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ENDOCOM : Abdominal Aortic Aneurysm test bench for in vitro simulation

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Abstract—**An abdominal aortic aneurysm (AAA) is a dilatation of the aorta at the abdominal level, whose rupture is a life threatening complication. Recent treatment procedures of AAA consists in endovascular treatment with covered stent grafts. Despite improving design of these devices, this treatment is still associated with close to 25% of failure, due to persisting pressure into the excluded aneurysmal sac. The follow-up becomes thus crucial and demands frequent examinations (CT-scan, IRM) which are not so liable given the complications. In order to evaluate the post-operative period of an AAA treatment, we designed a communicative stent, comprising of an integrated pressure sensor. This paper presents the conception of a communicative sensor, the elaboration of a numerical model, and the development of an experimental testbench reproducing the aortic flux across an AAA and allowing the optimization and validation of the measurement principle.**

I. INTRODUCTION

AAA is a pathology of the aortic wall, responsible for a localized and permanent dilatation of the arterial lumen most often located between the kidney artery and the aorto-iliac bifurcation. Over 3 million people in the world are nowadays subject to an abdominal aortic aneurysm (AAA) illness. It is the third cause of death among people over 60 years of age. The mortality due to its rupture, for treated or untreated, still remains high, in the neighborhood of 80% of ruptured cases. It becomes obvious that aneurysms must be treated in advance in order to prevent rupture.

Endovascular treatment of the pathology consists in introducing a covered stent in a peripheral artery which can unfold into the aneurysmal sac excluding the aneurysm from the blood flow. The great interest of the method is its mini-invasive character coupled to the absence of aortic clampage. It is thus particularly recommended for patients presenting a high surgical risk. However, the stent is not always perfectly waterproof meaning that blood leaks may occur between the arotic wall and the stent. Subsequently, the aneurysmal sac remains under pressure and the possibility of rupture persists. In order to detect possible leaks, or endotension phenomena (secondary rupture even without detection of leaks), the patient is regulary submitted to medical imaging examinations (IRM and CT scan).

Within this scope, measuring the pressure into an aneurysmal sac turns out to be of great challenge for medical scientists. A remotely controlled electronic system embedded into the aneurysmal sac could significantly improve the diagnosis and intensify the follow-up without being aggressive for the patient. This promising electronic device is the main objective of the ENDOCOM project, which lead to a patent license (1).

Beyond medical purposes, ENDOCOM also addresses the questions concerning the pressure field evolution into an excluded aneurysmal sac and extends knowledge on the non so well known phenomenon of the endotension (2).

II. ENDOCOM

The ENDOCOM project deals with design of a communicative stent dedicated to the post-operative follow-up of the AAA (Fig. 1). The stent have an integrated electronic system composed of a pressure transductor and a communication architecture. This remotely system allows for a regular follow-up of the pressure into the aneurysmal sac giving rise to a reliable and cost effective alternative to the present medical imaging techniques. The operational architecture of the system corresponds to an RFID tag working at 13,56 MHz, provided with a pressure sensor. This architecture is described in details elsewhere (3).

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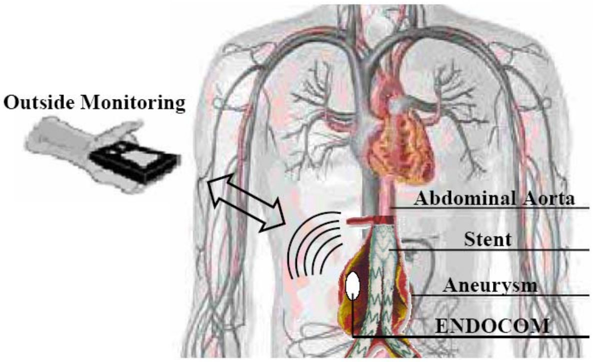

Fig. 1. Anatomical Position of the ENDOCOM system

The intrinsic aneurysm features - such as variable geometry or the changing nature of the blood clot - and the distribution of the hypothetical leaks into the aneurysmal sac suggest an inhomogeneous distribution of the pressure field within the excluded aneurysmal sac. Consequently, the sensor fails to detect a very localized and confined leak if it is not optimally positioned. For this reason, on top of the conception-basis of the project lies the parallel development of an electronic system and a numerical simulator. The latter aims to determine the optimum position of the sensor in the aneurysmal sac depending on the geometrical characteristics of the patient's aneurysm. In order to verify if the hypothesis is correct, an in vitro experimental protocol has been set up.

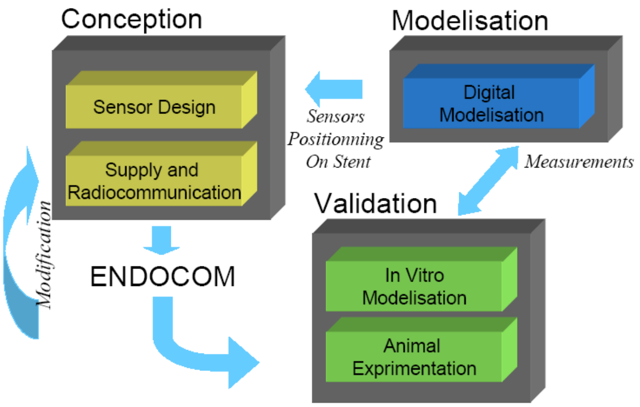

Fig. 2. Conception Flow

III. AAA TEST BENCH FOR IN VITRO SIMULATION

Validating the measuring process and the modelisation bases requires the construction of an experimental test bench as close to reality as possible.

Numerous works on this type of in vitro simulation have already been carried out (4,5,6,7,8,9). However, the need to measure the pressure profile as well as the blood flow into the aneurysm in order to establish the numerical model -a powerful simualtion tool - lead us to develop our own instrumental testbench.

The principal novelty of this experimental protocol consists in the possibility to measure the pressure field variation inside a compliant aneurysm model. In this way the experimental bench reproduces in closed circuit the aortic flux in an elastic aneurysm model around an artificial heart. The intrinsic properties of the aneurysm influence the pressure profile measurment which needs to be determined in the three dimensional space. We were then lead to include a network of sensors directly into the elastic wall. The conception of this bench can be divided in two parts

A. Testbench mechanical development

The experimental device is based on the development of an aneurysm model inserted into a closed pulsating circuit. Using a tank, we are also able to modulate the compliance and the aneurysm post and pre-load. The aneurysm model is made of silicone rubber, a material providing many advantages: nonlinear elasticity, lightness, water and heat resistance, resistance in diluted glycol solutions, and of course radio-transparency (useful for the control imaging of the excluded aneurysmal sac). Thus, the model approaches satisfactorily the physiological conditions. The AAA model is immersed in a transparent tank for the simulation of the intra-abdominal pressure. In order to obtain a wider distribution of the sensors on the internal aneurysmal wall, the aneurysm dimensions are upscaled by a factor of 2 compared to the known pathological average (55mm in diameter call for an intervention). In addition, the aneurysm prototype includes two extra inputs/outputs flows in order to simulate a retrograde flow in collateral arteries (type II endoleak).

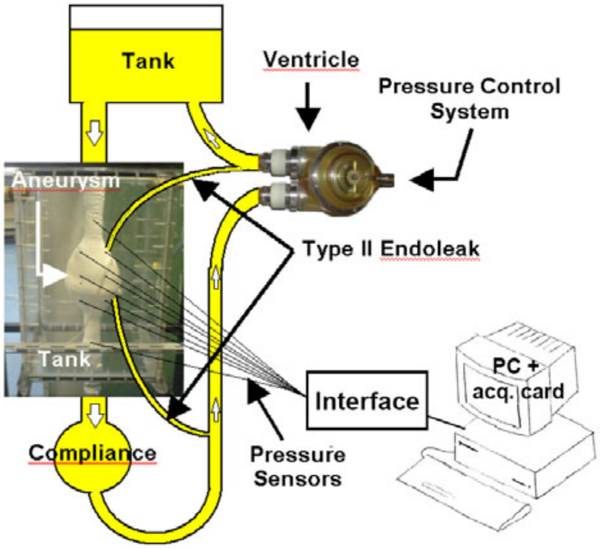

Fig. 3. Testbench Assembly Diagram

An artificial ventricle Thoratec type, equipped with its pressure interface, is used to simulate the aortic flow. Measurements are being carried out in different media. First, measurements have been carried out into a perfusion liquid, a glycerol/water solution whose viscosity is similar to that of blood. The flows and heart frequencies were adjusted to take into account the upscale factor of the stent, in order to obtain flows similar to the physiology.

In a second set of experiments, whole blood will be injected directly into the aneurysmal excluded sac in order to mimic intra-aneurysmal thrombus. This will permit to study the distribution of the pressure field in the case of an endoleak (type I, II or IV) or in the case of an endotension. A global description of the testbench is presented in Fig. 3.

B. *Electronic conception and instrumentation*

Data acquisition precision depends on the choice of the sensors used (in our case, MPX2300DT1 purchased by Freescale, sensibility 0,1mmHg, in the range of pressures between 0 and 300 mmHg for a sensibility of 30µV/mmHg).

The pressure field measurement is carried out using sensors which had been placed inside the aneurysm wall during moulding, leaving the sensitive part of the sensor in contact with the inner side the aneurysmal wall. This type of positioning allows optimal use of the sensor sensiblity. Their distribution into the stent was made homogeneously without taking into account the type of the endoleak, allowing to validate out hypothesis. However the sensors are differential and need to have the atmospheric pressure as reference in order to be able to give a reliable measurement. We devised a watertight encapsulation box which was introduced into the aneurysm model in order to be able to have an outside atmospherique pressure reference.

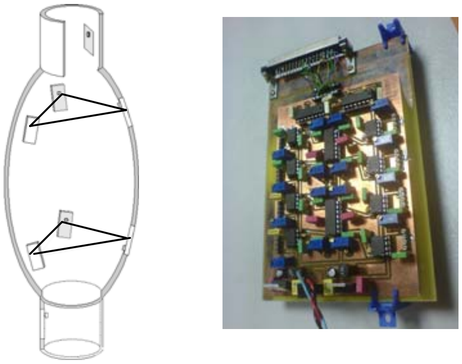

Fig. 4 & 5. Interface Photography & Location of the sensors in the aneurismal sac

An interface had been design with separate acquisition channel for each sensor allowing a signal treatment before even digital sampling. Each output comprises an amplificator in order to minimise noise that interferes with the error measurement (watertight twist wire paire between sensor and interface, instrumentation amplifier, stabilized supply, ground plan …).

. All outputs are connected to a multiplexer for using with the acquisition card (National Instrument PCI6110E). This acquisition card (4 simultaneous channels, 5Msample/s, 12bits resolution) can easily carry out cardiovascular type measurement not exceeding 4KHz of calibration frequence.

The card was used with LabView allowing for an easy development of the algorithm controlling for the detection of the endoleak and for monitoring / calibration / display tool in real time. This work leads to determination of a low consumption architecture base for integration of future systems .

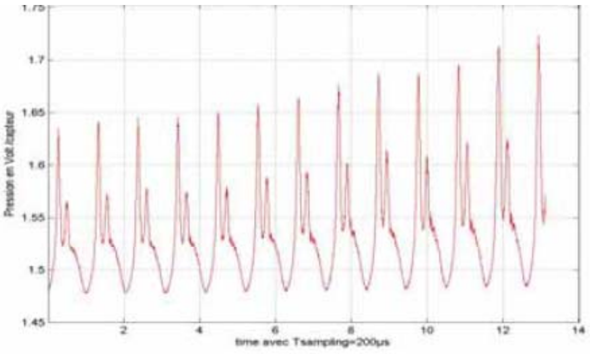

Fig. 6. Response example of pressure measurement

IV. MECHANICAL MODELISATION

The experimental measurements before, inside and after the aneurysm are used for a numerical simulation of a simplified fluid/structure interaction.

Basically, the equations are obtained from an average across the section of the unsteady laminar axi-symetrical Navier-Stokes equations. The compliance of the solid is modeled by an area-to-pressure relation of thin-wall tubes. Using as boundary conditions the measured pressure before and after the aneurysm, we try to fit the parameters of the simulation in order to reproduce the pressure signal in the aneurysm.

In the future, we will use a more systematic inverse technique (10) to obtain optimal numerical fitting between the parameters of the experimental system and the computation.

On the figure 7, the simulated pressure as function of time at the center of aneurysm is increased. The input and output pressures come from the experiment.

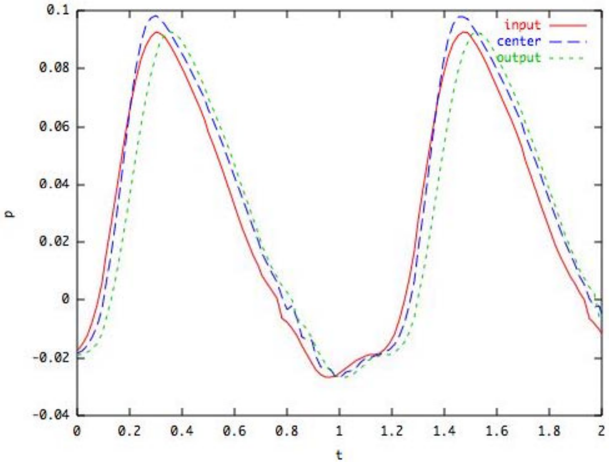

Fig. 7. Calculed Pressure in the middle of aneurysmal model with input/output pressure measurement

V. CONCLUSION

This article proposes the elaboration of an experimental in vitro testbench for blood flow simulation in an AAA model This will allow further study of the inhomogeneity of the pressure field into the aneurysmal sac of an AAA, already excluded by the stent, in case of complications such as endoleaks turn in to endotension. It will also allow to check, before animal testing, whether the communicating stent operates correctly and to further carry out measurements in order to optimise the numerical model. It is the first bench able to deliver information on the pressure field evolution in a compliant aneurysm. In the long term it will be capable of mapping the pressure field distribution on the thrombus and to detect even the pressure variation due to different types of leaks, , which can have dramatic consequences on the health of the aortic wall.

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