

An Implantable Pressure Sensor for Aneurysmal Disease

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Abstract

Abdominal aortic aneurysm is the swelling of the main artery in the body due to the weakening of the arterial wall, making it vulnerable to life-threatening ruptures. Current treatment involves implanting a graft to exclude the problem area. However, there is still a danger of increased pressures in the excluded area as a result of leakage at the graft boundaries. These pressures are generally monitored semi-annually with costly medical imaging. The proposed device is a biocompatible MEMS pressure sensor implanted in the aneurysmal sac that can provide real time pressure measurements such that imaging is unnecessary. The sensor presented here has a width of 1mm and a height of 530 μ m so that it may be implanted along with the graft. It is sensitive enough to resolve 1 mmHg for a pressure range of 0-3000 mmHg.

Background

An aneurysm is an irreversible dilation of an artery to at least one and one-half its normal diameter. An abdominal aortic aneurysm (AAA) is therefore defined as a localized or diffuse enlargement of the abdominal aorta, usually exceeding 5 to 6-cm in diameter. AAA's develop from a weakness or defect in the aortic wall, and have a tendency to be a self-perpetuating process. The natural history of AAA's is one of progressive enlargement over time as a result of tension related to passive dilation from hemodynamic forces, and a complex remodeling process involving the aortic wall that leads to a focal

loss of elastic tissue.¹ The ultimate result of this progression is the rupture of the AAA, producing serious and even lethal consequences.

Although AAA is one of the most serious cardiovascular diseases, in clinical practice 70% to 80% of AAA patients are asymptomatic at the time of initial diagnosis. This is because AAA's are generally coincidentally discovered either as a pulsatile mass on physical examination or unexpectedly during the course of an evaluation for other medical conditions.²

Autopsy reviews have determined that the incidence of AAA in the general population is between 1.8% and 6.6%³⁻⁵, reaching as high as 20% in high risk patients⁶⁻⁸, of which 190,000 cases per year are diagnosed in the United States.⁹ If untreated, the 5-year survival rate in AAA patients is 17% to 19%, with 35% to 63% of deaths resulting from aneurysm rupture.^{10,11} Aneurysm rupture kills more than 15,000 people each year in the United States, making it the thirteenth leading cause of death in both sexes and the tenth leading cause of death in males greater than 55-years of age.¹²

A minimally invasive approach (developed by Juan Parodi¹³) is being investigated for the repair of AAA's, using endovascular techniques to place an intraluminal stent-anchored prosthetic graft within an aneurysm, effectively excluding the aneurysm from normal circulation. Generally, the components of this technique include an endovascular graft (EVG), stents that anchor the graft to the arterial wall, and the delivery system used to deploy the prosthesis to its appropriate anatomic location following retrograde cannulation of the common femoral artery.

EVG repair of AAA's has been experimentally used in humans since 1991.¹⁴ The surgery takes two to four hours and has a mortality rate of 0-2% with fewer serious complications than open surgery.¹⁵ The average cost per procedure is \$12-13,000 (excluding physicians' fees), hospital stays are usually 1-3 days and convalescence is faster compared with open surgery.¹⁵

Endovascular repair therefore represents an important alternative to open surgery and will likely become the standard treatment for a large proportion of AAA patients. Controlled clinical studies are now in progress to compare the results of endovascular and open repair of AAA's. The results of these trials are expected to allow governmental approval of appropriate medical devices, which in effect will minimize the morbidity and mortality of AAA repair.

Although EVG repair of AAA shows promise, there are several important limitations to consider with respect to the usefulness of the EVG. These include endoleak (leakage of blood into the aneurysm sac), graft migration, aortic neck dilatation and inadequate normal cuff dimensions for graft fixation. These observed problems not only reduce the eligibility criteria for AAA patients but also necessitate close and prolonged follow-up regimens with CT and MR imaging studies, which incur considerable costs.

The pathogenesis of AAA's involves the attenuation of all arterial wall components following a decrease in collagen and elastin content in the media and adventitia, which places a greater load on each aortic muscle fiber causing it to dilate progressively. Because the lateral wall tension of a vascular tube is related to the radius by Laplace's law (tension = pressure x radius), then as the aneurysm radius increases, the greater the wall tension. Rupture eventually occurs when the lateral tension at any point exceeds the tensile strength of the vessel wall. Generally, further imaging is performed to determine the extensions of the aneurysm or evidence of adequate collateralization for

operative planning. When endovascular repair with stent-grafting is performed, the graft material of most prosthetics is polyester, and the stents are made of stainless steel or nitinol and may be self-expanding or balloon-expandable. The fixation may be through barbs on the outer aspect of the stent, but some stents rely on friction alone. The delivery system is via catheter and at present, the outer diameter of the introducers is from 18 to 24 F, allowing placement through most but not all femoral and iliac arteries with a groin cutdown. Postoperatively these patients recover faster with lower mortality and complication rates compared to open surgery.

However EVG repairs have important limitations and complication profiles such as the re-expansion of the excluded AAA as a result of persistent endoleak leading to repressurization of the aneurysm with the risk of rupture. Endoleaks are insidious because they appear long term and are unpredictable, necessitating long-term regular follow-up visits and imaging studies. The incidence of endoleaks varies from 10-44% for various trials of the EVG device, with more than half of these cases being short-term and self-sealing.¹⁶⁻²⁰ The endoleaks depend on the security of fixation at the upper and lower ends and on the nature of the graft wall support.²¹ White et al.²² have classified endoleaks into four types based on their mode of development. Type I endoleaks occur at the proximal and/or distal attachment zones, Type II endoleaks occur as a result of retrograde flow from patent lumbar and inferior mesenteric arteries, Type III endoleaks arise from a defect in the graft fabric, and Type IV endoleaks are due to graft fabric porosity.

Implantable pressure sensors are devices we propose to add to the endovascular technique (EVT) in order to improve patient follow-ups with real time continuous pressure monitoring, thereby providing earlier notification of potential complications. Our pressure sensor developed using MEMS technology will be incorporated in the redundant aneurysmal sac in

order to continuously monitor pressure changes in the excluded aneurysmal sac. It will be able to detect and alert the surgeon of elevations in pressure both intra- and post-operatively. Intraoperatively this enables the surgeon to further investigate for backbleeders or Type II endoleaks; and postoperatively this potentially decreases the costs from expensive follow-up imaging studies presently used to monitor the occurrence of Types I – IV endoleaks.

Design

The basis of the design is an existing piezoresistive pressure sensor which consists of doped polysilicon structures for the sensing elements, a silicon nitride layer as a membrane for deflection, and a silicon substrate as a structural foundation. The original pressure sensor needed to be modified for the following constraints: 1) biocompatibility, 2) dimensions, 3) pressure range, 4) operational temperature range, 5) sensitivity, and 6) cost.

By coating the entire device with a layer of Parylin PI 2555 polyimide from Dupont, biocompatibility is ensured as the polymeric material has been proven to be implantable as seen with its use in the various pacemakers on the market.

In order to insert the implantable pressure sensor, the device must be small enough to fit within a catheter. This requires the width and height of the device each not exceed 1 mm.

The normal pressure range of a human being is 120/90 mmHg, the former being the systolic blood pressure; the latter, diastolic. Patients are considered in danger when their pressures reach 200 mmHg. After the proposed graft/implant procedure, there should be no pressure in the excluded aneurysmal sac, so a pressure range of 0-300 mmHg is desired.

To be functional, the device must be able to operate at body temperature, which ranges from 35-40 °C. This is a trivial matter, since all

the materials being used can withstand much greater temperatures.

The device should be able to detect pressure variations of as little as 1 mmHg for valid detection. This value is more than adequate to sense backflow of blood in the area.

This MEMS solution is being proposed to compete with the existing post-operative procedure of routine medical imaging, which can cost a patient approximately \$600 per year. Market studies show that MEMS PS solution should cost no more than \$150 per device. For the patient, this device is virtually free three months after implantation!

Implementation

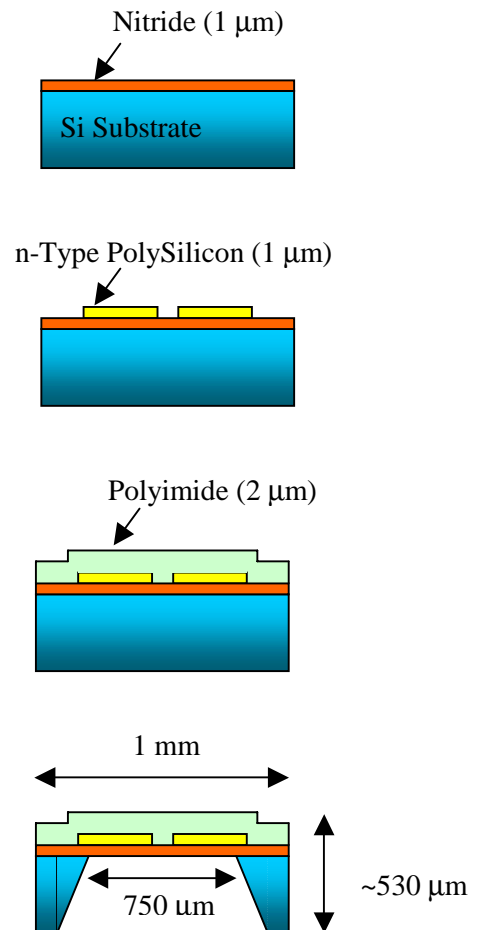


Figure 1. Process flow

Fabrication of the proposed device begins with a typical Si substrate of thickness 525 μm . A 1 μm coat of low stress silicon nitride is deposited using LPCVD. Then n-doped polysilicon structures of thickness 1 μm are deposited and patterned. Next, a series of polyimide layers are spun coated and baked until the desired thickness of 2 μm is reached. Finally the membrane is released by bulk back-side etching of the silicon substrate. Another substrate should then be bonded to the back-side to seal the cavity and then a deposition of polyimide should be repeated on the back side to seal the entire design.

Analysis

The MEMS device was analyzed to determine the effect of the additional polyimide layer on the device's performance and to establish whether this design is capable of being used as a preventative measure for aortic rupture.

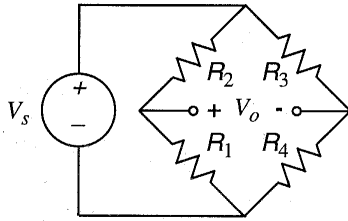


Figure 2. Wheatstone Bridge Configuration

A Wheatstone bridge configuration is used to convert the change in resistance to a change in voltage. The transfer function²³,

$$\frac{V_o}{V_s} = \frac{R_1 R_3 - R_2 R_4}{(R_1 + R_2)(R_3 + R_4)}$$

can be simplified and equated to the strain²⁴ on the membrane by assuming $R_1 = R_3$ and $R_2 = R_4$.

$$\frac{V_o}{V_s} = \frac{R_1 - R_2}{R_1 + R_2} = \frac{\Delta R}{R} = -\varepsilon \times \text{gauge factor}$$

For calculation purposes, the square membrane was approximated as a circular membrane since a general expression for the bending of a uniform thickness rectangular membrane does not exist and numerical methods are generally utilized to obtain stress-strain relations for the plate.

From Roark's Formulas for Stress and Strain²⁵,

$$\varepsilon = \frac{\Delta P}{E} \times \frac{3a^2}{8t^2} \times \left[(3 + \nu) \left(\frac{r}{a} \right)^2 - (1 + \nu) \right]$$

The maximum strain occurs at the edges of the square membrane where r equals a . This eliminates the dependence on the Poisson ratio, ν . The Young's Modulus, E , was approximated for the nitride-polyimide membrane using a weighted average²⁶ according to the following:

$$E = \frac{E_{\text{Nitride}} \times t_{\text{Nitride}} + E_{\text{Polyimide}} \times t_{\text{Polyimide}}}{t_{\text{Nitride}} + t_{\text{Polyimide}}} = 91.33 \text{ N/m}^2$$

A relationship between change in pressure and measured voltage can now be found easily as:

$$\Delta P = \frac{4Et^2V_m}{3 \times G.F. \times V_s \times a^2}$$

The gauge factor of n-doped polysilicon is 20. The supply voltage was assumed to be 5V. The result of this calculation is that for every 1 mmHg of pressure change, a 1.7mV change in voltage can be measured, which leads to the conclusion that 1 mmHg change is detectable.

When the sensor is calibrated such that 0 mmHg outputs 0 V, the maximum output should be 5V which corresponds to a maximum pressure of approximately 3000 mmHg.

Conclusion

Using MEMS PS technology, all of the required parameters for biocompatibility have been achieved. The polyimide coating is not

only implantable but it does not significantly affect the stress-strain properties that are crucial for the deflection of a pressure sensor membrane. The width and height requirement of not exceeding 1 mm in order to fit within the catheter was achieved. Over a range of 0-3000 mmHg, we are able to detect a sensitivity of 1.7mV/mmHg. All of our materials function within the necessary normal human body temperature range. Finally, in terms of manufacturing, the projected cost falls way below that of the competing technology's, namely an estimate of \$150/year in comparison with the standard \$600/year.

Furthermore the benefits of this technology are astronomical. The application of this device can carry over to many other pressure-sensitive biomedical situations.

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