Wireless Communicative stent for follow-up of Abdominal Aortic Aneurysm

Johan Mazeyrat, Olivier Romain, Patrick Garda
Université Pierre et Marie Curie
Laboratoire des Instruments et Système de l'Ile-de-France
Paris, France
olivier.romain@lis.jussieu.fr

Erwan Flecher, Mourad Karouia, Pascal Leprince
AP-HP Groupe Hospitalier de la Pitié-Salpêtrière
Service de Chirurgie Thoracique et Cardio-Vasculaire
Paris, France
pascal.leprince@psl.ap-hop-paris.fr

Pierre-Yves Lagrée, Michel Destrade
Université Pierre et Marie Curie
Laboratoire de Modélisation en Mécanique
Paris, France
pyl@ccr.jussieu.fr

***Abstract*—An abdominal aortic aneurysm (AAA) is a dilatation of the aorta at the abdominal level, which rupture is a life threatening complication Recent treatment of AAA consists in endovascular treatment with covered stent grafts. Despite improving devices, this treatment is still associated with close to 25% of failure related to persisting pressure into the excluded aneurismal 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 breconstituting the aortic flux across an AAA and allowing the optimization and validation of the measurement principle.**

I. INTRODUCTION

Over 3 million people in the world are nowadays subject to an abdominal aortic aneurysm (AAA) illness. AAA illness is the third cause of death among people over 60 years of age. AAA is a pathology of the aortic wall, responsible for a localized and permanent dilatation of the arterial lumen most often situated between the kidney artery and the aorto-iliac bifurcation. The mortality due to its rupture still remains high, in the neighborhood of 80% of ruptured cases [1]. The most effective cure is prevention, which consists in treating the AAA before rupture. Most recent treatment are mainly based on endovascular methods, where the aneurysm is excluded by a covered stent introduced by the femoral artery and fixed to the arterial wall. The great interest of this method is its mini-invasive character, particularly recommended for elderly patients or for those suffering from associated heart or pulmonary diseases.

Although short term results obtained are very encouraging, in the long term this operation has failed for over one of four patients [2]. The failure may be due to blood flow persistence circulating outside the stent's lumen / inside the aneurismal sac, a phenomenon called endoleak. An endoleak is generally due to a re- injection into the aneurismal sac of a retrograde flow coming from the collateral arteries (still permeable) or to an anchoring problem of the stent.

In order to detect possible leaks, the patient is submitted to frequent imaging examinations, such as CT-scans, which are most often carried out at 3, 6, 12, 18, and 24 months after the operation and then once a year. Besides the extravagant expenses that such repetitive examinations require, the irradiation the patient accumulates is not negligible and must be taken into account. Additionally, it has been demonstrated that breakings may occur even if there are no identified endoleaks (the so-called endotension) [3]. A cost effective method, monitoring repeatedly the pressure evolution inside the aneurismal sac without using any irradiation sources, would be ideal. A biocompatible embedded system with telemetric transmission of energy, placed into the aneurismal sac, might be the answer to the problem; however its realization seems delicate from a technical and medical point of view as implant depth and environmental inhomogeneity are issues which need to be answered first. Furthermore, a series of other questions also need to be answered regarding the pressure distribution evolution in the aneurysm and the influence of a leak on the endotension [4].

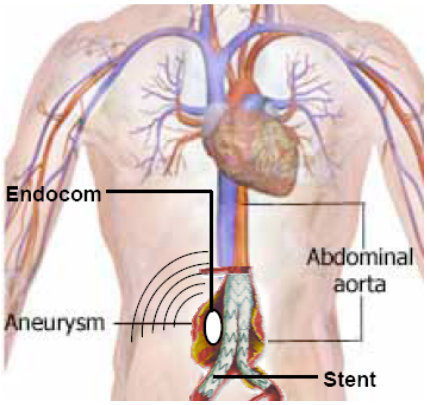

Figure 1. Principle of the ENDOCOM system

II. STATE OF THE ART

There is a constant stream of research being undertaken on the understanding, the prevention, and the improvement of medical treatments in the fight against cardiovascular disease; in particular, a major effort is taking place in implanted biomedical technology, with the development of prosthetic or endo-prosthetic devices. Numerous international academic and industrial laboratories in the biomedical world are working on the development of mini-invasive technologies for cardiovascular applications.

It is now acknowledged that the measurement of blow pressure in the aneurismal sac is a relevant monitoring criterion. Currently, several generic systems using sensors or transponders are under development [5, 6]. In particular, projects monitoring glaucoma and stenosis through intra-ocular pressure [7] and arterial pressure [8, 9] share common characteristics with those monitoring aortic aneurisms, albeit at a different depth. Among the many patents and industrial solutions available [10], we cite the Endosure [11, 12] device from Cardiomems, which is simply placed with a catheter inside the aneurysm sac during the stent introduction; the sensor then behaves as a resonance circuit whose frequency follows the intrinsic surrounding pressure. We also cite the RemonAAA technology [13, 14, 15] from Remon Medical Technology, which uses acoustic waves as a source of energy and as a communication medium. Finally, we cite Dehennis and Wise (Integrated Devices and Circuits, Solid State Electronics Laboratory, University of Michigan) who integrated two pressure sensors inside an endoprothesis in order to monitor blood flow [16, 17].

III. ENDOCOM

A. Introduction

The ENDOCOM project consists in the conception and design of a communicative stent dedicates to the post-operative follow-up of the AAA (Fig. 1). The stent is equipped with an integrated electronic system composed of a pressure transductor and a communication architecture. The technical concept is based on the inductive telemetric transmission of energy to the endograft implant, and the transmission of data through the patient's body to an external monitoring. It would allow a regular follow-up of the pressure into the aneurismal sac, with giving rise to a reliable and cost effective add-on to the present medical imaging techniques.

Fig. 2 represents the functional architecture. The instrumentation block provides a measurement of the absolute pressure, which is adapted for numerical treatment. The treatment block makes sure that the sensor tasks are operating correctly (acquisition, energy management, emission/reception) and are in accordance with its internal state and its supply level. The communication block contains, in addition to the telecommunication part, a rectenna function for the circuit supply management in respect to the antenna's output signal.

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 aneurismal sac suggest an inhomogeneous distribution of the pressure field within the excluded aneurismal sac. Consequently, the sensor fails to detect a very localized and confined leak if it is not optimally positioned. It seems thus logical to set up an experimental protocol to check if the above hypothesis is justified. This protocol is based on a numerical modeling of the pressure profile and of the blood outflows within the aneurysm, and on an experimental testbench which reconstitutes the aortic flow into the aneurysm, around an artificial heart.

B. Numerical model

The numerical simulation of the fluid/structure interaction is done using two different approaches.

First, we developed a one-dimensional simplified set of equations for the 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 modelized by an area-to-pressure relation of thin-wall tubes. We try to fit the parameters of the simulation in order to reproduce the pressure signals. In the future, we will use a more systematic inverse technique [18] to obtain optimal numerical fitting between the parameters of the experimental system and the computation.

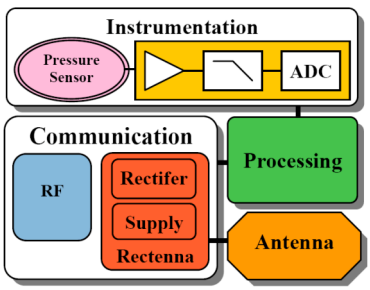

Figure 2. Electronics Synoptic of Endocom

Second, we developed a long-time (compared to the pulsating time of the hearth) evolution of the aneurysm. Here, we decouple the fluid/structure interaction. We compute a mean flow over a time period, using a modified Navier-Stokes solver and assuming a rigid geometry; from this averaged flow we obtain the pressure distribution on the wall. Then we compute the resulting large deformation of the aneurysm by feeding a nonlinear hyperelastic model into a finite element model software (here, the code CASTEM). The strain-energy density of the solid was derived by curve fitting from uniaxial extension tests on several samples of the rubber silicon used in the model experiment (in those tests, the rubber silicon was found to capture quite well the main mechanical characteristics of arteries: large deformations, nonlinear constitutive equation, strain-stiffening, etc. [19]) Finally, the mean flow is then recomputed with the new configuration at each stage of the interaction.

Up to now, we found that for this mechanical model, the aneurysm stiffens and settles into a final shape without dramatic blow-up.

C. *The testbench*

The experimental testbench must be elaborated according to physiological mechanisms in order to develop an accurate and valid measurement procedure. The experimental device conception is divided in two parts. The mechanical part deals with the reconstitution of the physiological conditions; the instrumentation part scans the pressure field inside the aneurismal sac. The mechanical development is presented first, and a description of the instrumentation follows.

1) *Testbench mechanical development*

The experimental device is based on the development of an aneurysm model inserted into a closed pulsatil 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 silicon rubber, a material providing many advantages: nonlinear elasticity, lightness, water and heat resistance, resistance in diluted glycol solutions, and of course radio-transparency. 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 aneurismal 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 comprises two more inputs/outputs: this system allows simulation of a retrograde flow in collateral arteries (type II endoleak.)

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 (according to Reynolds (1) and Strouhal's number (2) conservation rule where Q is the flow, D the diameter and ν the viscosity).

$$\mathrm{Re} = \frac{\bar{v}D}{\nu} = \frac{4\bar{Q}}{\nu\pi d} \tag{1}$$

$$S_r = \frac{fL}{V} = \frac{fd^3\pi}{4\bar{Q}} \tag{2}$$

In a second set of experiments, whole blood will be injected directly into the aneurismal excluded sac in order to mimic intra-aneurismal 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.

2) *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). 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 aneurismal wall. Eight sensors were distributed uniformly inside the aneyrismal sac without taking into account the type of the eventual endoleak (Fig. 4). This will allow us to check the validity of our hypothesis.

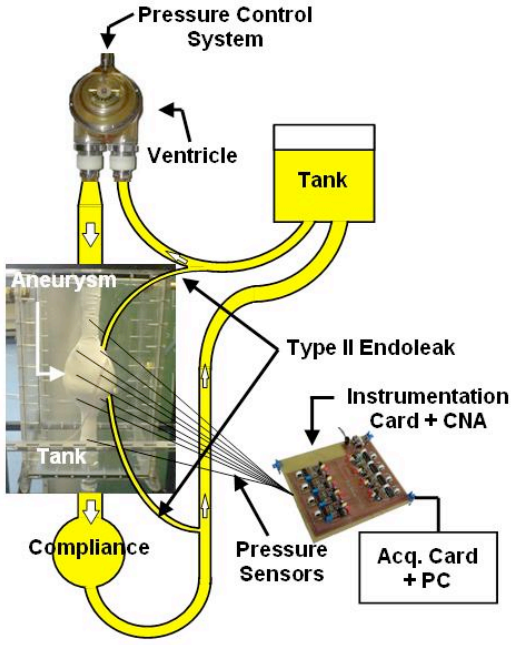

Figure 3. Testbench Assembly Diagram

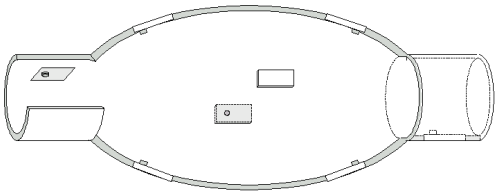

Figure 4. Locasition of the sensors in the aneurismal sac

The acquisition outputs of each sensor were amplified using an instrumentation amplifier, in order to minimise the noise possibly interfering with the data information. They were then numerised using an acquisition card. Labview software was used for the algorithmic signal treatment. Data monitoring under this rapid development environment allowed to regulate the bench in order to obtain the nearest flows and profiles with the physiological pressure (fig.5).

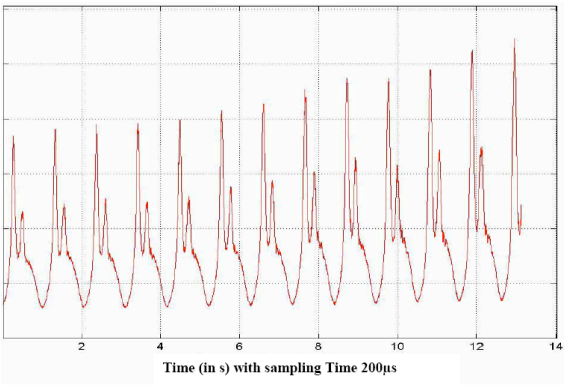

Figure 5. Response example of pressure measurement

IV. CONCLUSION

This first development of a numerical model and the elaboration of an appropriate testbench, is the fundamental part of the Endocom project, aiming for an addition to the medical imaging of AAAs, through an electronic system. This may allow to study the pressure field distribution inside the aneurismal sac, excluded by a stent, especially when an endoleak appears leading to an endotension. The monitoring of this pressure may become a fundamental parameter for the fiollow-up of AAA.

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