

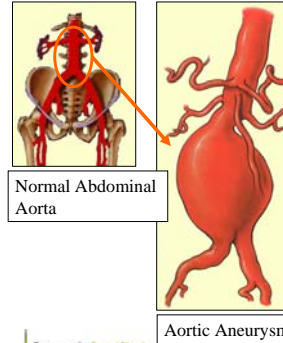
Wireless Implantable Micromachined Pressure Sensors: Approach and Clinical Demonstration

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The Problem: Abdominal Aortic Aneurysms (AAA)



- Magnitude of the problem**
- 13th leading cause of death
 - 3rd leading cause of sudden death in men >60
 - Prevalence 1.3-1.5 mil. 200K newly diagnosed annually
 - Congress likely to add AAA screening benefit



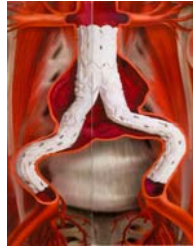
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AAA Therapy

Traditional Therapy: **Surgical Graft** Growing Therapy: **Stent-Graft**



Open procedure, long recovery



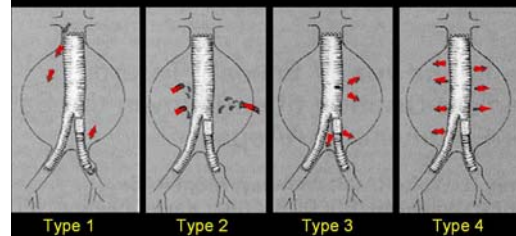
Endovascular procedure, quick recovery



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But: what if it leaks?

Endovascular Repair of AAAs "Endoleak" Persistent pressurization of AAA



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Potential for Rupture Following AAA EVAR Over Time Requires Long-term Monitoring

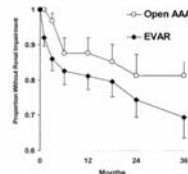
All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft, aneurysm size, and occlusion of vessels in the treatment area. (excerpt from stent graft product label; required by FDA)



CT scan with IV contrast; biannually to annually

Relationship of proximal fixation to postoperative renal dysfunction in patients with normal serum creatinine concentration

Scott M. Surowiec, MD,* Mark G. Davies, MD, PhD,^{1,2} Allison J. Fogley, MD,² William J. Tanoki, MD,² Vickie N. Pannoskian, MD,² Yaron Sternbach, MD,² David L. Waldman, MD,² and Richard M. Green, MD,² Rochester, NY



# at Risk	0 Months	12 Months	24 Months	36 Months
EVAR	113	60	46	30
Open	55	42	22	13

Conclusions: A decrease in kidney function is seen after EVAR, regardless of fixation level, that is independent of renal disease and renal arterial occlusion. The decrease in renal function is likely related to the repetitive administration of contrast agent.

Surowiec SM et al. J Vasc Surg 2004;39:804-10

A better monitoring concept

- Place a sensor inside the aneurysm sac to monitor sac pressure
 - » Wireless
 - » Exists for lifetime of patient
 - » Area is inaccessible - no opportunity for sensor replacement or battery replacement
- Increase in sac pressure indicates potential problem to be addressed
 - » Look carefully with CT scan
 - » Endovascularly repair stent graft
 - » Open repair

Comparison of Monitoring Techniques

	CT/MRI	Pressure Sensing
Location	Hospital	Office/home
Contrast Agents	Yes	No
Parameter Measured	Diameter change, volume change, presence of contrast	Mean Pressure Pulsatile Pressure
Sensitivity	Low	High
Timing	1-2 per year	As needed (hourly - monthly)
Risk to patient	Contrast reaction	None
Pacemaker Compatibility	CT - Compatible MRI - Not compatible	Compatible

Wireless AAA Sac Pressure Measurement System

System Features:

- Non-invasive stable sac pressure measurement
- Endovascular introduction at time of procedure
- Compatible with all stent-grafts
- Simple & fast external monitoring



Technology Partitioning

- There is a part that goes inside the patient (sensor) , and a part that is external to the patient (readout apparatus)
- Sensor + readout = system
- Murphy's law: total complexity is preserved

• Approach 1

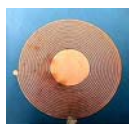
- » Make sensor as simple as possible
- » Consequence: readout apparatus is complex

• Approach 2

- » Make readout apparatus as simple as possible
- » Consequence: sensor is complex

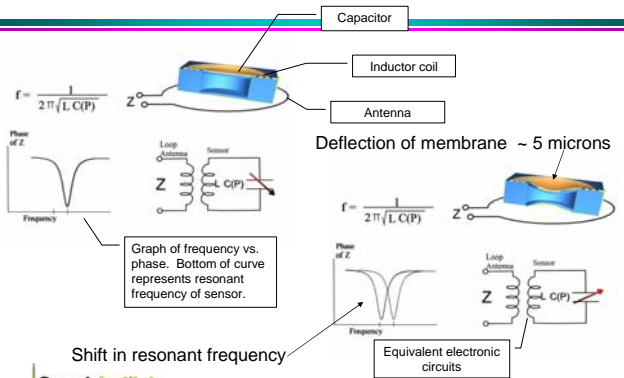
Approach 1 allows the potential for increased sensor reliability, continual upgrading of readout apparatus

Previous Work: Wireless Passive Pressure Sensor

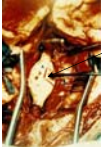


Research program sponsored by the Army Research Office and NASA focused on the design, fabrication and implementation of wireless micromachined ceramic sensors for high temperature environments serves as the basis of the biomedical sensor technology

Sensor Concept



In-vivo Wireless Pressure Measurement Chronic Evaluation: Animal Model

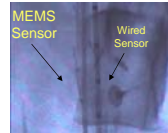


Mock aneurysm
with wired sensor

Chronic Animal Trial

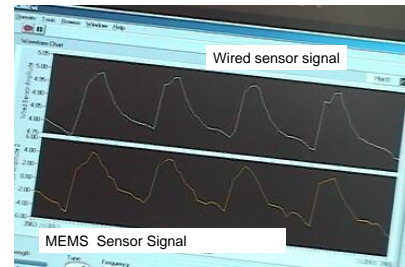
- » Adult canine model
- » Mock aneurysm with wired pressure transducer
- » Endovascular delivery of sensor
- » Stent-graft implantation

In-vivo Wireless Pressure Measurement Chronic Evaluation: Animal Model



MEMS
Sensor

Wired
Sensor



AAA Pressure Monitoring System

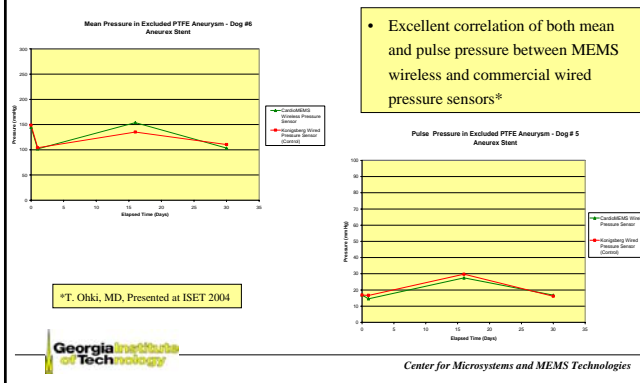
Sensor Evolution

- Acute pressure measurements
- Long term safety (one year implants)
- Folding prior to delivery
- Dual antenna system

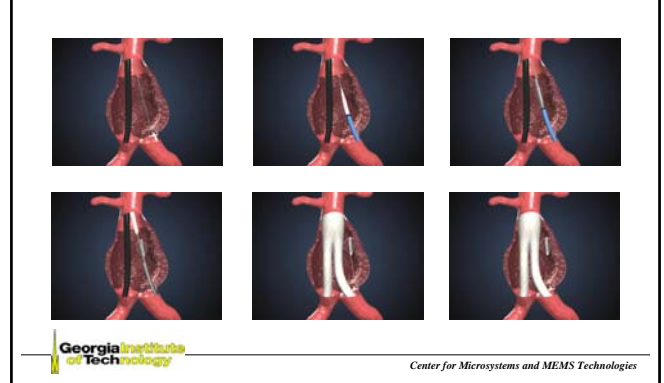


- Long term stability in vivo
- Improved accuracy
- Simplified delivery
- Single antenna system

In-vivo Wireless Pressure Measurement Chronic Evaluation (Animal Study)



Implant Procedure



Clinical Case - Example

AAA Repair with Insertion of CardioMEMS Pressure Sensor

Date: March 19, 2004

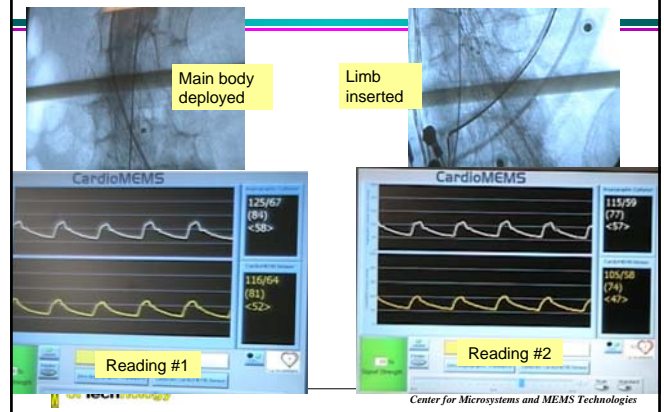
Location: S.O.S. Cardio, Florianopolis, Santa Catarina, Brazil

Device: Apolo Stent-Graft, Nano Endoluminal

Attending Physicians: Takao Ohki, MD; Pierre Silveira, MD., Mariano Ferreira, MD



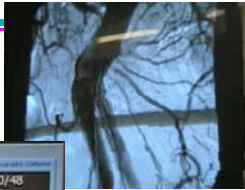
Clinical Study



Clinical Study



Insertion of extender cuff



Completion angiogram



Clinical Case – Second Example

Date: July 22, 2004

Location: Cleveland Clinic, Cleveland, Ohio

Device: AneuRx Stent-Graft, Medtronic

Attending Physicians: Ken Ouriel, MD, Dan Clair, MD, Takao Ohki, MD; Jay Yadav, MD



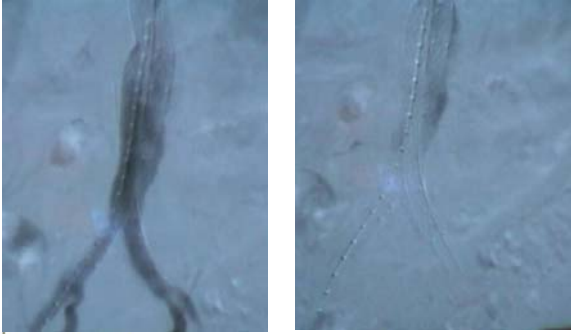
Initial Angiogram and Graft Deployment



Pressure Measurement



Endoleak Present on Angiography

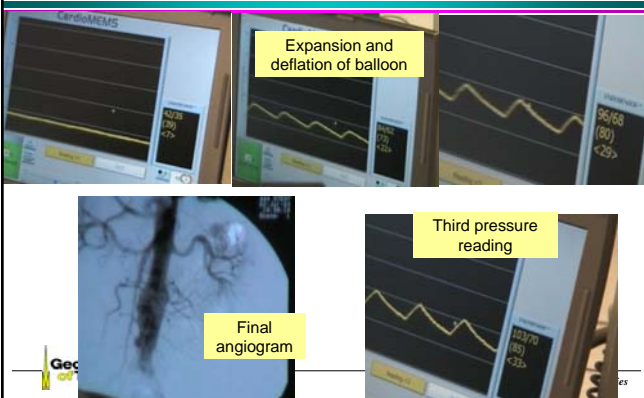


No Change to Intra-sac Pressure

Sensor marker bands



Pressure Guided Intervention



Expansion and deflation of balloon

Final angiogram

Third pressure reading

Low Pressure at 24 Hour Follow-up



Cough test

Conclusions and Lessons Learned

- There is a tremendous opportunity for implantable MEMS devices (structures, sensors, actuators) in the body
 - » Matching of size scales
 - » Improvements in electronics
- Make what you put in as complex as it has to be, but no more
 - » Reliability and functionality are paramount
- There is a tremendous gulf between working on the bench and in the body
 - » 'Real-world' technical issues
 - » Regulatory - FDA, IRB, FCC, etc.
- **Let's get to work!**

Acknowledgements

- Collaborators:
 - » Jay Yadav, M.D. (Cleveland Clinic Foundation)
 - » Takao Ohki, M.D. (Montefiore Medical Center, NY)
 - » David Stern (CardioMEMS, Inc.)