

Pressure Sensors to Monitor Thoracic Stent Graft Procedures

An advantageous alternative to CT.

BY KARTHIK KASIRAJAN, MD

The ultimate goal of thoracic aneurysm repair is to extend the life expectancy of the patient by decreasing the risk of rupture. Hence, the early and late risks of rupture must be eliminated with the least amount of procedure-related complications. A review of existing literature demonstrates that thoracic stent grafts (TSGs) can accomplish this with low morbidity and mortality rates compared to the higher early complication rates associated with open repair of thoracic aortic aneurysms (TAAs).¹ A unique early and late complication of TSGs is the occurrence of endoleaks and the associated potential pressurization of the aneurysm sac (Figure 1).²

Currently, CTs are considered the gold standard for detection and surveillance of these endoleaks. However, contrast CT scans are contraindicated in patients with pre-existing renal insufficiency due to the need for administration of nephrotoxic contrast agents. Even patients with normal renal function may develop progressive renal dysfunction secondary to the repeated contrast administration required with each CT scan.³ The only other noninvasive imaging option for surveillance after TSG repair is MRA. However, MRAs cannot be performed in patients with metal implants, such as pacemakers and the Cook TSGs (Cook Medical, Bloomington, IN) due to the presence of ferromagnetic materials. Additionally, a recent warning letter was issued by the FDA on the use of the standard MRA contrast agent (gadolinium) in patients with moderate-to-severe renal dysfunction due to the detection of subcutaneous calcification and skin necrosis secondary to skin deposition of gadolinium. For this reason, both CT and MRA are not usable in all patients and

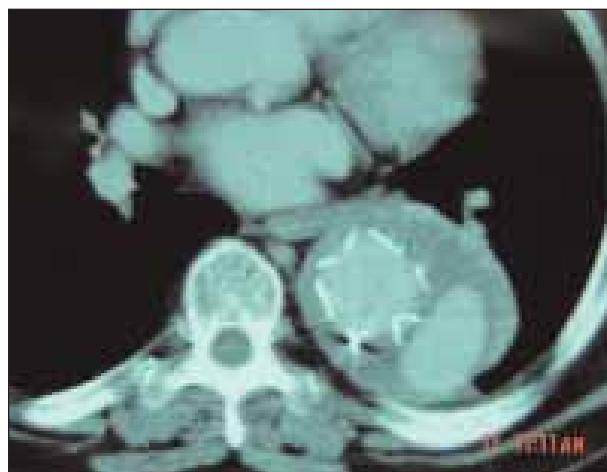


Figure 1. Delayed type III endoleak in a patient with a TSG.



Figure 2. The EndoSure (CardioMEMS, Inc., Atlanta, GA) wireless pressure sensor.



Figure 3. The new-generation thoracic sensor.

may have significant long-term side effects. High cost, use of ionizing radiation, and poor patient compliance are other factors underlining the need to establish safer and more patient-friendly surveillance techniques.

WIRELESS PRESSURE SENSORS

Thoracic aneurysm sac pressure monitoring by wireless sensor has the potential to become a valuable adjunct for surveillance after TSG repair and may eventually replace CT/MRA imaging.⁴ On March 28, 2007, CardioMEMS, Inc. announced FDA clearance of the EndoSure wireless pressure measurement system for measuring intrasac pressure during TAA repair. The first thoracic sensor implant in the US was performed by the author on January 8, 2006.

The EndoSure Pressure Sensor

The EndoSure is composed of two components: a miniaturized, wireless implantable sensor and an external electronics module (Figure 2). The external electronics module wirelessly communicates with sensors to deliver intrasac pressures. The wireless sensors are powered by radiofrequency energy transmitted from an external electronics module and transmit real-time data without batteries. The sensor is designed and manufactured using microelectromechanical systems, or MEMS, technology, which

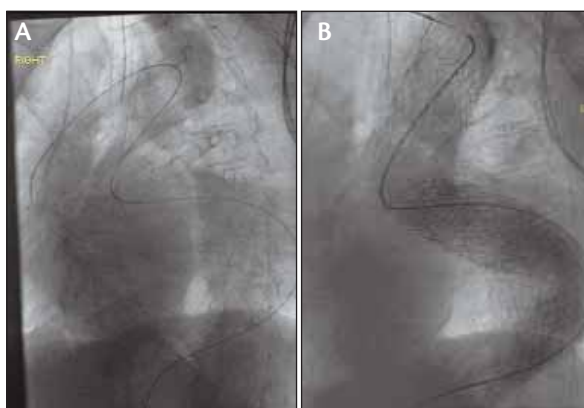


Figure 4. Highly tortuous thoracic aorta in a patient with an aneurysm (A). The sensor was able to track easily across the acute thoracic aortic angles and is shown deployed in the aneurysm sac (B).

ty result in changes to the sensor's resonant frequency. These changes correlate to pressure changes in the aneurysm sac.

The sensor can be delivered through a 14-F sheath that enables the physician to insert the sensor during the same procedure as the stent graft (Figure 3). Radiopaque markers assist in delivery of the sensor by clearly defining the sensor location within the aneurysm sac between the stent graft and aortic wall. The delivery catheter and sensor are made for easy trackability across the thoracic aortic angles (Figure 4).

The external electronics module consists of three parts: the internal signal processing electronics, or main unit, the antenna used to wirelessly communicate with the sensor, and the graphical user interface that displays the patient information. During a reading, the antenna is placed near the implant site and communicates with the sensor by

enables the fabrication of millimeter-scale devices with internal features in the nanometer to micrometer range. The sensor is approximately the size of a paper clip, and the hermetically sealed circuit is encapsulated in fused silica and silicone, which is surrounded by a PTFE-coated nickel-titanium wire. Inside the fused silica is a micron-scale cavity. Changes to the membrane of this cavi-

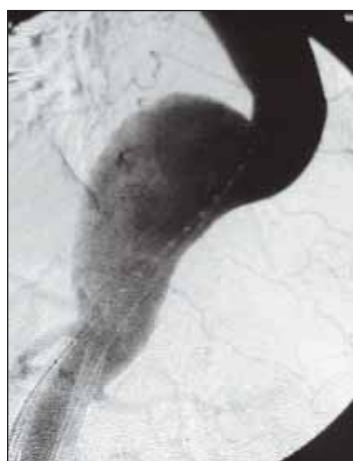


Figure 5. A TAA with a limited distal landing zone.



Figure 6. The sensor and TSG in position before deployment.

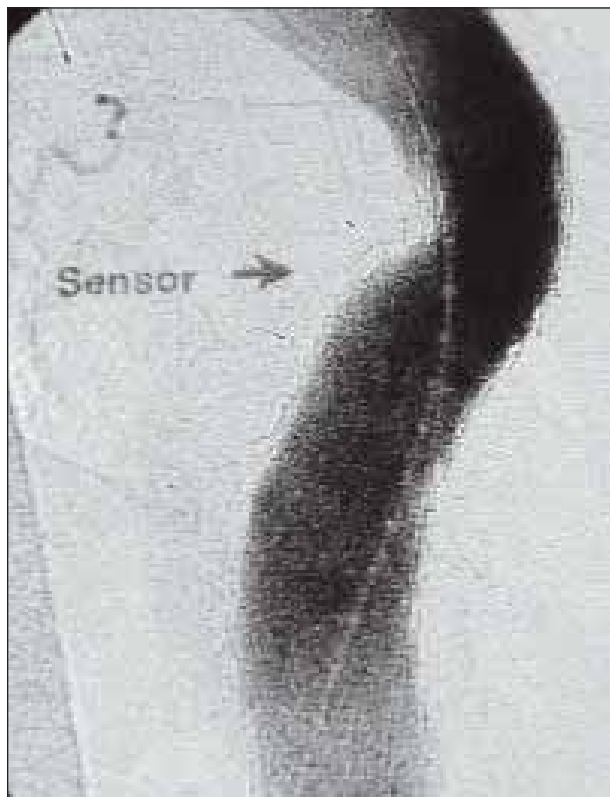


Figure 7. Type I endoleak.

way of a radiofrequency signal that is generated and processed by the main unit. The graphical user interface allows for system operation and data entry and displays information generated by the sensor. This information includes a pressure waveform and readings, such as mean pressure, systolic pressure, diastolic pressure, and heart rate. By comparing pressure waveforms before and after stent graft deployment, aneurysm sac exclusions can be confirmed.

EMORY EXPERIENCE

The endosensor was successfully deployed in the thoracic aneurysm sac of 13 patients and one patient with a chronic dissection during thoracic endograft repair. After sensor placement, a baseline recording was obtained and calibrated with an arterial pressure recording. Subsequent pressure measurements were obtained after graft deployment, balloon dilatation, and prior to patient transfer from the operating room. Postprocedure intrasac pressures were obtained before discharge and at 6-month intervals and correlated with CT imaging. Sac pressures were normalized using the ratio of intrasac to systemic (I/S) arterial pulse pressure. No intent-to-treat failures were noted, nor was technical difficulty in delivery or release of the sensor encountered. Sensor signals were detected in all patients



Figure 8. Interrogation of the sensor in the sac with the antenna.

during the follow-up period. Before graft placement, the I/S ratio was 1.17 ± 0.1 . In patients without visible endoleak, the intraoperative I/S ratio on completion was 0.56 ± 0.2 , which further decreased to 0.29 ± 0.2 at discharge. In two patients with type I endoleak, the intraoperative and discharge I/S ratios were 0.89 ± 0.16 and 0.82 ± 0.26 , respectively. One of these patients underwent a reintervention with a subsequent I/S ratio of 0.18 at 1 month. Currently, seven



Figure 9. Sac pressure waveforms demonstrate incomplete aneurysm exclusion.



Figure 10. Total visceral abdominal debranching.

patients have reached the 6-month follow up with no evidence of endoleak and an I/S ratio of 0.15 ± 0.04 . Hence, sensor reading showed perfect correlation to the presence of endoleaks.



Figure 11. Pressure waveforms demonstrate complete aneurysm exclusion.

FIRST US IMPLANT

The patient was a 72-year-old man who presented with recent-onset back pain. A CT scan demonstrated a 7.2-cm TAA and a 6.7-cm juxtarenal AAA. Due to a significant history of chronic obstructive pulmonary disease and chronic renal dysfunction (creatinine level of 1.8), the surgeon elected not to perform an open thoracoabdominal aneurysm repair. The plan was to attempt to repair the thoracic aneurysm with a TSG despite the limited distal landing zone by covering the celiac axis (Figure 5). A sensor was placed alongside the stent graft prior to TSG deployment to confirm sac exclusion and decrease the need for repeated contrast injections (Figure 6). After graft deploy-

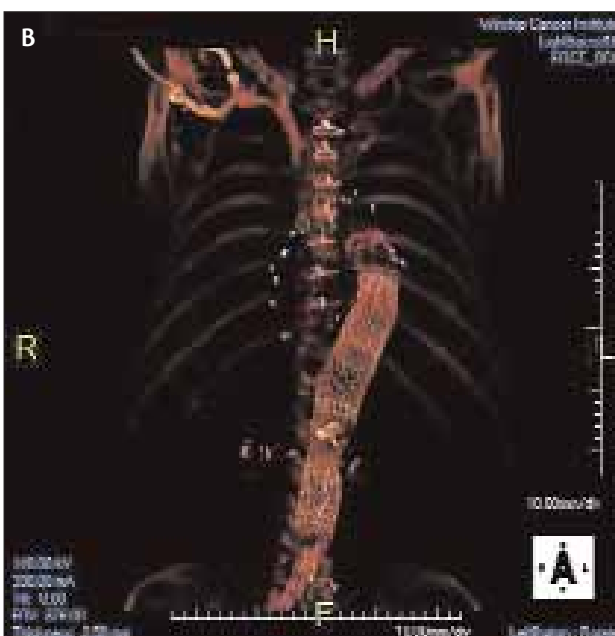
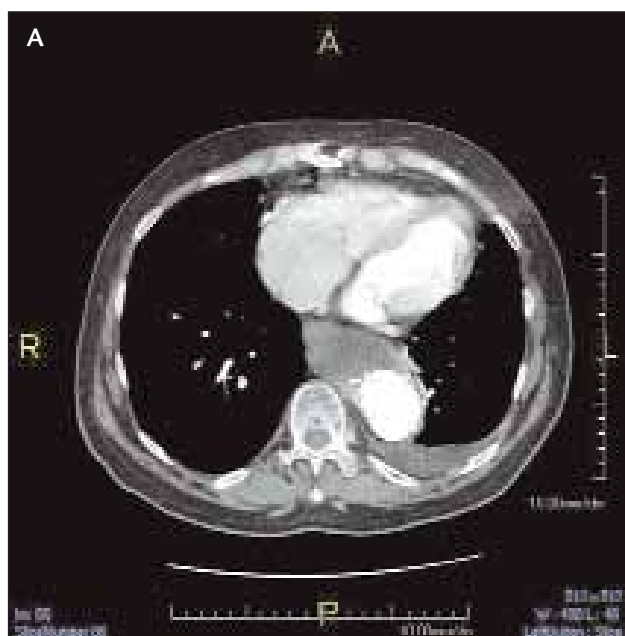


Figure 12. CT scan with the sensor in the excluded aneurysm sac (A). CT scan at 1 year confirms no migration of the sensor (B).

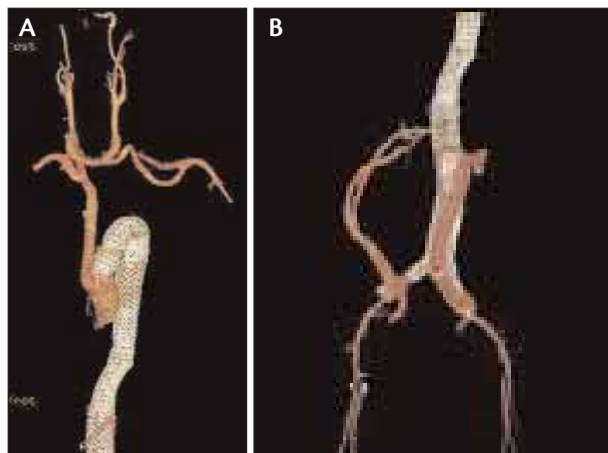


Figure 13. Total arch debranching and TSG exclusion of the arch and descending thoracic dissection (A). Total abdominal debranching and stent graft exclusion of the dissection (B).

ment and balloon dilatation, a faint contrast blush was noted in the sac on delayed films (Figure 7). On interrogation of the sac with the wireless antenna (Figure 8), the sac was found to have pressurized (Figure 9), highly suggestive of a distal type I endoleak. The patient was subsequently re-evaluated 1 week later for a total visceral debranching to facilitate complete exclusion of the thoracoabdominal aneurysm (Figure 10).⁵ After the debranching and stent graft extension, the sac pressure was found to be flat, which suggested complete sac exclusion (Figure 11). Follow-up CT scan at 1 year confirmed sac exclusion with no migration of the pressure sensor (Figure 12).

SENSORS FOR THORACIC AORTIC DISSECTION

A single patient presented with an extensive aortic dissection involving the entire arch. The thoracic and abdominal segment had a sensor implanted in the false lumen at the time of the TSG repair. This was possible due to the total thoracic and abdominal debranching required in this patient (Figure 13). In the absence of these debranching procedures, the author has not routinely used pressure sensors in the false lumen due to the potential risk of distal migration because the false channel often remains open despite successful proximal exclusion of the entry tear (Figure 14).

CONCLUSION

The advantage of using sensors for surveillance of TSGs is enormous. It eliminates the need for nephrotoxic contrast administration, eliminates patient exposure to repeated doses of ionizing radiation, and is the only available surveillance technique in patients who cannot toler-

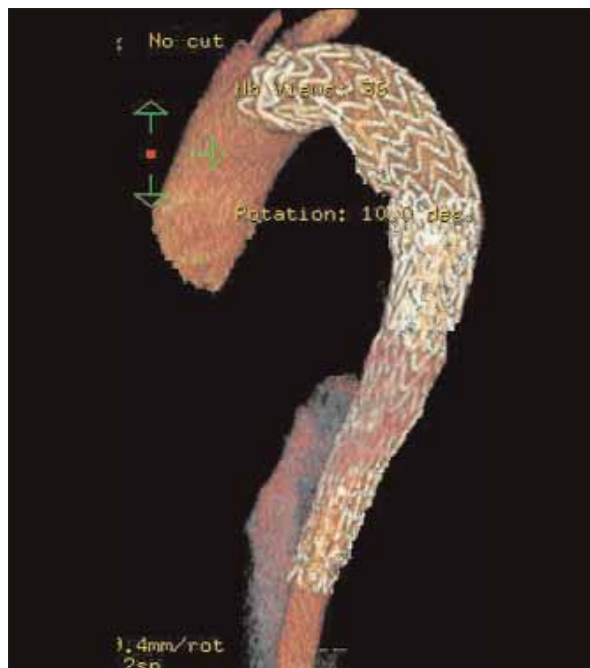


Figure 14. Persistent false lumen in a patient with chronic dissection distal to the TSG.

ate contrast agents. Additionally, it can be done in the office in a few minutes and does not require a visit to an imaging center.⁶ The use of sensors provides a significant time-saving and cost-saving benefit with minimal patient discomfort. Thoracic sensors should be an important adjunct to TSG surveillance, and further studies may establish this method as the gold standard, eliminating the need for other harmful and expensive imaging techniques currently in use. ■

Karthik Kasirajan, MD, is with the Department of Surgery at Emory University Hospital in Atlanta, Georgia. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Kasirajan may be reached at (404) 727 8407; karthik.kasirajan@emoryhealthcare.org.

1. Makaroun MS, Dillavou ED, Kee ST, et al. Endovascular treatment of thoracic aortic aneurysms: Results of the phase II multicenter trial of the Gore TAG thoracic endoprosthesis. *J Vasc Surg.* 2005;41:1-9.
2. White GH, Yu W, May J. "Endoleaks"—A proposed new terminology to describe incomplete aneurysm exclusion by endoluminal grafts [letter]. *J Endovascular Surg.* 1996;3:124-125.
3. Surowiec SM. Post-operative renal dysfunction following aneurysm repair. *J Vasc Surg.* 2004;39:804-810.
4. Dias NV, Ivancev K, Malina M, et al. Intra-aneurysm sac pressure measurements after endovascular aneurysm repair: differences between shrinkage, unchanged, and expanding aneurysms with and without endoleaks. *J Vasc Surg.* 2004;39:1229-1235.
5. Kasirajan K. Visceral debranching to facilitate repair of complex thoracic and thoracoabdominal aneurysms. *Future Cardiol.* 2007;3(3):271-281.
6. Milner R, Kasirajan K, Chaikof EL. Future of endograft surveillance. *Semin Vasc Surg.* 2006;19:75-83.