31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

Hybrid Micro-Technologies for Medical Applications

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***Abstract*—Medical applications have long provided an impetus for research in silicon-based microsystems. This paper explores micro-technologies that complement and extend conventional manufacturing approaches and applications. For example, lithographic microfabrication methods can be used to fabricate stents and integrated microsensors that can monitor lumen patency in cardiac and biliary applications. These methods can also be extended to the fabrication of ceramic-based piezoelectric transducers. One potential application is to provide tissue density measurements at the tip of a biopsy needle. Piezo-thermal elements may additionally provide the means for precise cauterization and tissue ablation. Other examples of hybrid micro-technologies are also provided.**

I. INTRODUCTION

Medical applications have historically provided a major impetus for microsystems research, and will continue to do so for the foreseeable future. In the past two decades, microsystems research has diversified substantially beyond the early successes in silicon-micromachined devices, such as pressure sensors, accelerometers, and neural probes [1-2]. This paper explores some of the emerging technologies. For example, it is now possible to use lithography-based manufacturing methods to fabricate stents, and to integrate wireless sensing capabilities with the stents. Antenna-stents fabricated from stainless steel may be instrumented with silicon-micromachined capacitive pressure sensors, resulting in a hybrid system that could be potentially useful for cardiac applications. Biliary stents, which operate in a low-flow regime, require a different transduction mechanism. Wireless magnetoelastic sensors look promising in this regard. In another context, piezoelectric transducers offer the capability for ultrasonic sensing of tissue density at the tip of a biopsy needle. This technology may be extended to provide tissue ablation and cauterization. More traditional piezoelectric actuation is also used in low-power valves that are integrated into a drug delivery pump.

II. STENTS

A. Pressure-Based Measurements

For chronic monitoring of blood flow in arteries, pressure measurements in stents are an attractive option. Takahata *et al.* described a stainless steel structure that was micro-electro-discharge machined from 50 µm-thick planar foil for intraluminal measurements of pressure and flow [3]. An inductive antenna stent (stentenna) with 20-mm length and 3.5-mm expanded diameter was coupled with capacitive elements to form resonant LC tanks that could be telemetrically queried to sense changes in pressure and flow. Using water as the test fluid, the resonant peaks shifted from about 215 to 208 MHz as the flow was increased from 0 to 370 ml/min.

B. Mass and Viscosity Measurements

Pressure measurements are less attractive for applications such as biliary stents, through which the flow is relatively slow, and the pressure is not regulated in a predictable manner. Magnetoelastic sensors are more promising in this context. A resonant frequency shift caused by the accumulation of sludge on the sensor can be detected remotely. This type of device presents different microfabrication challenges than the pressure-sensing stent: while a pressure sensing diaphragm does not have to be fabricated and integrated with the stent, it is necessary to integrate magnets that provide a magnetic field of fixed orientation relative to the sensing element.

Green *et al.* described a system for wirelessly monitoring the accumulation of sludge in a biliary stent [4]. Two types of systems were reported. The first utilized a 2 x 37.5-mm^2 ribbon sensor, along with 0.8-mm-thick x 1.6-mm-diameter neodymium magnets to bias the sensor. Both components were integrated with a 4-mm-diameter stainless steel stent. The second system used similar sensors, but the magnetic bias was provided by a layer of strontium ferrite particles suspended in a conformal polymer covering of the stent. In both cases, the sensors were fabricated from 28-µm-thick foils of magnetoelastic 2826MB Metglas, an amorphous Ni–Fe alloy. The response of each system to the type of viscosity changes (over a 10-cP range) that would normally accompany biliary sludge accumulation demonstrated resonant frequency changes of 2.8% and 6.5%, respectively. Resonant frequency change due to mass loading by simulated sludge was similar for both types of systems, showing a 40% decrease with 20-50 mg of mass loading.

III. BIOPSY NEEDLES

A. Tissue Density Measurements

Another hybrid technology involves the use of a micromachined piezoelectric sensor, integrated into a cavity at the tip of a stainless steel biopsy needle, for assisting needle guidance during fine needle aspiration (FNA) biopsy

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Manuscript received April 6, 2009. The author acknowledges support through the IR/D program while working at the National Science Foundation. The findings do not necessarily reflect the views of the NSF.

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978-1-4244-3296-7/09/$25.00 ©2009 IEEE

[5]. The sensor is fabricated from bulk lead zirconate titanate (PZT), using a customized process. In this process, micro electro-discharge machining is used to form a steel tool that is subsequently used for batch-mode ultrasonic micromachining of the bulk PZT ceramic. The resulting sensor is 50-μm thick and 200 μm in diameter. It is placed in the biopsy needle cavity, against a steel diaphragm that is 300 μm in diameter and has an average thickness of 23 μm. Devices were tested in materials that mimic the ultrasound characteristics of human tissue, and with porcine fat and muscle tissue. The magnitude and frequency of an electrical impedance resonance peak showed tissue-specific characteristics as the needle was inserted. For example, in the porcine tissue, as the needle moved from fat to muscle, the impedance peak frequency changed approximately 13 MHz from the initial 163 MHz, and the magnitude changed approximately 1600 Ω from the initial 2100 Ω. Samples including oils and saline solution were tested for calibration, and an empirical tissue contrast model showed a proportional relationship between measured frequency shift and acoustic impedance of the sample. These results suggest that the device can complement existing methods for guidance of precise biopsies.

B. Piezo-Thermal Stimulation

An extension of the piezoelectric tissue density sensors involves the use of piezoelectric ultrasonic micro-heaters for cauterization of biological tissue, possibly in tumor ablation and hemostasis applications [6]. Ultrasonic heaters using PZT-5A ceramic of 3.2 mm diameter and 191-μm thickness were used in the prelimnary experiments. The ultrasonic heaters attained maximum temperature and thermal efficiency at the frequencies corresponding to maximum conductance and maximum impedance, respectively. The thermal efficiency at each resonance frequency (0.5-3 MHz) was proportional to effective coupling factor (0.25-0.5) for that mode. The thermal efficiency was 930°C/W for biological tissue. Stacked heaters provided about three times higher efficiency.

IV. DRUG DELIVERY DEVICE

An example of a medical application that benefits from multiple types of micro-technologies can be found in drug delivery devices. In [7], Evans describes preliminary results from a dual-chamber drug delivery device that achieved high volume efficiency. It provided regulated flow from two spring-pressurized balloon reservoirs using microvalves to modulate the flow rate. Micromachined bulk metal springs (Co-Ni-Cr alloy), with an in-plane spring constant exceeding 300 N/m, were used in conjunction with 18.8-ml balloon reservoirs, and provided 15 kPa pressure when the balloons were fully inflated. A piezoresistive pressure sensor that was embedded in the microvalves was used to monitor the reservoir pressure with a sensitivity of 250 ppm/kPa; this information was used to regulate bolus delivery. In a demonstration of regulated bolus delivery, 1.5-ml bolus doses were delivered at different rates.

V. CONCLUSION

The microsystems described here provide examples of the integration of silicon-micromachined capacitive pressure sensors with stainless steel-micromachined antenna stents; magnetoelastic resonant sensors with stents; and piezoelectric ceramic tissue density sensors with biopsy needles; as well as the possible future integration of piezo-thermal elements with micro-surgical tools. A drug delivery device included elements with silicon, ceramic, and metal micromachining. These are only a few examples of what is possible with the wide palette of micromachining technologies and transduction methods that are now available. Future years will bring yet more diversity in manufacturing and transduction methods, and thereby impact a wider range of medical instrumentation.

ACKNOWLEDGEMENT

The author gratefully acknowledges K. Takahata, K.D. Wise, S. Green, T. Li, R. Gianchandani, K. Visvanathan, A. Evans, J.M. Park, S. Chiravuri, and other collaborators whose efforts contributed to the projects described in this paper.

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