A BATCH-PATTERNED SELF-EXPANDING BILIARY STENT WITH CONFORMAL MAGNETIC PDMS LAYER AND TOPOLOGICALLY-MATCHED WIRELESS MAGNETOELASTIC SENSOR

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ABSTRACT

This paper presents a system for wirelessly monitoring the accumulation of sludge within biliary stents. The system comprises a sensor and biasing permanent magnet layer that conform to the meshed topology and tubular curvature of a biliary stent. The sensors have an active area of 7.5 mm x 29 mm and a mass of 9.1 mg. Annealing the sensor at 375°C results in reducing the required biasing magnetic field from 6 Oe to 2 Oe. The integrated system shows a 38% decrease in resonant frequency (from 61.6 kHz to 38.2 kHz) after an applied mass load of 20.9 mg, or 2.3x the mass of the sensor. The system architecture allows the mechanical properties of the stent to be maintained while adding important monitoring capabilities to the implanted device.

INTRODUCTION

Stents are mesh tubular structures used to impart and maintain patency in a variety of vessels and ducts that have become constricted as a result of stenotic pathology. Though the act of implanting a stent relieves symptoms caused by the constriction, in-stent restenosis – a reappearance of the narrowing, typically due to the reaction of the body to the presence of the stent – is a risk associated with all stenting procedures.

An example of a stent application area – and the focus of this work – is the bile duct. Restenosis can occur in a biliary stent over an unpredictable timeframe of 2-12 months via formation of a bacterial matrix known as biliary "sludge" [1]. Current diagnostic techniques are indirect or invasive. As such, a direct, non-invasive method of diagnosis – such as that shown in Fig. 1 – would enable timely intervention, minimize patient discomfort, and eliminate unnecessary procedures.

We have previously reported on magnetoelastic wireless sensing of sludge accumulation utilizing externally applied AC interrogative and stent-integrated DC biasing magnetic fields [2-3]. The magnetic fields cause a magnetoelastic sensor integrated with the stent to resonate at a frequency that changes as local viscosity increases and as sludge accumulates. The mechanical resonance generates an oscillating magnetic flux that can be measured with an external pick-up coil. Our previous work utilized discrete neodymium magnets to optimally bias the anisotropy of a ribbon sensor – i.e. a rectangular strip of magnetoelastic material – that was similar in design to sensors used in industrial/environmental applications [4-6]. Although this combination was shown to be effective in benchtop testing, the discrete nature of the magnet and sensor components leaves room for improvement – especially with regards to maintaining important distributed flexibility of the biliary stent. Components that conform to or mimic the open, flexible structure of the stent would lead to a system that is better able to withstand and accommodate the deformations required during catheter-based delivery, as well as lead to a system that preserves the structural functionality of the stent. With this viewpoint, this work focuses on an integrated magnetoelastic system with a sensor and biasing permanent magnet layer that match the meshed topology and tubular curvature of a biliary stent. Further, we investigate the impact of sensor shaping and material optimization via thermal annealing.

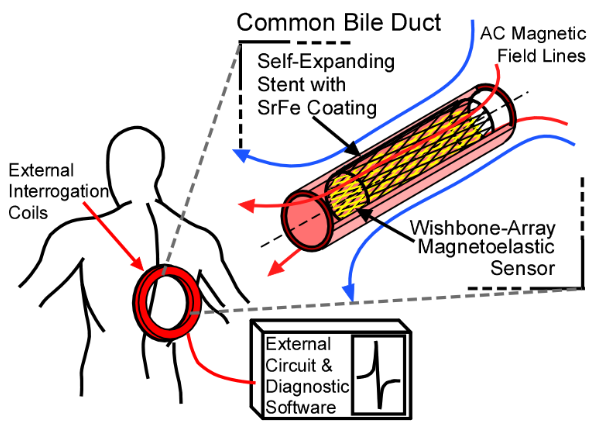

Figure 1: Conceptual diagram of in vivo magnetoelastic sensing of sludge accumulation for biliary stents.

DESIGN AND MODELING

Stent – Biliary stents generally reach their final *in situ* diameter via an elastic self-expansion. This is in opposition to the plastic expansion of typical balloon-assisted cardiac stents. The need for large elastic diameter recovery in biliary stents leads to not only the utilization of materials with superior elastic properties (e.g. chrome-nickel Elgiloy or nickel-titanium Nitinol) but also to the use of open diamond-shaped patterns. Often these patterns are formed by braiding filaments into a tubular shape, or by serially cutting the pattern from a metal tube.

In this work, we have investigated the batch-patterning of self-expanding stents from a planar Elgiloy foil utilizing a photochemical machining (PCM) process [2]. As shown in Figure 2, an elongated wishbone-array pattern is used; this pattern allows high elastic expandability for the stent. By mechanically joining the long sides of the planar pattern together, a tubular stent is formed. Two methods for joining the sides of the stent are described in the fabrication section.

Wishbone-Array Sensor – In keeping with the philosophy of mimicking the design of the stent with the design of the magnetoelastic sensor, we would like to use a material with superior elastic properties and to shape the material in diamond-shaped patterns. Fortunately, Metglas™ alloys are materials with excellent magnetostrictive properties as well as excellent elastic properties. For instance, the 2826MB alloy as used in this work is reported to have a yield strain of 1.6% [7], which is even higher than most cold-reduced Elgiloy yield strains of ~1% [8]. Metglas™ is readily available in foil form and suitable for batch-patterning using PCM. Again,

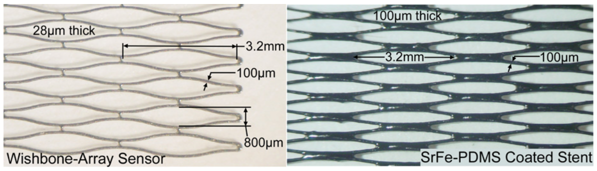

Figure 2: LEFT: A portion of a wishbone-array sensor. RIGHT: Stent with SrFe-PDMS coating.

the elongated wishbone-array pattern is used to improve the expandability of the structure and to avoid plastic strain in the sensor during deformation that is required during catheter-based delivery (Fig. 2).

Because the wishbone-array pattern represents a significant departure from typical ribbon sensors – which are analyzed for this application in detail in [2,9] – we developed an FEA tool that is appropriate for estimating mode shapes and expected signal amplitudes from sensors with complicated structures. Linearized piezomagnetic equations [10] are implemented in this work utilizing COMSOL Multiphysics and coupled time-harmonic (frequency response) induction current and stress-strain modes. A detailed look at an FEA implementation for magnetostrictive materials is in [11]; the approach used in this work is modified for application to resonant sensors. In Figure 3, the calculated mode shape at 61.6 kHz results in the largest response signal amplitude. Note that the mode shapes combine significant longitudinal and transverse motion, whereas mode shapes of traditional ribbon sensors are limited to longitudinal motion.

Conformal Magnetic Layer – To achieve optimal magnetomechanical coupling, the magnetoelastic material must be biased with a DC magnetic field. This field offsets the as-fabricated anisotropy of the magnetic domains in the material, and sets the operating point of the sensor in response to the small AC interrogative signal.

While sensor performance is improved when the bias field is as uniform as possible, this uniformity is difficult to achieve with integrated discrete magnets because the field strength will necessarily decay as the distance from the magnets increases. In addition, localized peaks and high magnetic field gradients lead to undesirable magnetic forces. The distributed magnet is chosen in this work to be a layer of strontium ferrite (SrFe) particles (~1 μm average diameter, Hoosier Magnetics) suspended in polydimethylsiloxane (PDMS, Sylgard 184, Dow Corning). This choice is made again in keeping with minimally altering the functionality and structure of the biliary stent with the additional components. In this case, the polymer-suspended particles can be applied in a thin, flexible layer conforming exactly to the stent structure (Fig. 2).

Other polymers have been used as a base for SrFe particles in microfabricated magnets described elsewhere [12]. SrFe particles have the advantages of being chemically inert (owing to their ceramic nature), and of being widely and inexpensively available in very small particle sizes. The chemical inertness is especially valuable in our implantable application. PDMS is chosen in this work due to its generally accepted biocompatibility and due to processing ease.

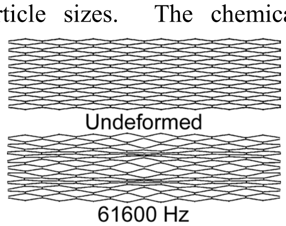

Figure 3: FEA calculated mode shape and frequency prediction.

FABRICATION

Stent – The stent is batch fabricated from a 100 μm thick foil of Elgiloy using the PCM process. The feature sizes and patterns are identical to those of the sensor (Fig. 2). The overall stent size is 4 mm (dia.) x 40 mm.

Wishbone-Array Sensor – The wishbone-array sensors for this work are batch fabricated from a 28 μm thick foil of 2826MB Metglas^{TM} (a NiFeMoB alloy) utilizing the PCM process. Feature sizes of the individual struts are 100 μm, which is near the feature size limit for the technology. The overall size of the active portion of the sensor (not including the anchor areas discussed later) is 7.5 mm x 29 mm, with a mass of 9.1 mg.

PCM is a planar process, so the as-fabricated sensors are also planar. Because the stent application calls for a tubular shape, and the lateral dimension of the sensor is larger than the diameter of the stent, the sensor must be curved into a tubular or semi-tubular shape to best match the stent geometry. Rolling the sensor into a tube inside the stent resulted in degradation of the signal amplitude. As such, the tubular shape is achieved in this work by placing the sensor against the inner wall of a fixture tube and annealing for 30 minutes at 375 ^{o}C. Various final radii can be achieved by either changing the fixture tube radius or by changing the anneal temperature.

Conformal Magnetic Layer – To form the conformal magnetic layer, the PDMS is first mixed in a 10:1 base-to-curing-agent ratio. Subsequently, the SrFe particles are introduced in 1:1, 3:1, or 1:3 SrFe-to-PDMS by weight ratios and mixed in by hand until the mixture is consistent (usually about 1 minute of mixing time). The mixture is then poured or spread into a mold containing the stent. The stent is then peeled out of the mold, with a conformal layer of the magnetic suspension adhered. The layer is then cured for 30 minutes at 60^{o}C. Thicker layers can be built up by repeating the process. Finally, the layer is magnetized uniformly along the long axis of the stent using a benchtop pulse magnetizer. In general, the 1:1 SrFe:PDMS ratio offered the best combination of workability and remnant strength of the ratios tested.

System Assembly – Lateral portions of the wishbone-array sensor are connected to the active area with single struts. These areas act as anchors, and the single struts isolate the vibrating active area from the anchors. The anchors are bonded to the stent with a thin layer of PDMS.

Subsequently, the stent is rolled into a tubular shape and the resulting seam where the edges of the stent adjoin is mechanically joined. This joining process is achieved with two methods in this work (Fig. 4). In one method, the edges are brought into alignment with a fixture that also acts as a mold. PDMS is poured into the mold and cured, encasing the seam edges. In the other method, a wire is formed in the pattern on one edge of the stent. The wire is then woven through both edges to join the seam. The entire assembly process is shown in Figure 5, and an assembly is shown in Figure 6.

EXPERIMENTAL METHODS AND RESULTS

Stent – Important characteristics for biliary stents include deliverable diameter, expanded diameter, and radial stiffness. The ratio of the expanded diameter and deliverable diameter is a measure of the expandability of the stent. This ratio should be high to minimize invasiveness during stent placement. Radial stiffness should be high so that the stent can act as a mechanical scaffold to prop the duct open.

To establish deliverable and expanded diameter, stents were passed through tubes of known diameter and measured after passing through the tube with calipers (Fig. 7). To evaluate radial stiffness, the stent was placed in a semi-cylindrical fixture and probed with a force gauge (Imada, Inc.). The force gauge was equipped with a blade probe that allowed a localized (5 mm x 1 mm) application of force to best simulate a local bile duct lesion. The stent was probed at the mid-length and end. The stent was also tested in two different orientations – with the force applied to the seam or with the force applied 90^o from the seam – to evaluate stiffness changes due to the seam. The testing was applied to uncoated stents, coated stents, stents with a bonded seam, stents with a woven seam, and to a commercially available biliary stent. Results are summarized in Table I.

Sensor Annealing – The optimal bias field – with which the amplitude of the response is largest (10 mVp-p) – is around 6 Oe for as-cast sensors (Fig. 8). The frequency and amplitude show repeatable performance across the tested sensors, indicating a repeatable PCM fabrication process.

The sensors were thermally treated either above (375^{o}C) or below (325^{o}C) the material Curie temperature (353^{o}C) and either remained planar or were given curvature. Post-treatment evaluation showed lower optimal biasing field (~2 Oe, Fig. 8) and improved signal level (up to 13.5 mVp-p). This important result shows that thermal treatment facilitates thinner SrFe-PDMS layers, which simplifies fabrication and minimizes

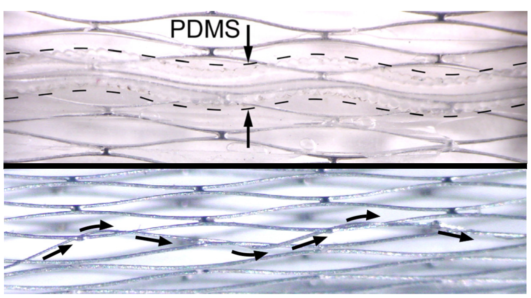

Figure 4: Seam joining techniques. TOP: PDMS seam joint (PDMS extent denoted by dashed line). BOTTOM: Woven wire seam (wire path denoted by arrows).

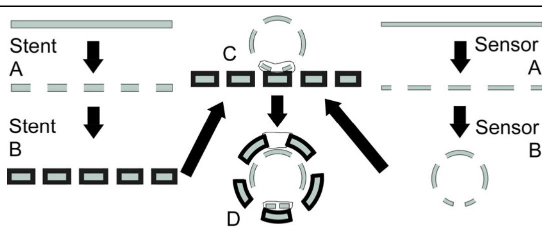

Figure 5: Fabrication process. A) PCM patterning of Elgiloy (stent) and Metglas^{TM} (sensor). B) Stent coated in SrFe-PDMS layer and magnetized. Sensor annealed in a tube. C) Sensor anchors bonded to stent with PDMS. D) Stent seam bonded with PDMS or joined by threading.

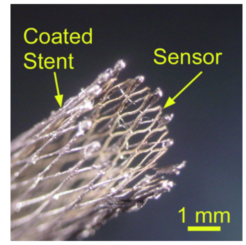

Figure 6: Assembled sensor and coated stent.

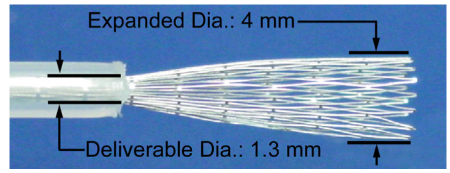

Figure 7: The batch-patterned stents are capable of 3:1 self-expansion from the deliverable diameter, similar to commercially available braided stents. The conformal coating requires higher forces to reach the deliverable diameter but does not change the elasticity.

concerns about chronically implanted magnetic fields.

Integrated System – The integrated system consists of a curved wishbone-array sensor and a SrFe-PDMS coated stent. For all tests, a swept-frequency network analyzer signal was amplified and sent through a transmit coil, while the same analyzer measured the EMF generated on a receive coil. The sensors were located concentrically with these coils. All biasing of the sensor was provided by the conformal SrFe-PDMS magnetic layer. For the integrated system, sensitivity to viscosity over a physiologically appropriate range was measured even as mass was added. This experimental process showed that the normalized frequency response of the sensor to viscosity changes was not significantly affected by mass buildup (Fig. 9). Application of the acrylate terpolymer sludge simulant as a mass load showed that the frequency and signal amplitude of the integrated sensor reacted to mass loads similarly to those of the isolated sensors (Fig. 10).

DISCUSSION

Three important advantages of the wishbone-array sensor over typical ribbon sensors in this application are made clear by this work. First, the fine features sizes and large open area of the pattern present little obstruction to bile flow, which is the primary objective of a biliary stent.

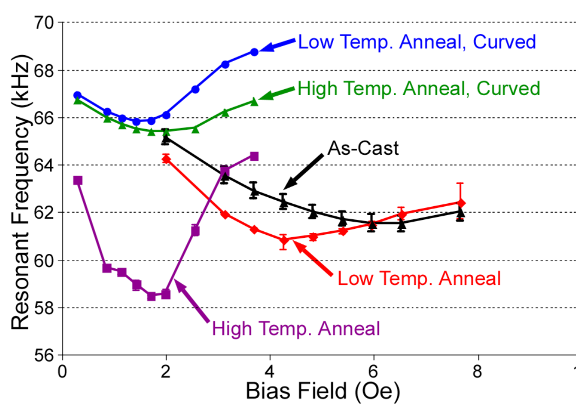

Figure 8: Thermal treatment of the sensor reduces the required biasing field from 6 Oe to 2-4 Oe depending on the treatment. The required biasing field is located at the minimum of each curve.

Second, the sensors are much more accommodating of the large deformations required for catheter-based delivery. Third, the sensors have a higher sensitivity to viscosity changes, which is a clinically relevant parameter in many pathological conditions [13]. The principal disadvantage of the wishbone-array sensor, at least with the present design, is the smaller signal amplitude. However, preliminary results show that the signal amplitude scales with the overall sensor length and width, so this disadvantage may be mitigated in future designs.

Prior to *in vivo* testing of the system, further evaluation of the mechanical properties of the stent must be done. Analytical models imply that the sludge simulants used in this work represent a worst-case scenario, as biofilms like sludge are likely to be less stiff than the test materials [14].

CONCLUSION

This work integrates a flexible wishbone-array magnetoelastic sensor and conformal magnetic layer with a biliary stent as a wireless system that monitors the stent environment. The system is sensitive to physiologically appropriate viscosity changes, showing a 7% decrease in resonant frequency in 10 cP fluid. The system also is capable of measuring mass buildup that is associated with sludge accumulation, showing a 38% decrease in the resonant frequency after an applied mass load of 20.9 mg, or 2.3x the mass of the sensor. The mechanical properties of the batch-patterned stents compare favorably with those of commercially available stents. Annealing the sensor results in control over the shape of the sensor and a reduced required biasing field. The integrated system is

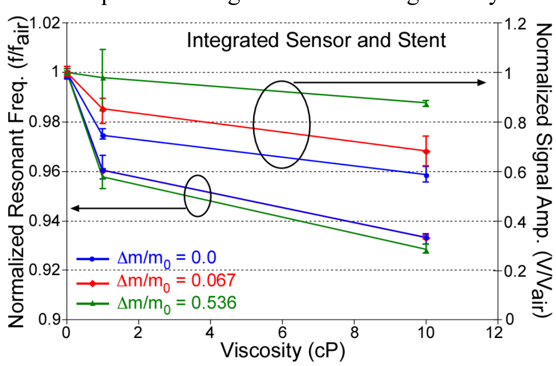

Figure 9: Integrated sensor response to physiologically relevant viscosity changes. The sensor was tested even as mass was added.

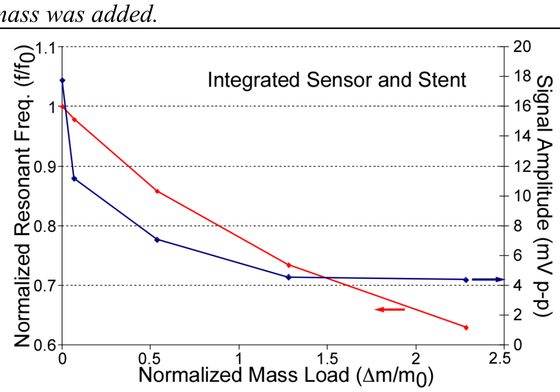

Figure 10: Mass was added to the fully integrated sensor with acrylate terpolymer. The signal amplitude and frequency of the integrated sensor responds to mass loading in a manner similar to isolated sensors.

Table I: Stent Mechanical Property Comparison

	Commercial	Batch-Patterned
Deliverable Dia.	1.2-1.3 mm	1.3-1.4 mm
Expanded Dia.	4 mm	4 mm
Radial Stiffness	0.07-0.15 N/mm	0.06-0.18 N/mm

robust to deformations required for delivery and provides a uniform biasing layer that minimally affects stent mechanics. With appropriate scaling, the sensing methodology may be applicable in any stent, including cardiovascular and esophageal stents. Additionally, the improved viscosity sensitivity of the wishbone-array sensor may find use in industrial applications like monitoring oil refinement.

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