Endocom and Cyclope – Two Smart Biomedical Sensors for Cardio-Vascular Surgery and Gastro-Enterology

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Abstract. In this paper we present two case studies of electronic embedded systems for biomedical applications: ENDOCOM and CYCLOPE. In the former, we designed and realized the prototype of an implantable pressure sensor for the follow-up of the abdominal aortic aneurysm treated by a stent. Numerical modeling, in vitro experiments and in vivo tests on large animal model demonstrated the successful real-time follow-up of the pressure in the aneurysm sac. In the latter, we designed an embedded active multispectral vision system for the real time detection of polyps based both on the classification of the 3D reconstruction of the polyps by SVM and the classification of the texture by boosting methods. An FPGA-based demonstrator of the system was realized. Experiments in laboratory, in vitro and in vivo on a pig were performed to obtain its performances. This system could be integrated into a wireless capsule for colorectal endoscopy.

Keywords: Smart sensors, implants, biomedical systems, embedded systems, mems, wireless communications, cardio-vascular surgery, abdominal aortic aneurysm, pressure sensor, 3d imaging, polyps, gastro-enterology, wireless capsule endoscopy.

1 Introduction

In this paper we present two case studies of implantable electronic embedded systems for biomedical applications: ENDOCOM and CYCLOPE. They were designed and studied in collaboration between the LIP6 and ETIS laboratories in the Paris area.

2 ENDOCOM: Smart Biomedical Sensor for the Follow Up of Abdominal Aortic Aneurysm

An Abdominal Aortic Aneurysm (AAA) is a localized and permanent dilatation of the aorta. It affects 6 to 7% of the population over 65 years [1] and the mortality rate of

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ruptured aneurysms is currently of 80% [2]. Several surgical procedures are available for the treatment of AAAs. The conventional surgical treatment is well established and results in a low mortality, below 3-5% [3] and a post-surgery morbidity rate between 15 to 35% [4]. In the endovascular treatment, a covered stent is introduced via the femoral aorta (see Figure 1). The aortic blood flow is then guided through the stent and the pressure on the aneurysm wall is stabilized [5]. Unfortunately, in some cases the rupture risk persists [6]. In order to prevent the rupture, the patient is subjected to many imaging examinations after the endovascular treatment [7]. The objective of the ENDOCOM was to investigate the possibility to replace this monitoring of the geometry of the aneurysmal sac, by a monitoring of the pressure in the sac.

2.1 ENDOCOM Overview

For several years, biomedical research and industrial laboratories have been developing new generic pressure sensors and transducer systems for cardiovascular applications [8] [9] [10] [11] [12]. Two of the most accomplished and relevant projects related to the problem of AAA leaks following an endovascular treatment are CardioMEMS [13] [14] and Remon Medical Technologies [15]. Both methods use analogue signal transmissions. Therefore, no wireless sensor network configuration can be used.

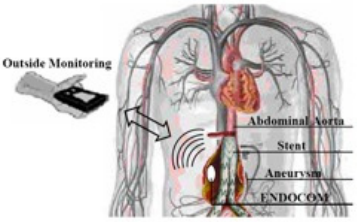

Fig. 1. ENDOCOM system

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 [16] 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 post-surgical 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

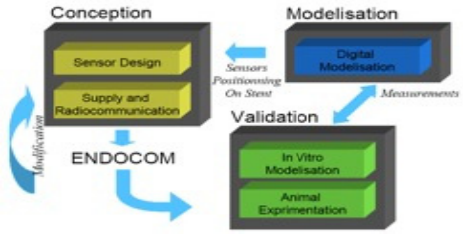

Fig. 2. Conception Flow

system 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* test bench, and, finally numerical modeling. The latter aimed to determine the optimum position of the sensor in the aneurysmal sac depending on the geometrical characteristics of the patient's aneurysm.

2.2 Architecture of the Implantable Wireless Sensor

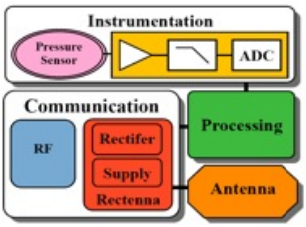

Fig. 3. ENDOCOM system

The architecture of the wireless pressure sensor is based on a RFID tag at 13.56MHz with an instrumentation block (Fig. 3). The wireless sensor uses both the 15693 RFID standard and I2C 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.

Fig. 4. RFID tag planar coil with the pressure sensor chip embedded in the middle

An integrated prototype was realized with a biocompatible titanium package (fig 4.). The transponder was composed of a 1.5cm × 1.85 cm planar rectangular coil.

2.3 In Vivo Experiments

The objective was 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, after several trials, an original AAA model was created, it presents 3 main characteristics: it is compliant, reproducible and its diameter represents 3 to 4 fold the native aortic diameter.

2.4 In Vitro Test Bench

An experimental device dedicated to the ENDOCOM project was sized and designed to mimic the blood flows in a model of abdominal aortic aneurysm of a pig (AAA).

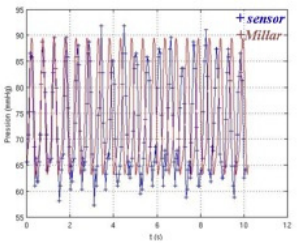

Fig. 5. Comparison between Endocom's sensor and Millar

Given the variability of geometric models of AAAs of animals, an average and axisymmetric geometry was 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.

Pressure measurements were 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 showed a good quantitative agreement (Figure 5).

2.5 3D Reconstruction and Numerical Modeling

In some animal trials, the vessel anatomy was obtained from 2 incidences of 2D angiography performed on pigs. The 3-D reconstruction was achieved using a specific algorithm developed under Solidworks®, previously described in [17] and adapted from coronary vessel to the specificity of AAA.

Then, a numerical model involving a compliant stent immersed in a compliant aneurysm was developed. A special effort was dedicated to devise a robust fluid-solid coupling algorithm adapted to this configuration. The incompressibility of the blood in a confined elastic region was indeed responsible for numerical instabilities with standard algorithms [18]. The simulations run with realistic physiological pressures and flow rates, provided by the data acquisitions in the in vitro or in vivo experiments. In the considered configurations, it was 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.

2.6 Discussion

This section proposed an overview of the ENDOCOM project. This project aimed to develop an implantable pressure sensor based on the RFID standard at 13.56MHz. A specific workflow was developed in order to design this sensor and to elaborate the *in vitro* and *in vivo* test benches for the interpretation of the measurements. In parallel, numerical modelling was 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 were presented. The implantable pressure sensor measures 5mm x 2mm and its flexible antenna 1.5cm x 1.85cm. In a near future, the wireless sensor will be tested in a pig and *in vitro*. These experiments will provide some data about the distribution of pressure in the excluded AAA.

3 CYCLOPE: Smart Biomedical Sensor for Colonoscopic Applications

The colonoscopic polypectomy consists of removing malignant colon polyps [19]. Therefore, an accurate and reliable 3D colon polyp classification is critical. We chose active stereovision methods as they offer an alternative approach to the classical use of two cameras. They are based on the projection of a set of structured rays on the studied object. In this case, only one image is necessary. In our research work, we focused on an integrated 3D active vision sensor: "Cyclope" [20]. This prototype sensor allows making real time 3D objects reconstruction and continues to be optimized technically to improve the consistency of differentiation between captured objects, while respecting the size and power consumption constraints of embedded systems [21].

A range of different materials and techniques were investigated to correctly realize the whole system. Among them, we focus in this section on the implementation of the support vector machines (SVM) in order to classify objects captured by our active stereovision system. The choice of support vector machines is motivated by the fact that they proved powerful classifiers in various pattern recognition applications [22].

To demonstrate the performance of the proposed technique, we applied it to the detection of polyps in the colon wall. Since, there are two different types of colon polyps, namely hyperplasias and adenomas [23]. Hyperplasias are benign polyps and do not have chance to evolve into cancer and, therefore, do not need to be removed. By contrast, adenomas have a strong tendency to become malignant. Therefore, they have to be removed immediately via polypectomy.

Our contributions are first, to extract the most suitable features describing the polyp models; second to choose an appropriate structure of the classification model to accurately discriminate between different 3D polyps respecting computation time and hardware requirements for our embedded sensor.

3.1 The Architecture of *Cyclope*

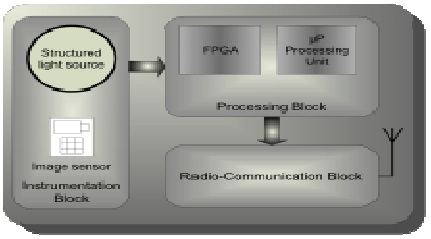

Fig. 6. Block diagram of CYCLOPE

The “Cyclope” system (figure 6) is composed of three essential parts [20] [21]:

Instrumentation block. It contains a CMOS camera and a structured light projection system. The laser projector illuminates the studied scene with an array of 361 (19x19) laser beams.

Processing block. It integrates a microprocessor core and a reconfigurable array, the microprocessor is used for sequential processing and the reconfigurable array is used to implement

time consuming algorithms needed for image processing and objects recognition task. The images captured by the active stereovision system are preprocessed to handle 3D information for extracted interest points. A small set of suitable features will be computed later from these points to be used as inputs to the SVM classifier.

Wireless communication block. This part is dedicated to the OTA (Over the Air) communication to have a wireless sensor.

3.2 Processing

As in traditional pattern recognition systems, discriminating between different shapes during endoscopic imaging is divided into three phases: data acquisition, feature extraction, and decision classification.

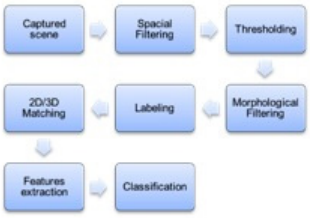

Fig. 7. CYCLOPE algorithmic chain

Data acquisition. This phase uses our stereovision system as input sensor by applying several processing techniques to the captured image in order to improve its quality and prepare it for the reconstruction stage. At the end of this phase a cloud of 3D points is obtained after stereo-matching operation.

Feature extraction. Given a cloud of points from the surface of studied objects (polyp models in this demo) defined by their 3D coordinates. We might wish to favor a small number of suitable characteristic features in order to discriminate as well as possible between different studied objects. These extracted features will be fed to the SVM classifier (third phase) in order to recognize the studied object.

Classification. We used an SVM classifier to make the final decision and classify the captured 3D objects. In this study, we tested the performance of our system for the colonoscopy, to make decision whether the captured image belongs to a benign or malignant polyp.

The input of SVM is a set of suitable features extracted from the surface of each object under study, and the output is a soft label denoting the class this object belongs to (Adenoma or Hyperplasia).

The recognition system involves several stages of operation to be performed beforehand during an off-line analysis. These activities include the calibration of the stereovision system, the feature selection process to reduce the dimensionality of the feature space, the training of the SVM classifier, the model selection and the cross-validation to find out the best parameters of the classifier.

3.3 Large Scale Demonstrator

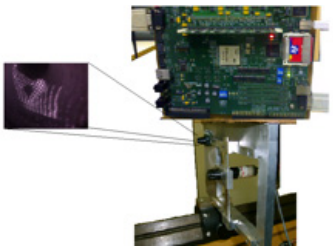

Fig.8. Large scale demonstrator

To test and validate our system, a large scale demonstrator was realized: several 3D models were created to generate a dataset consisting of 111 polyps (40 adenomas and 81 hyperplasias). These polyps were built in silicone with a scale factor of 2. Polyps are fixed on the internal wall of the intestine. The intestine was simulated by a tube in silicone with a scale factor of 2 compared to the human size.

Their image sequences were captured by an active stereovision sensor (see figure 10) created by an original ¼" color CMOS imager with digital output (356×292 array size), and a structured light generator constituted by an array of 361 laser beams [24]. The Processing block was constituted by a XUP Virtex-II Pro Development System Board, and a Zigbee module was used for communication.

3.4 Discussion

We described a multi-stage system for the automatic feature extraction and classification of colon polyps using 3D data obtained from active stereovision system. On our own polyp database, we achieved a correct classification rate of approximately 96.9%, obtained by combining RBF kernel function and SVM models.
Note that this was an ideal example, because the scene was very simple and the size of the training set iwa small. Further work is clearly required to investigate different feature areas, like second order statistics features (co-occurrence matrices), and to evaluate system performance for multi-classification.

4 Conclusion

We presented two case studies of implantable electronic embedded systems for biomedical applications: ENDOCOM and CYCLOPE. Both led to prototype realizations and in vivo measurements.

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