Wireless Pressure Sensing of Aneurysms

Will the use of this technology after EVAR make CT scanning obsolete?

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Endovascular aneurysm repair (EVAR) is known to fail over time. A recent FDA analysis estimated that the aneurysm-related death rate after EVAR is 0.4% per year compared to 0.18% per year after open surgery.[1] Such aneurysm-related death is secondary to endograft failure, including various types of endoleaks, endograft migration, kinking, and ultimately rupture of the AAA.[2,3] Therefore, surveillance after EVAR has become an important part of overall patient care.

Although the primary goal of EVAR is to depressurize the sac and prevent rupture, there are currently no devices available to noninvasively measure intra-aneurysm pressure on a long-term basis. Incomplete exclusion of the aneurysm sac or endoleak is among the most common complications of EVAR and results in ongoing perfusion and pressurization of the sac.[4]

Current surveillance techniques, which consist primarily of CT scanning with intravenous contrast, are not sensitive enough to detect all endoleaks or stent graft failure. In fact, studies have demonstrated that aneurysm sac pressure can be elevated even in the absence of a visible endoleak on CT exam.[5,6] However, Sonesson et al recently reported that sac pressure was significantly reduced in aneurysm sacs that were shrinking after successful EVAR.[7] Thus, it appears that direct assessment of sac pressure after EVAR could provide additional information that may be valuable for surveillance after EVAR and in preventing rupture.[7-10]

Additional disadvantages of the CT surveillance protocol are that it cannot be repeated often and that it utilizes radiation, as well as nephrotoxic contrast agents. Although MRA does not utilize nephrotoxic agents, the accuracy of this test in detecting endograft failure has not been established, and moreover, it cannot be repeated often. Furthermore, MRA is a costly test that requires a highly trained technician.

Figure 1. Example of a micromachine.

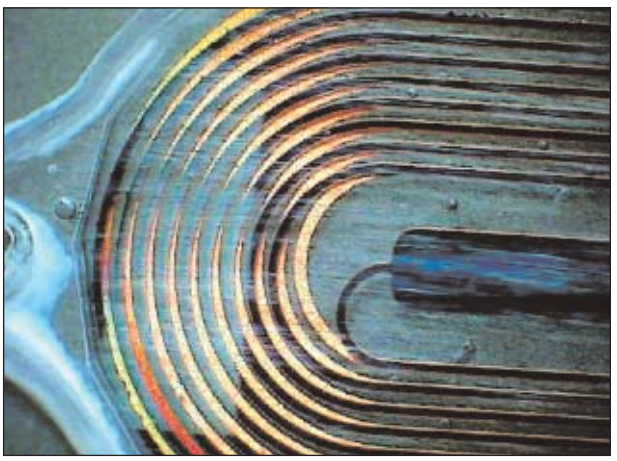

Figure 2. Closeup view of the CardioMEMS pressure sensor. MEMS allows the fabrication of precise components on the micron scale.

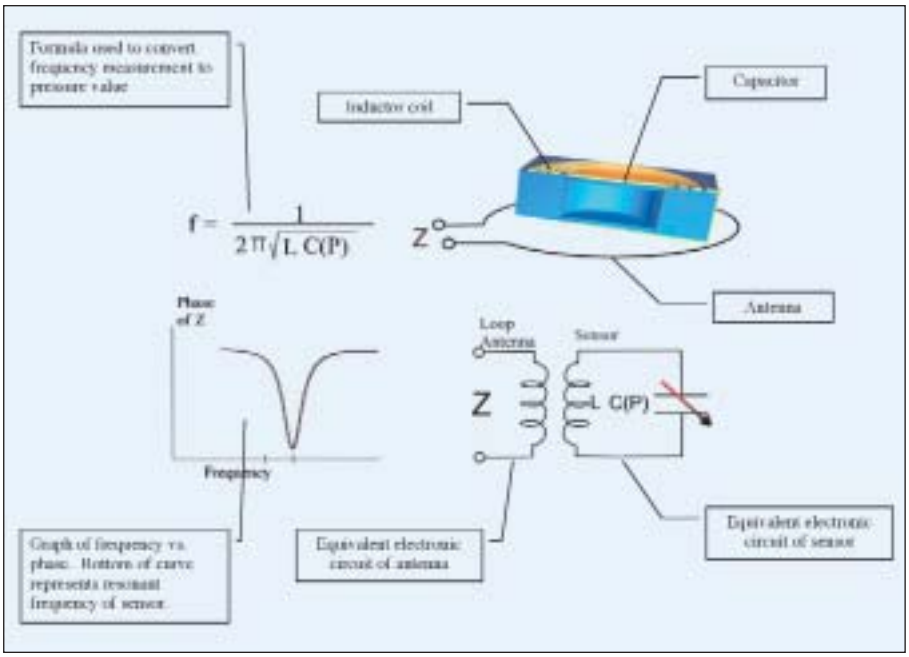

Figure 3. Theory of operation.

MONITORING TECHNOLOGY

Advancements in technology have allowed for the development of methods to monitor intrasac pressure in a noninvasive fashion. Currently, there are two different approaches being developed, one of which utilizes an ultrasound-based format (ImPressure, Remon Medical Technologies, Caesarea, Israel). CardioMEMS, Inc. (Atlanta, GA) has developed an implantable pressure sensor that can be strategically located within the excluded aneurysm sac to provide long-term, noninvasive, real-time measurements of intrasac pressure after EVAR utilizing the radiofrequency approach. In addition to providing enhanced sensitivity to identifying problems associated with stent graft failure, such an approach to patient monitoring would be safer, easier to repeat (allowing for more frequent sampling), and potentially more cost effective. The potential benefits of this technique are summarized in Table 1.

The Ideal Aneurysm Sac Pressure Sensor

The ideal aneurysm sac pressure sensor would have the following characteristics: (1) it needs to be batteryless because the sensor cannot be exchanged or recharged once it is placed inside the sac; (2) it needs to be small enough that it can be delivered through a transfemoral route at the time of EVAR; (3) it must able to measure pressure accurately over time; and (4) it must be able to communicate the information wirelessly through human tissue to a readout device.

MEMS Radiofrequency-Based Pressure Sensors

The technology we have developed evolved from pressure sensors designed to improve the operating curve of a turbine engine. The use of such micromachined pressure sensors is a well-established practice in both the automotive and aeronautical industries (Figure 1). The MEMS (micro-electro-mechanical systems) approach to sensor fabrication allows for the creation of a device that is small, accurate, precise, durable, robust, biocompatible, and not adversely affected by changes in body chemistry and biology (Figure 2). The sensor does not require the use of wires to relay pressure information externally, nor does it need an internal power supply to perform its function.

The pressure sensor features an inductive-capacitive (IC) resonant circuit with a variable capacitor. The capacitance varies with the pressure of the environment in which the capacitor is placed. Consequently, the resonant frequency of the IC circuit of the pressure sensor changes depending on the pressure of the local environment. Pressure-related data can be gathered using an external measuring device and various excitation systems (Figure 3). When in operation, a current is induced in the sensors, and this current oscillates at the resonant frequency of the sensor. This oscillation causes a change in the frequency spectrum of the transmitted signal. From this change, resonant frequency of the particular sensor may be determined, from which the corresponding change in pressure can be calculated.

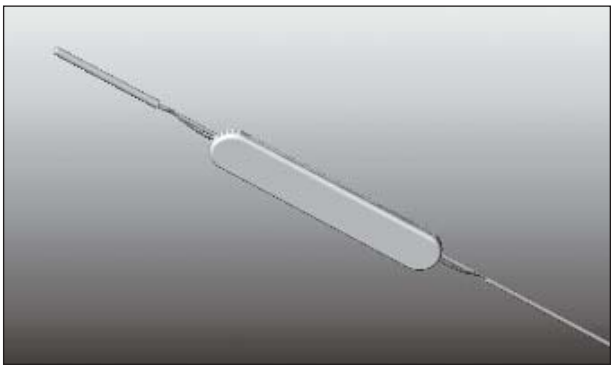

Figure 4. The AAA pressure sensor on a tether system.

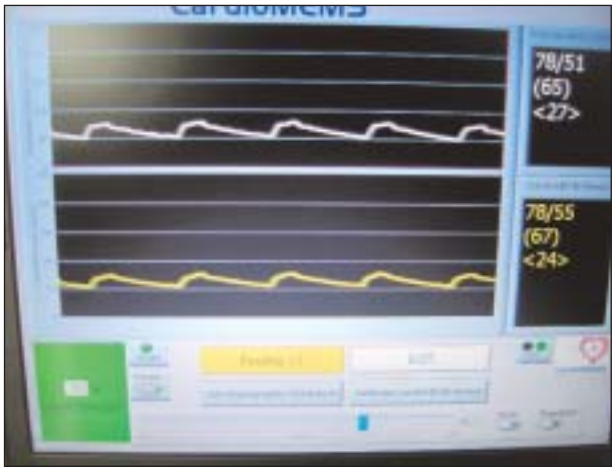

Figure 5. Note the excellent correlation between the catheter and the CardioMEMS wireless sensor readings.

Ultrasound Versus Radiofrequency Energy

Alternative systems have been devised in which ultrasound energy is used to externally power an implanted sensor and transmit intra-aneurysm pressure information out of the body. This has led to the development of a miniaturized sensor (ImPressure) that is physically attached to the stent graft during device manufacturing. Ultrasound is widely used for medical imaging and it is very safe and can easily transverse a fluid environment. However, to couple to the patient, direct contact with the skin and the transducer is necessary, as is the use of ultrasonic gel. Also, because ultrasound cannot travel though air or bone, one may encounter difficulties communicating with the often calcified AAA sac located deep in the abdomen. We chose to use the radiofrequency approach to data transmission because of the particular advantages associated with it. Specifically, the complex component of the system is the electronics (which remain outside the patient and have been created to accurately detect small signals emanating from deep within the body), while the internal implant is mechanically and electrically simple. The sensor is assembled without the need for electrical connections that could break with prolonged use. The sensor is also hermetically sealed to ensure long-term stability and durability. These design features allow reliable operation of the device. Acquisition of pressure information from the sensor is accomplished without the need to place the external antenna in contact with the patient's skin or even have them remove their clothes. This will potentially allow daily/weekly sampling at home.

PROGRAM STATUS

CardioMEMS

Sensors, along with a custom-designed delivery system and associated external communication system, have been assembled and extensively tested on the bench and in the animal lab. In practice, the sensor is introduced through the femoral artery contralateral to the side in which the main endograft will be inserted. The current version can be introduced through a 14-F sheath and deployed inside the aneurysm sac. During subsequent introduction and deployment of the designated stent graft system, the sensor is maintained in position with the tethering system (Figure 4). Once the stent graft and the contralateral limb are deployed, the sensor is released from its tether and the tether system is removed, leaving the sensor inside the sac.

In vitro and *in vivo* evaluation of the sensor has demonstrated that they are stable, accurate, and biocompatible. Long-term implants in an animal model have confirmed that the device is safe, that the delivery method is predictable, and the pressure information is accurate.[11] Based on this extensive bench and animal work, we recently performed the first-in-man implant in Brazil. The sensor was delivered inside the aneurysm sac without difficulty in five consecutive patients undergoing EVAR. The pressure signals were detected intraoperatively, as well as postoperatively, readily by applying the external antenna. Excellent correlation was seen between the catheter-based pressure measurement and the wireless sensor (Figures 5 and 6).

TABLE 1. COMPARISON OF CT SCAN TO PRESSURE SENSING FOR CHRONIC PATIENT MONITORING

	CT	Pressure Sensing
Cost	High	Low
Location	Hospital	Office/home
Contrast Agents	Yes	No
Parameter Measured	Diameter change, volume change, presence of endoleak	Mean pressure pulsatile pressure
Sensitivity	moderate	Potentially high
Timing	1 to 4 per year	As needed
Risk to Patient	Contrast reaction/radiation	None
Patient Comfort/ Convenience	Uncomfortable/ inconvenient	Minimal patient issues

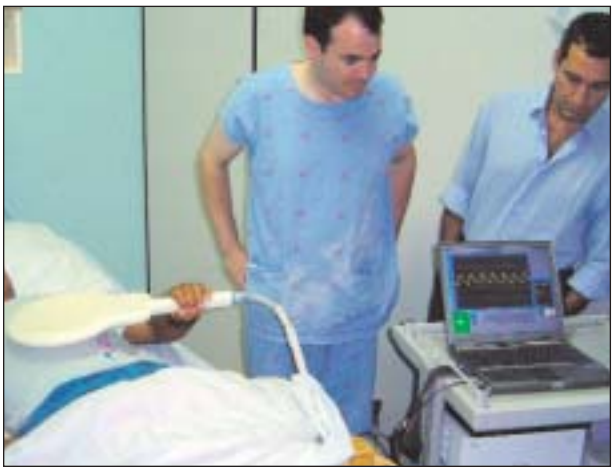

Figure 6. Aneurysm sac pressure measurement in a patient who underwent EVAR and CardioMEMS pressure implantation 4 hours earlier. The signal can be readily acquired with the antenna. Note the pressure wave form within the excluded sac is still pulsatile.

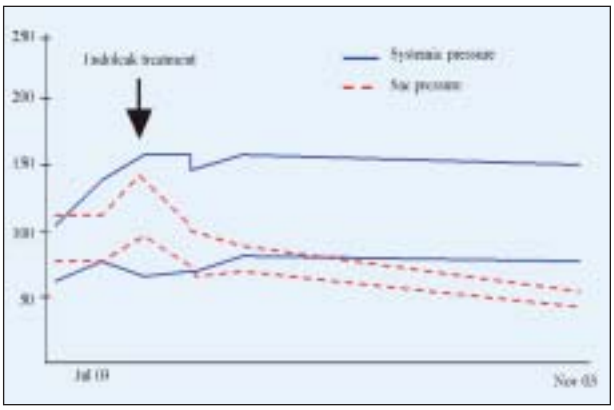

Figure 7. A Remon pressure sensor was implanted in a patient undergoing EVAR. The sac pressure was initially high. Follow-up MRA detected a distal type 1 endoleak, which was treated with an extension cuff. While the systemic pressure remained stable, the sac pressure gradually decreased during the next 3 months (modified from Lookstein R et al[12]).

Remon Medical Technologies

The ImPressure device has already been implanted in humans at Mt. Sinai Medical Center in New York City.[12] To date, the ImPressure has been implanted in 14 patients. One device became nonfunctioning, whereas the remaining devices continued to function up to 6 months (Figure 7).

FUTURE OF EVAR SURVEILLANCE

Once pressure sensors become available to the physician, it is possible that a device would be implanted during every EVAR procedure. Frequent measurements of aneurysm sac pressure could be performed at home or at the physician's office and comparisons to previous readings could provide valuable trending information regarding changes in both mean sac pressure and the pressure pulsatility. Future surveillance protocol may include weekly pressure sensing coupled with plain abdominal x-ray imaging obtained two to three times a year. Plain x-ray imaging can detect stent migration and stent fractures, as well as early signs of limb dislocation. CT scan/MRA and angiography will be reserved for those patients who show abnormal findings on x-ray imaging or pressure sensor exams. This protocol is not only less costly but will allow more frequent sampling, which potentially can lead to earlier detection of failures. Long-term clinical evaluation will ultimately determine the medical value of this innovative technology. ■

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