

# Remote Pressure Sensing for Thoracic Endografts

Is this recently FDA-cleared technology applicable to the acute exclusion and follow-up of thoracic aortic aneurysms?

BY ROSS MILNER, MD

**T**horacic aortic aneurysmal disease presents unique challenges to successful endografting as compared to the abdominal aorta. The tortuosity of the thoracic aorta and proximity to important branch vessels can make the technique very complex.<sup>1</sup> In addition, a long length of the thoracic aorta is routinely covered. This length of coverage commonly necessitates the placement of more than one endovascular device. All of these issues increase the chance of encountering an intraoperative type I or III endoleak. These unique features of the thoracic aorta also increase the risk of developing a type I or III endoleak during surveillance after repair. The current standard of care for intraoperative aneurysm exclusion is a completion arteriogram. The standard of care for follow-up surveillance is plain chest radiographs and CTA.<sup>2</sup> Remote pressure sensing

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allows for direct measurement of the systolic and diastolic pressure within the residual aneurysm sac. This technology recently has been cleared by the FDA for acute implantation and confirmation of exclusion of an abdominal aortic aneurysm (AAA). Remote pressure sensing for the thoracic aorta is still being investigated. It may serve as an adjunct to the standard imaging techniques or possibly replace them as standard of care for the confirmation of aneurysm exclusion and surveillance after repair.

## REMOTE PRESSURE SENSING FOR THE ABDOMINAL AORTA

As mentioned previously, the FDA recently cleared for marketing the CardioMEMS EndoSure Wireless AAA Pressure Sensor (CardioMEMS, Inc., Atlanta, GA) for acute implantation and assessment of intraoperative exclusion of an AAA (Figures 1 and 2). The data for FDA marketing clearance were collected during the APEX trial (Acute Pressure measurement to confirm aneurysm sac EXclusion). Seventy patients were enrolled in nine centers in the US and three centers outside of the US.<sup>3</sup> The data clearly demonstrated the efficacy of the technology in



Figure 1. The CardioMEMS EndoSure Wireless AAA Pressure Sensor.



Figure 2. CTA in a patient with a large AAA 1 month after treatment with an endograft and a remote pressure sensor. The pressure sensor is highlighted by an arrow.

assessing intraoperative aneurysm exclusion. There was also minimal morbidity and mortality during the trial, with none of these complications occurring as a result of the EndoSure insertion.

Long-term data for postprocedure surveillance are being collected and evaluated. An additional trial is being established to more formally evaluate chronic surveillance efficacy with the EndoSure sensor. Part of the difficulty with the surveillance of AAA repair is the identification and management of type II endoleaks. The sensor may assist with the determination of worrisome type II endoleaks based on elevated residual sac pressures. The type II endoleak enigma is usually not an issue with thoracic endografting. This characteristic makes pressure sensing even more attractive for determining endograft failures in the thoracic aorta.

### REMOTE PRESSURE SENSING FOR THORACIC AORTIC ANEURYSMS

The anatomic distinctions of the thoracic aorta have been clearly described. These characteristics lead to a propensity to develop type I and/or type III endoleaks, with the development of systemic pressure within an aneurysm sac. This is true for acute exclusion during the implant procedure and for follow-up surveillance. The current intraoperative confirmation of exclusion is the completion arteriogram. The completion arteriogram may be limited in its efficacy due to a large amount of contrast material used during the endograft insertion and the concern for total contrast load. In addition, there are times when the arteriogram leads to questionable findings

of an endoleak. This doubt can lead to the insertion of unnecessary extension cuffs.

Follow-up surveillance usually consists of plain chest radiographs and CTA. Due to the contrast load and radiation exposure, these examinations are obtained annually or semiannually. Significant changes in the location of the device or devices can occur, as well as expansion of the aneurysm in this extended time period. Type I or III endoleaks are the real concern with thoracic endografting because type II endoleaks rarely occur. Therefore, systemic pressurization within the aneurysm sac will occur when endoleaks develop.

Remote pressure sensing may be able to eliminate the difficulties mentioned for intraoperative exclusion and postoperative surveillance. A reduction in pressure during the implant procedure will confirm appropriate exclusion. In addition, because there is no risk to frequent evaluations with the remote pressure sensing system, multiple examinations may be performed for a given patient on an annual basis. This may allow earlier detection of systemic pressurization within a previously excluded aneurysm sac. In light of these properties, remote pressure sensing appears to have a significant advantage over the current paradigms for aneurysm exclusion and follow-up in the thoracic aorta.

### THE TARGET TRIAL

The first successful implant of a remote pressure sensor into a thoracic aneurysm was performed in Florianopolis, Brazil, by Pierre Silveira, MD, and myself (Figure 3). The details of the procedure and patient surveillance will be presented at the International Congress on Endovascular Interventions XIX in February 2006. The initial success has allowed the development of a clinical trial to further evaluate the technology's utility in the thoracic aorta.

The TARGET trial (Thoracic Aneurysm Pressure During

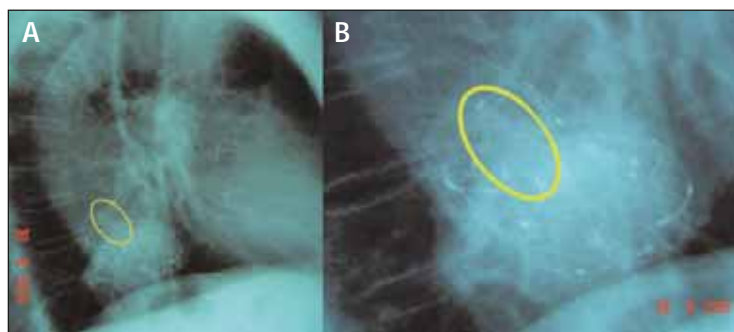


Figure 3. Lateral chest x-ray performed 1 month after treating a thoracic aortic aneurysm by an endovascular graft. The pressure sensor is circled in yellow on the chest x-ray within the residual aneurysm sac. The sensor in the thoracic aorta on a plain chest radiograph (A). A magnified view of the sensor itself (B).

Endografting) will begin in the early to late spring of 2006. TARGET will be a multicenter study to evaluate the safety and efficacy of the CardioMEMS EndoSure Wireless AAA Pressure Sensor in the thoracic aorta. The key component of the study will be the evaluation of intraoperative aneurysm exclusion as determined by postendograft pressure reduction. This trial will be limited to aneurysmal disease treated with an FDA-approved endograft.<sup>4</sup>

## FUTURE DIRECTIONS

An additional thoracic aorta pathology in which remote pressure sensing may have a role is in the management of aortic dissections. The endovascular management of type B aortic dissections is rapidly expanding. One of the treatment goals is depressurization of the false lumen. Remote pressure sensing may be useful in assisting with determination of appropriate exclusion of the false lumen during treatment of a type B aortic dissection.

## CONCLUSIONS

Remote pressure sensing has already proved efficacious in confirming acute exclusion of an AAA by endovascular means during the APEX trial. These data have allowed for






FDA clearance of remote pressure sensing for AAAs. Its role in the thoracic aorta seems clear with the risks of type I and type III endoleaks. The initial successful implant in Brazil has spawned a clinical trial that will hopefully prove its safety and efficacy for thoracic aneurysms. The technology may be useful in the long-term in a variety of thoracic aortic pathologies. ■

*Ross Milner, MD, is an Assistant Professor of Surgery in the Division of Vascular Surgery in the Emory University School of Medicine, Atlanta, Georgia. Dr. Milner serves as an advisor for CardioMEMS, Inc., and is a paid consultant for Gore & Associates. Dr. Milner may be reached at (404) 727-8407; ross.milner@emoryhealthcare.org.*

1. Tse LW, MacKenzie KS, Montreuil B, et al. The proximal landing zone in endovascular repair of the thoracic aorta. *Ann Vasc Surg.* 2004;18:178-185.
2. Grabenwoger M, Fleck T, Ehrlich M, et al. Secondary surgical interventions after endovascular stent-grafting of the thoracic aorta. *Eur J Cardiothorac Surg.* 2004;26:608-613.
3. Ohki T. Presentation. Preliminary outcome of wireless pressure sensing for EVAR (the Apex Trial). Society for Vascular Surgery, Philadelphia, PA. June 18, 2005.
4. 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.

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