prolapse-state valve after creation of a posterior central prolapse (section of marginal chordae). We demonstrate that the forces recorded were notably higher in the normal valve compared to the prolapsed one under similar hemodynamic conditions (Figure 3). Our tests also demonstrated the limitations of piezoresistive technology (noise due to bending, loss of calibration), and that our chosen BioSimulator is not an ideal testing model for this measurement since the pump ejection generated a functional MR due to annular dilatation.

A provisional patent based on our novel method has been filed. Further development of the device is in progress as we move our invention toward clinical trials: selection of optimal sensing technologies, optimization of force sensitivity, substrate flexibility and biocompatibility. In the near future, this technique could be useful to assist surgeons during MVr while providing real-time objective measurements in support of the conventional intraoperative morphological assessment. Coaptation forces characterization could also be useful to improve our understanding of physical changes occurring during and after MVr.

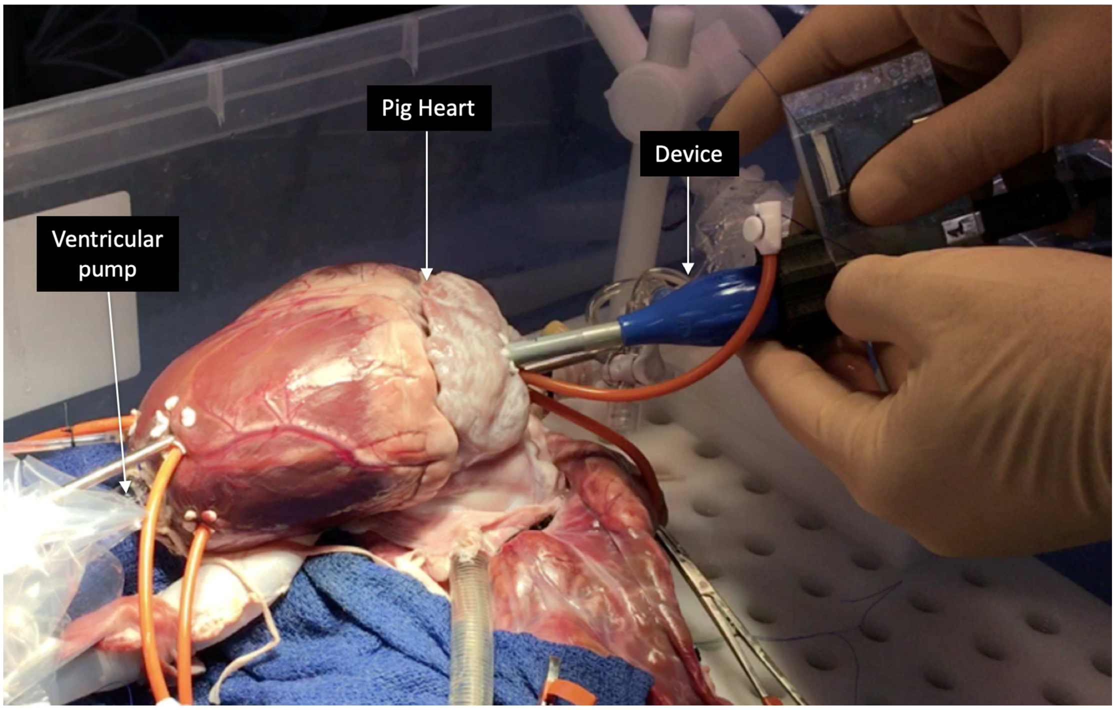
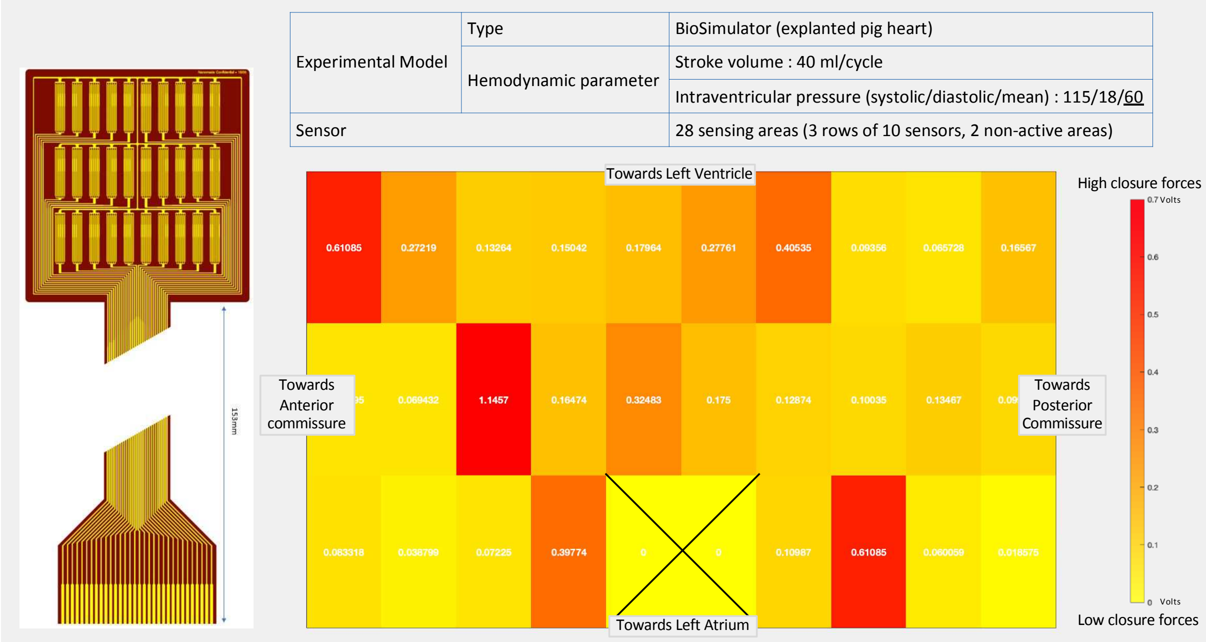


Figure 1- Testing on *ex vivo* beating heart model. The surgeon is holding the device, that was introduced through the posterior wall of the left atrium into the mitral valve. This *ex vivo* model is activated by an apical pump.



Experimental Model	Type	BioSimulator (explanted pig heart)
	Hemodynamic parameter	Stroke volume : 40 ml/cycle
		Intraventricular pressure (systolic/diastolic/mean) : 115/18/60
Sensor		28 sensing areas (3 rows of 10 sensors, 2 non-active areas)

Figure 2 – Design of the sensors used (left), and graphical render of mitral coaptation forces mapping (right). Red colors correspond to high forces. Every colored rectangle corresponds to a sensing areal of 1x3mm. This mapping provides a 2-dimensional representation of pressure repartition.

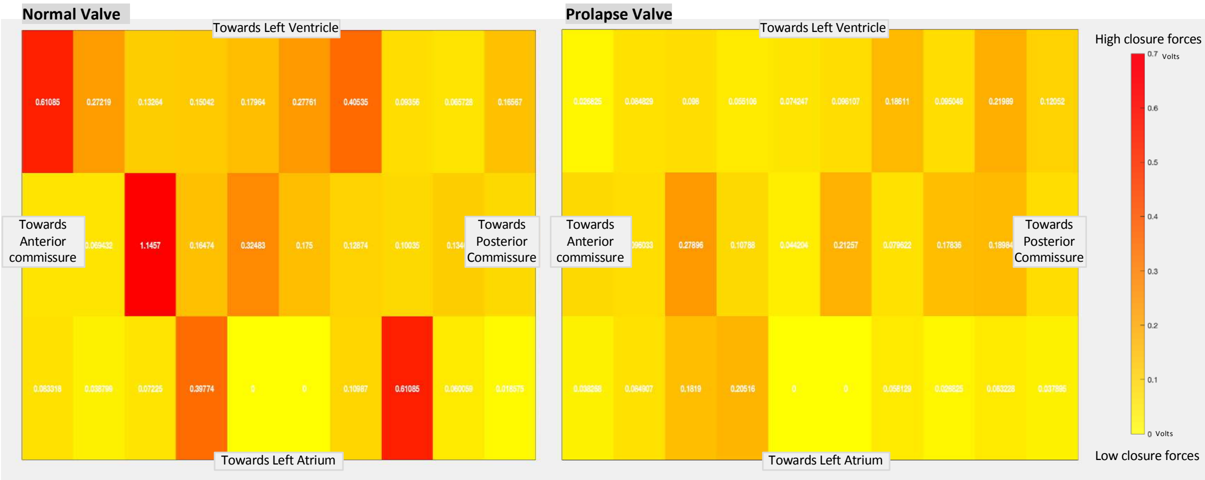


Figure 3- The mapping of forces was obtained in a normal valve (left) and in a prolapsed valve (right).
A simple visual observation recalls higher coaptation forces in a normal valve than in a pathological one.

Caption for Video : render of mitral coaptation forces mapping in “BioSimulator” model. Red colors correspond to high forces. Every colored rectangle corresponds to a sensing area.

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KEYWORDS:

Mitral valve repare, Coaptation surface, beating heat, sensor MAPPING device, force measurments

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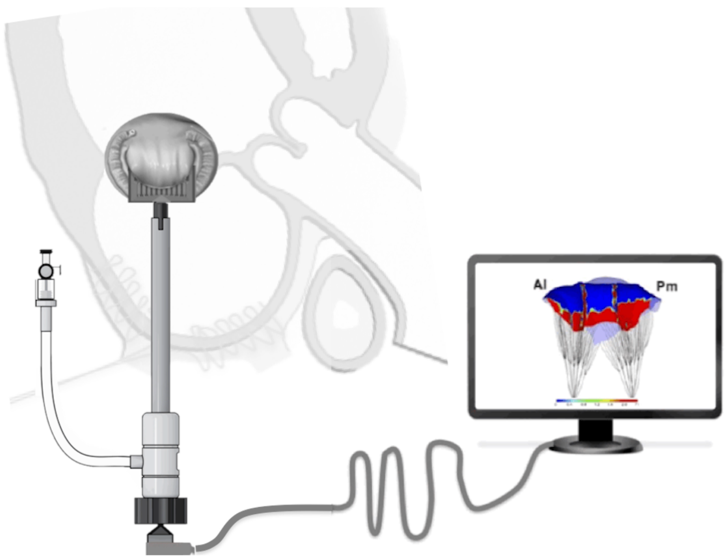

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