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IRBM

IRBM 32 (2011) 163–168

Original article

ENDOCOM: Implantable wireless pressure sensor for the follow-up of abdominal aortic aneurysm stented☆

ENDOCOM : capteur de pression sans fils pour le suivi des anévrismes de l'aorte abdominale traités par stent

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Received 31 December 2010; received in revised form 15 January 2011; accepted 21 January 2011
Available online 31 March 2011

Abstract

An abdominal aortic aneurysm (AAA) is a dilatation of the aorta at the abdominal level, the rupture of which is a life threatening complication with an 80% mortality rate. Even though those devices keep improving, the failure rate of the endovascular treatment is due to persisting pressure into the excluded aneurysmal sac. Since 2005, several integrated sensors have been designed for the follow-up of the AAA treated by a stent. Solutions are based on the use of a single sensor. Thrombus in the excluded AAA can modify the field of pressure when leaks appeared and a network of sensors should be used. We present in this paper the ENDOCOM project that aims to design an implantable pressure sensor that can be used in a network configuration. To validate the new materials, we developed a framework composed of in vitro experiments and in vivo tests on large animal model. Numerical modeling has been investigated from the experimental data to determine the optimal position of sensor. Some results of those different parts are shown in this paper.

Keywords: RFID pressure sensor; Numerical modelling; AAA, in vivo experiments

Résumé

Un anévrisme de l'aorte abdominale (AAA) représente une dilatation de l'aorte à la hauteur de l'abdomen dont la rupture entraîne dans 80 % des cas le décès du patient. L'essor des procédures de chirurgie mini-invasives fait que le traitement des AAA par voie endovasculaire (mise en place d'un stent couvert), est aujourd'hui prédominant à plus de 65 % mais à risques (40 à 50 % des patients traités présente une repressurisation du sac entrainant une rupture secondaire). Le suivi postopératoire devient alors cruciale et nécessite actuellement de fréquents examens (CT scan et IRM). Le projet de recherche industriel ENDOCOM vise à concevoir une endoprothèse intégrant un capteur de pression, dédiée aux traitements des AAA et aux suivis postopératoires des patients tout en respectant les prérogatives des technologies pour la santé. Ainsi, les consultations postopératoires permettront de suivre l'évolution régulière de la pression dans le sac anévrismal exclu, et constituerons donc une aide au diagnostic fiable et moins onéreuse que les consultations actuelles.

Mots clés : Capteur de pression RFID ; Modélisation numérique ; Anévrisme aorte abdominal ; Expérimentation in vivo

☆ Cet article a été rédigé en vue de la publication dans le numéro spécial ANR TECSAN « Technologies pour la santé et l'autonomie », volume 32/2 publié en avril 2011.

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1959-0318/$ – see front matter © 2011 Published by Elsevier Masson SAS.
doi:10.1016/j.irbm.2011.01.017

1. Introduction

An Abdominal Aortic Aneurysm (AAA) is a pathology of the aortic wall, leading to a localized and permanent dilatation of the aorta. It is generally located between the aorto-bi-iliac bifurcation and the renal arteries, which it can sometimes incorporate. It is believed that 6 to 7% of the population over 65 years [1,2] has an AAA. The global mortality rate of ruptured aneurysms is currently of 80% [3]. This percentage explains why there is a strong drive to treat AAAs effectively, before their rupture.

Several surgical procedures are currently available for the treatment of AAAs. The conventional surgical treatment consists of opening the abdominal wall, and replacing the aneurysm with a synthetic prosthesis. This surgery procedure is well established and results in a low mortality, below 3–5% [4]. The post-surgery morbidity rate is stable, at between 15 to 35% [5,6]. This morbidity is directly linked to the aortic clamping and the invasive character of the surgery.

In the endovascular treatment, a covered stent is introduced via the common femoral artery, usually the femoral aorta. The stent is compressed inside a catheter and is then deployed in the aneurysmal sac, and hooked on the inner side of the lower and upper parts of the aneurysm (Fig. 1). In this way, the aortic blood flow is guided through the stent and the pressure on the aneurysm wall is stabilized [7–9].

This treatment requires minimal invasive surgery, no abdominal incision and no aortic clamping. It is thus particularly suited for patients with elevated surgical risk. However, the hooked stent may become permeable and blood may leak in between the stent and the aortic wall. As a result, the aneurysmal sac remains pressurized and the rupture risk persists [11]. In fact, it has been shown that rupture could also occur in the absence of an identified leak: this is the so-called endotension phenomenon [13,14]. In order to detect leaks, endotension as well as aneurysm enlargement, the patient is subjected to repeated imaging examinations, i.e. mainly CT-scans or ultrasound [15] after three, six, 12, 18, and 24 months, followed by yearly checks [10,11,16]. Not withstanding their cost, these repeated imaging examinations also represent a substantial quantity of irradiation.

In an ideal scenario, the pressure in the aneurysmal sac should be measured and monitored, instead of the geometry of the sac. Measuring the pressure by a remotely powered electronic system placed inside the aneurysmal sac is a real challenge for technology for health. Such a system would allow for simple and easily repeated monitoring of a patient's condition, without placing a financial burden of public healthcare systems.

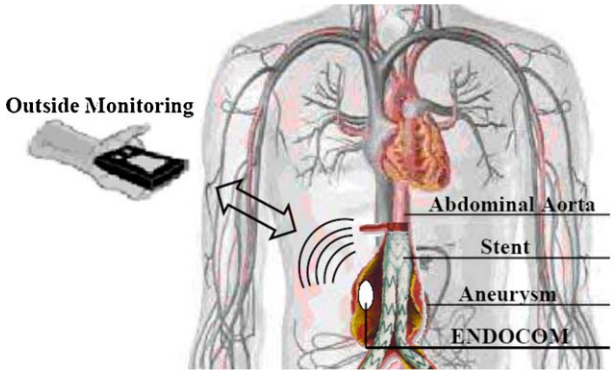

Fig. 1. ENDOCOM system.

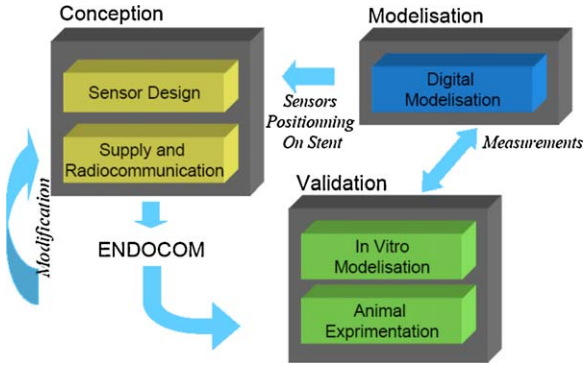

Fig. 2. Conception flow.

2. ENDOCOM overview

Recent progress in microelectronics, in Micro Electro Mechanical Systems (MEMS), and in telecommunication techniques has opened up new perspectives for smart sensors, in particular in the case of transducers combined with integrated circuits for biomedical applications. For several years, biomedical research and industrial laboratories have been developing new generic pressure sensors and transducer systems for cardiovascular applications [17–21]. Two of the most accomplished and relevant projects related to the problem of AAA leaks following an endovascular treatment are CardioMEMS [22–24] and Remon Medical Technologies [25–28]. Both methods use analogue signal transmissions. Therefore, no wireless sensor network configuration can be used.

The changing properties (geometry, elasticity) of the aneurysm, the changing nature of the blood clot, and the distribution of hypothetical leaks lead us to assume that the pressure field inside an excluded aneurysmal sac is non-uniform. As a consequence, we expect that a randomly placed sensor could be inefficient at detecting a highly localized leak. Moreover, due to the aneurysm location deep inside the abdomen, several layers (skin, fat, muscle, thrombus) may perturb the transmission signal.

Placing itself within this context, the ENDOCOM project aims [29,30] to develop a communicating endo prosthesis (Fig. 1) based on a wireless sensor network. This prosthesis will include integrated sensors, made of a pressure transducer and a wireless processing architecture. The electronic system will be remotely powered during radio transmission. Regular recordings of the pressure in the aneurysmal sac during postsurgical consultations will provide a means to monitor the evolution of the AAA's condition after the intervention. This represents a reliable and cheaper alternative to current medical imaging options.

The full development of the system has required a specific workflow (Fig. 2) that integrated three main parts: the design of the implantable wireless pressure sensor, the in vitro and in vivo

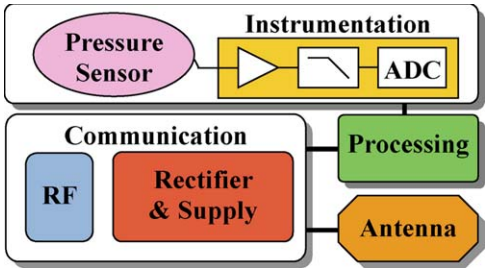

Fig. 3. ENDOCOM system.

test bench, and, finally numerical modelling. 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.

3. Implantable wireless pressure sensor

3.1. Architecture of the implant

The architecture of the wireless pressure sensor is based on a RFID tag at 13.56 MHz with an instrumentation block (Fig. 3). The wireless sensor uses the 15693 standard for the communication. 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 ted coil and a rectifier for the circuit supply management in respect to the antenna's output signal. An integrated version has been realized with a titanium package (Fig. 4).

3.2. Antenna design

The antenna is a planar coil measuring 1.5 cm × 1.85 cm with eight turns. The conductors have a rectangular cross section of thickness h = 35 μm and width w = 100 μm. The distance between each neighboring conductors is 100 μm. The employed printed circuit board (PCB) is the FR4 Epoxy ($\varepsilon r = 4.4$ and $\tan \delta = 0.02$) with a thickness of 100 μm. It is well known that the system can be viewed as a parallel RLC equivalent circuit, whose values are usually estimated from empirical formulas. To extract the values given in Table 1, impedance measurements are performed using a vector network analyzer (VNA).

Table 1
Electrical parameters.

Cp	LP	Rp	RT	CT
1.05pF	1.69μH	7.41kΩ	3.62kΩ	82.8pF

The measurements show the feasibility of the transmission data of the pressure since the quality factor equals 21.34 at 13.56 MHz. The question that arises now is the following: is it possible to fix the transponder on an aortic stent in a body while maintaining the same performances? On the one hand, measurements using the VNA and confirmed by rigorous electromagnetic simulations using full-wave analysis demonstrate nearly the same performance since the curvature radius of our transponder is negligible with respect to that of the aortic stent having usually a diameter of 2.5 cm. On the other hand, in vitro measurements and simulations confirm that when the transponder is in contact with water (soft or salt), the resonance is shifted and the quality factor is strongly deteriorated preventing any possibility to activate the pressure sensor. Consequently, the equivalent circuit can be modified by adding parasitic capacitors between rectangular conductors and including a loss resistance having a value that depends on the water salinity (i.e. the conductivity). To avoid this problem, it is proposed to encapsulate the transponder in a biocompatible material, as silicon or polyethylene.

4. The in vivo and in vitro test benchs

4.1. In vivo experiments

The objective is to create a porcine model of AAA similar to the human pathology in order to finally perform in vivo implantation of the pressure sensor fixed on an endograft.

For that purpose, the AAA model presents three main characteristics:

- a diameter which represents three to four fold the native aortic diameter
- compliant
- reproducible

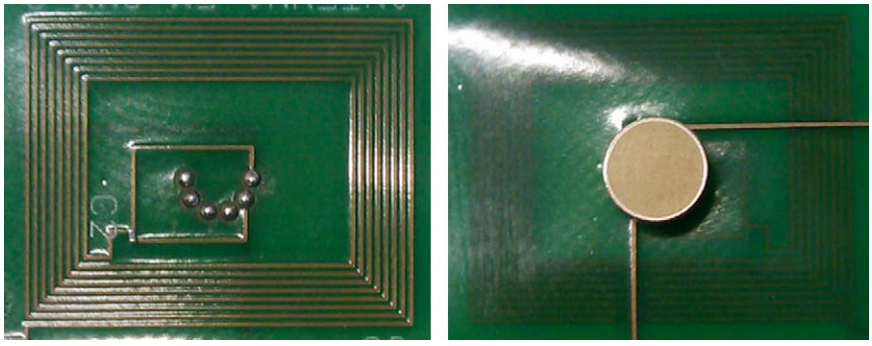

Fig. 4. ENDOCOM prototype.

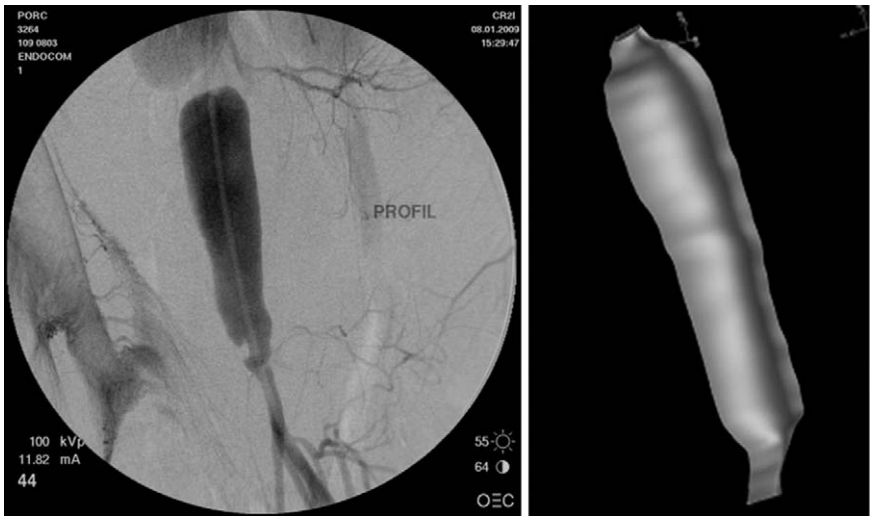

Fig. 5. Angiographic view and 3D reconstruction in one example of the pig model of AAA.

After several trials, the AAA model is created by a heterologous grafting of an aortic segment of a second pig. This segment graft is prepared by peeling the intima and media structures of the vessel before the grafting. The AAA evolution is followed by angiographic controls for three to five days, when the rupture of the AAA occurs if non stented. When the AAA is stented with an endograft (Fluency®, Bard), the AAA is totally excluded in the 48 following hours. The AAA model can be adapted to obtain a model with endoleaks type I.

Up to now, the same procedure has been applied six times, with a good reproducibility. In some trials, angiographic images are specifically acquired for 3D reconstruction (see next part) and further numerical simulations. In others, the AAA model is employed for sensors investigations (see previous part).

4.2. 3D reconstruction and data acquisition

In some animal trials, the vessel anatomy is obtained from two incidences of 2D angiography performed on pigs. The 3D reconstruction (Fig. 5) is achieved using a specific algorithm developed under Solidworks®, previously described in [31] and adapted from coronary vessel to the specificity of AAA.

In the same experiments, pressures and flow rates are measured upstream and downstream the AAA, before and after stenting. These data are then used as references for the in vitro trials and numerical simulations.

To feed these models, various mechanical characterizations are also performed on samples from normal arteries, aneurysmal arteries and thrombus.

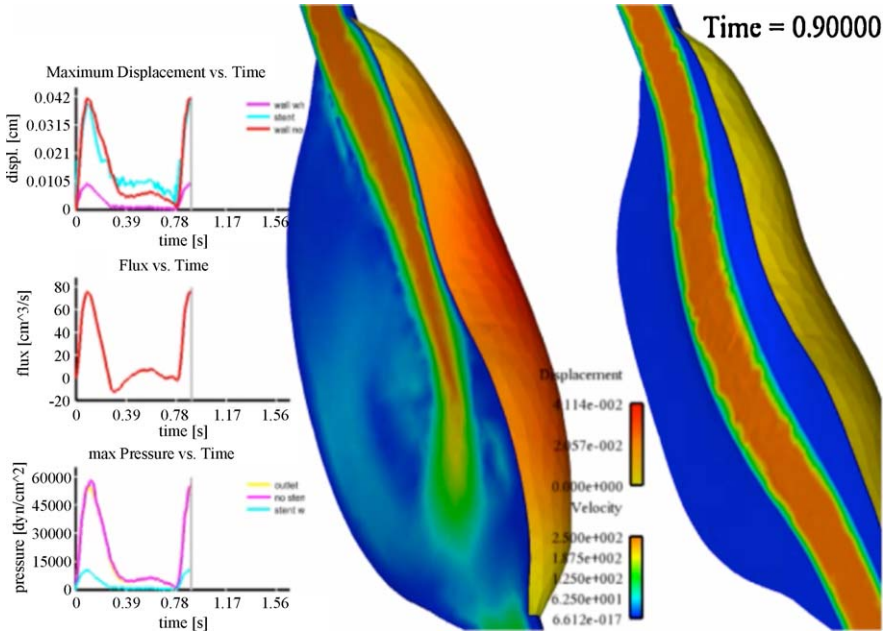

Fig. 6. Numerical modeling of AAA.

4.3. In vitro Test Bench

An experimental device dedicated to the ENDOCOM project is sized and designed to mimic the blood flows in a model of abdominal aortic aneurysm of a pig (AAA). Given the variability of geometric models of AAAs of animals, an average and axisymmetric geometry is first chosen. Given the variability of flow curves and pressure recorded during animal protocols, mean values of flow rates and pressures are taken to model these quantities in the in vitro experiments. Materials analogous (in term of mechanical properties) to those characterized during the animal trials are then used in the experiments. Controlled by a computer, the experimental test bench reproduces the hydrodynamic conditions close to those encountered in vivo in pigs.

Pressure measurements are performed in the non excluded AAA and in the aneurysm sac excluded by a stent similar to that used in vivo. These measurements are obtained using Millar pressure sensors and wired pressure sensor designed during the ENDOCOM project. Comparisons between the different signals obtained in the non-excluded AAA show a good quantitative agreement. The work is now on going with pressure measurements within the excluded sac, containing thrombus.

5. Numerical Modelling

A numerical model involving a compliant stent immersed in a compliant aneurysm is developed. A special effort is dedicated to devise a robust fluid-solid coupling algorithm adapted to this configuration. The incompressibility of the blood in a confined elastic region is indeed responsible for numerical instabilities with standard algorithms [32]. The simulations run with realistic physiological pressures and flow rates, provided by the data acquisitions in the in vitro or in vivo experiments (Fig. 6). In the considered configurations, it is observed that the pressure is essentially homogeneous in the sac. The pressure sensor could therefore be safely located anywhere within the aneurysm. Future works will address other situations, including for example collateral vessels.

6. Conclusion

This article proposes an overview of the ENDOCOM project. This project aims to develop of an implantable pressure sensor based on the RFID standard at 13.56 MHz. A specific workflow has been developed in order to design this sensor and to elaborate the test benches in vitro and in vivo. Numerical modelling has been also investigated in order to determine the optimal position of the sensor in the aneurysmal sac depending on the geometrical characteristics of the patient's aneurysm. Some preliminary results have been presented. The implantable pressure sensor measures 5 mm × 2 mm and its flexible antenna 1.5cm × 1.85 cm. In a near future, the wireless sensor will be tested on a pig and in vitro. These experiments will provide answers to the question of the distribution of pressure in the excluded AAA.

Disclosure of interest

The authors have not supplied their declaration of conflict of interest.

Acknowledgement

This project was supported by the national research agency (ANR) on the TECSAN program in 2007.

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