Initial Animal Studies of a Wireless, Batteryless, MEMS Implant for Cardiovascular Applications

Nader Najafi1* and Achiau Ludomirsky2
1Integrated Sensing Systems (ISSYS), Ypsilanti, MI
E-mail: issys@mems-issys.com
2Department of Pediatrics, Washington University, Medical Center, Saint Louis MO

Abstract. This paper reports the results of the initial animal studies of a wireless, batteryless, implantable pressure sensor using microelectromechanical systems (MEMS) technology. The animal studies were acute and proved the functional feasibility of using MEMS technology for wireless bio sensing. The results are very encouraging and surpassed the majority of the application’s requirements, including high sampling speed and high resolution. Based on the lessons learned, second generation wireless sensors are being developed that will provide total system solution.

Key Words. congestive heart failure, Bio-MEMS, MEMS sensor, wireless sensors, implantable sensors

Introduction

National Institute of Health (NIH) has identified congestive heart failure (CHF) as a new epidemic in the United States [1]. CHF, a condition in which the heart fails to pump efficiently, is the only major cardiovascular disease that is rapidly getting worse. CHF affects 4.8 million United States patients, has more than 400,000 new patients per year in the United States, accounts for 5–10% of all hospitalizations, and costs the United States over $38 billion per year. The fatality rate for CHF is high, with one in five persons dying within one year, more than half of the CHF patients dying within five years, and sudden death occurring at a rate of six to nine times that of the general population [1–2]. One in five of all discharged patients age 65 and older had CHF as a primary or secondary diagnosis [1–2]. A person age 40 or older has a one-in-five chance of developing congestive heart failure [1–9].

CHF is currently treated with medication. Long-term medication for CHF patients is, however, a very delicate task that requires a good understanding of the well-being of the patient. Incorrect medication dosages can cause adverse (and potentially fatal) secondary effects, such as pulmonary edema [3–16]. Following diagnosis of congestive heart failure, physicians typically monitor disease progression on a continuing basis to better tailor drug treatment. Mean left atrium pressure (MLAP) and left ventricular end diastolic pressure (LVEDP) are the best parameters for characterizing CHF in patients. Clinical evaluation of MLAP or LVEDP is currently limited to a cardiac catheterization procedure, which provides a snapshot of pressure data a few times per year at most, carries a morbidity risk, and is expensive.

One of the most important problems facing the effective treatment of CHF, as well as many other cardiovascular diseases, is the lack of a viable method to regularly monitor the effectiveness of the medication (as well as the severity of its side effects) in order to tailor the treatment medication. Currently, physicians mostly make major medical decisions based on rudimentary imprecise and subjective symptom presentation. Ideally, physicians could have access to direct measurement of detailed hemodynamic waveforms of the pressure in the left side of the heart to better tailor treatment. “Most patients...do benefit from a medical regimen tailored to individual clinical and hemodynamic profiles” [14].

There is a growing need for non-invasive continuous monitoring of cardiac physiological parameters. Microelectromechanical system (MEMS) technology has the potential to enable clinicians to continuously monitor cardiac physiology [17–37]. This paper reports the results of the initial animal studies of a wireless, batteryless, miniature pressure sensing implant in order to assess its feasibility and accuracy for monitoring of a wide range of cardiac pressures. These devices provide chronic, detailed, real time, continuous, non-invasive measurements, with the potential to change the way physicians monitor their patients.

The pressure monitoring system consists of two major parts: a miniature, implantable, batteryless, telemetric sensor and a companion hand-held readout unit. This system is shown in Figure 1. The miniature implantable micro-device is suitable for implantation via a custom catheter for a minimally-invasive, outpatient procedure. It contains a micromachined pressure sensor along with custom electronics and a telemetry antenna. Using magnetic telemetry, the reader transmits power to the sensor and the sensed pressure is in turn transmitted back

*Corresponding author.
to the reader. Data collected by the sensor will be used by physicians to tailor treatment. Since the implant does not require a battery for its operation, its useful life is greatly extended.

It should be mentioned that although wireless technology has been mentioned for a variety of applications (e.g., ID tags) [38–41], they lack many features required for implantable applications, such as miniature size and long life time. The presented technology is custom designed for miniature, chronic, implantable sensors that operate without a battery and can simultaneously receive power, very rapidly sample detailed data, and telecommunicate the sampled data. Adding other requirements such as delivery via a transcatheter in an outpatient procedure, long-term biocompatibility, and nonthrombogenic operation within the left side of the heart, these MEMS implantable pressure sensors require far more than the current commercial RF industry can offer.

**Initial Animal Study Results**

The animal study method used was an open chest model performed in three canines. The batteryless, wireless MEMS sensors were implanted and anchored by sutures in the right atrial appendage of one dog and the descending aorta of two dogs. The MEMS sensors communicated and were powered via wireless magnetic telemetry with an external, handheld, readout unit. Millar solid-state catheters were used to record reference pressure data from the right atrium and the descending aorta adjacent to the sensor location. Blood pressure waveforms derived from the MEMS sensor and Millar catheters were compared.

Figure 2 shows the results of one of the tests where both the MEMS implant and the control Millar catheter were placed in the aorta. As it can be seen there is a good correlation between the two signals. The lower pressures in the waveform are the same; however, Millar catheter shows higher pressures at the waveform peak. It is hypothesized that this is due to the fact that the Millar catheter obstructed the blood flow (since this was a small animal: a beagle dog weighing 14 kg) and as a result at high blood flow rates the pressure increased accordingly.

Figure 3 shows 20 seconds of wireless pressure measurements with the MEMS implant in the aorta; the heartbeat is superimposed on dog’s breathing pattern. Figure 4 shows a comparison of dp/dt (measure of contractility), from Figure 3, of the MEMS implant vs. the control Millar catheter (MEMS implant in the aorta vs. Millar catheter in the carotid). There is a great correlation between the waveforms. The MEMS implant provided outstanding performance, as summarized below:

- Significant data correlation was found between the MEMS implant and Millar catheter tracings, as well as the expected waveforms.
- Dicrotic notch clearly visible.
- Continuous heart pressure waveform.

![Fig. 1. An overview of the system used for the first set of animal study: Control PC used data acquisition, Handheld Readout Unit, Computer Screen, and MEMS Implant.](image1)

![Fig. 2. A comparison of the MEMS implant and the control Millar catheter (both placed in the Aorta).](image2)
Fig. 3. 20 seconds of wireless pressure measurements with the MEMS implant in the aorta (the heartbeat is superimposed on dog’s breathing pattern).

Fig. 4. A comparison of $dp/dt$ (measure of contractility) of the MEMS implant in the aorta vs. the Millar catheter in the carotid.
• Real time heart pressure waveform.
• 400 samples/second of heart pressure measurement.
• Wide pressure dynamic range (−200 to +300 mmHg).
• High accuracy (< 1 mmHg).
• Observed heart rate of up to 200 beats/min.
• Observed breathing pattern.
• Telemetry distance of 3–4 cm.
• Tele-powering distance of 3–4 cm.

While the first-generation devices offered excellent performance that surpassed most of the application’s needs, there were three major shortcomings:

• Communication distance was limited (< 4 cm).
• Sensor shape was not optimum for catheter delivery and chronic anchoring.
• Anchoring method was not incorporated into the implant design.

The second-generation implantable sensors are being developed to satisfy all of the application’s requirements (Total Solution), in order to become a viable product. In collaboration with cardiologists, a top-down approach is followed in developing this family of implantable cardiology pressure sensing implants. These MEMS implants will provide over 15 cm distance for both telecommunication and tele-powering, will include an anchor for chronic implantation (> 10 years), will be delivered via a custom-designed catheter, and will provide accurate pressures (< 0.5 mmHg) at a high sampling rate (> 200 samples per second).

Second-Generation Wireless Systems

A wireless, batteryless implant coupled with a handheld reader for chronic measurement of left atrium pressure

Advantages

• Minimally Invasive (catheter delivered).
• Long-term/chronic operation (> 10 years).
• Very small, mechanically rugged transducer adapted to human size constraints.
• Batteryless, wireless RF readout scheme with long lifetime.
• Safe (biocompatible and nonthrombogenic).
• Continuous, real time, pressure measurements.
• High speed pressure measurement (> 200 samples/second).
• High resolution pressure measurement (< 0.3 mmHg).

• Communication distance over 15 cm.
• Allows the custom tailoring treatment.
• Permits earlier detection of disease related conditions.
• Improves patient management.
• Minimizes patient discomfort.
• Prevents of hospitalizations through improved outpatient and home care.
• Carries the potential to revolutionize home care management of cardiac patients.

Conclusions

This paper reported the initial animal studies of a wireless, batteryless, implantable pressure sensing systems. The implantable sensors were made using MEMS technology. Three animal (dog) studies were performed using the first generation sensors. The tests were performed using an IACUC-approved protocol at the University of Michigan facilities [29]. The batteryless, wireless MEMS sensors were implanted and anchored by sutures in the right atrial appendage and the descending aorta. Millar solid-state catheters were used to record pressure data from the right atrium and the descending aorta adjacent to the sensor location. Blood pressure waveform derived from the new MEMS sensor and Millar catheters were compared to tracings from Millar catheters. The implant performance was outstanding. It provided continuous heart pressure waveform monitoring; real time heart pressure waveforms; 400 samples/second of heart pressure measurement; wide pressure dynamic range (−200 to +300 mmHg); and high accuracy (< 1 mmHg). The major shortcomings were short communication distance (< 4 cm) and lack of a delivery scheme via a catheter. Second generation devices are under development that will satisfy the entire CHF application’s requirements.

References

15. Ibid., p. 631.