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A thin-film pressure transducer for implantable and intravascular blood pressure sensing

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ABSTRACT

The mm-scale of micromachined pressure transducers limits numerous cardiovascular applications, including implantable pressure sensing. Here, a pressure transducer is presented which adds approximately 15 μm to the surface of an intravascular device, potentially enabling low profile implantable devices with pressure sensing functionality. The capacitive transducer consists of a polyimide diaphragm which can be transferred to an arbitrary substrate, including cardiovascular catheters, stents, or other intravascular devices. The transducer has good static and dynamic characteristics for cardiovascular applications, including pressure sensitivity of 2.5% over 400 mmHg and an estimated flat frequency response of 500 Hz. Additionally, good waveform fidelity was demonstrated in a flow loop relative to a research grade cardiovascular pressure transducer.

1. Introduction

Elevated blood pressure, or hypertension (HTN), is the leading modifiable risk factor for cardiovascular mortality in the United States [1–4]. HTN is responsible for about 50% of strokes and heart attacks, and is a primary causative factor in heart failure, renal disease, and other end organ damage [5,6]. Prevalence is high and rises with age, such that over half of the population over age 60 is hypertensive [7].

Continuous monitoring of blood pressure offers advantages in the diagnosis and therapy of HTN and its comorbidities [8–13]. However, implantable blood pressure sensors face severe size constraints in the vasculature, which have limited their application. Conventional battery-powered sensors are match-book sized devices which are implanted extravascularly and have intravascular pressure sensing probes [14]. This approach complicates surgical implantation and long term stability [15,16]. Alternative resonant sensing permits sufficient miniaturization for fully intravascular implantation, yet current devices are not small enough for placement outside of cardiac chambers or large elastic arteries [13,17–20].

A critical limitation for conventional and resonant sensors is the overall size of pressure transducers, which are about 500 μm thick and 1×1 mm^2 in area [21–28]. This scale is inappropriate for intravascular implantation into a typical artery, with internal diameters of several mm or less. Clinical risks would include thrombosis and obstruction of blood flow. Additionally, clinical experience from cardiovascular stenting indicates that structures greater than 100 μm may induce vascular damage and prevent long term stability [29–33]. Fig. 1 compares two modern micromachined pressure sensors with a cardiovascular stent strut to emphasize the degree of down scaling necessary for ideal vascular compatibility.

Interestingly, while the overall size of micromachined pressure transducers is large, the active sensing portion is a micron-thick slice which rests on the surface of an otherwise inert support chip.

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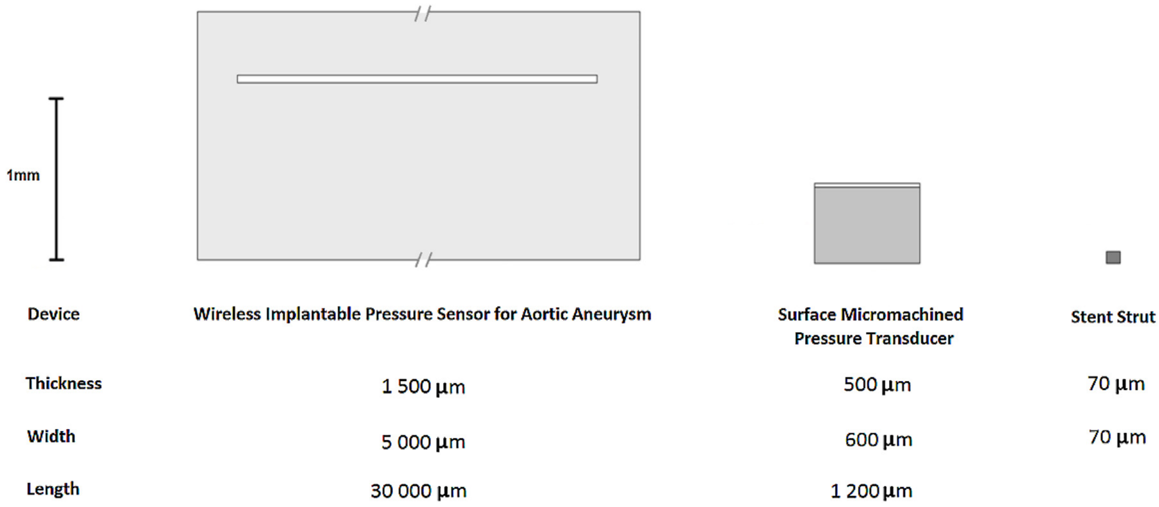

Fig. 1. Cross-sections of three potential intravascular devices: a wireless implantable pressure sensor for aortic aneurysm pressure monitoring (CardioMEMS EndoSure) (20), a state-of-the-art surface micromachined pressure transducer (MicroFAB E1.3N) (21), and a coronary artery stent (Palmaz-Schatz Crown) (33). In practice, the CardioMEMS device is typically further insulated with silicone to 2 mm in total thickness.

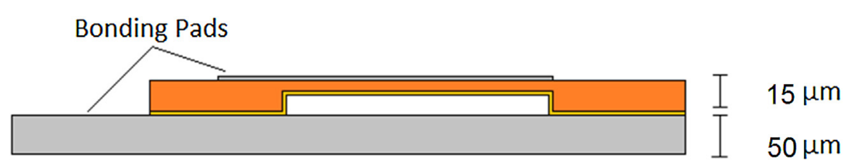

Fig. 2. The low profile transducer adds approximately 15 μm thickness to an arbitrary surface. Here, the transducing diaphragm was constructed from PMDA-ODA polyimide and adhesively bonded to stainless steel foil, a stent-like substrate.

For surface micromachined transducers, sensing diaphragms are commonly on the order of 1 μm thick and $100 \times 100\,\mu m^2$ in area [21,28,34,35].

One potential solution to the overall scale problem is thus the development of transducers which are built independently of their bulky ceramic substrates, eliminating hundreds of microns of thickness. Low profile transducers could then be used to functionalize the surface of an intravascular device, such as a stent, catheter, or other implantable device, with minimal impact. Here, a demonstration of such a low profile pressure transducer is presented.

2. Design and theory

A thin film capacitive transducer was designed as a metalized diaphragm structure over a conductive base, illustrated in Fig. 2. For prototyping, this consisted of a polyimide diaphragm over stainless steel foil, to simulate the surface functionalization of a cardiovascular stent.

The diaphragm structure was fabricated from various polyimides, a class of polymers which are well regarded for their strength, stability, and biocompatibility [36–39]. To date, several pressure sensors with polyimide diaphragms have been reported for biomedical and other applications [40–42]. Reasons for polymer construction included ease of fabrication and mechanical advantage in deflection due to material properties.

It is important to review the mechanics of transducing diaphragms because a polymer was chosen the diaphragm material. The fundamental characteristics of diaphragms for pressure transducing include deflection behavior, stresses, and resonant frequency. Respectively, these factors determine pressure sensitivity, mechanical stability, and the frequency response of the diaphragm. The impact of diaphragm dimensions and material are shown below in the relationships for maximum deflection d_{max}, maximum stress σ_{max}, and resonant frequency f_0.

$$d_{max} \,\alpha\, P\frac{l^4}{t^3 E} \tag{1}$$

$$\sigma_{max} \,\alpha\, P\frac{l^2}{t^2} \tag{2}$$

$$f_0 \,\alpha\, P\frac{t}{l^2}\sqrt{\frac{E}{\rho}} \tag{3}$$

where t is diaphragm thickness, l is length, E is elastic modulus, ρ is density, and P is applied pressure. These relationships apply to circular and rectangular diaphragms with most boundary conditions, and only hold when intrinsic stresses in the diaphragm are low [43,44].

As can be seen from Eqs. (1)–(3), the dominant factor in the diaphragm behavior is its *thickness: length* aspect ratio. Mechanical properties like elastic modulus are impactful, but considerably less important. Most ceramic diaphragm based pressure sensors have a t: l ratio of about 1: 100 [28]. A polymer based diaphragm of the same aspect ratio, with a lower E (order of 1 GPa vs 100 GPa), should have more deflection and thus higher sensitivity. Also, unlike piezoresistive transducers, pressure sensitivity in capacitive sensors is a function of diaphragm deflection rather than film stresses on surface piezoresistors. Still, film stresses are important to consider for polymer diaphragms in particular. If film stresses approach or exceed the polymer yield stress anywhere on the diaphragm, the diaphragm will be subject to mechanical creep or plastic deformation. This will first change the behavior of the diaphragm and ultimately will result in mechanical failure.