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Mechanics of stretchable electronics on balloon catheter under extreme deformation

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ABSTRACT

Stretchable electronics has been applied to balloon catheters for high-efficacy ablation, with tactile sensing integrated on the surface, to establish full and conformal contact with the endocardial surface for elimination of the heart sink caused by blood flow around their surfaces. The balloon of the catheter folds into uniform 'clover' patterns driven by the pressure mismatch inside (~vacuum) and outside of the balloon (pressure ~1 atm). The balloon catheter, on which microelectrodes and interconnects are printed, undergoes extreme mechanical deformation during its inflation and deflation. An analytic solution is obtained for balloon catheter inflation and deflation, which gives analytically the distribution of curvatures and the maximum strain in the microelectrodes and interconnects. The analytic solution is validated by the finite element analysis. It also accounts for the effect of inflated radius, and is very useful to the optimal design of balloon catheter.

1. Introduction

The major push in the electronics industry has always been toward smaller and faster devices. These hard, rigid and flat devices are confined to the planar surface of silicon wafers. Stretchable and flexible electronics have emerged to offer the performance of conventional wafer-based devices, but mechanical properties of a rubber band (e.g., Kim et al., 2010b; Rogers and Huang, 2009). This type of technology offers many new application opportunities, particularly for mounting on soft, elastic and curved objects, such as tissues of the human body (Kim et al., 2012b; Kim et al., 2010b). Examples range from cameras that use biologically inspired designs to achieve superior performance (Jin et al., 2004; Jung et al., 2011; Ko et al., 2008) and flexible sensors (Lumelsky et al., 2001; Mannsfeld et al., 2010; Someya et al., 2005; Someya and Sekitani, 2009; Takei et al., 2010), to surgical and diagnostic implements that naturally integrate with the human body to provide advanced therapeutic capabilities, such as conformal bio-integrated electronics for monitoring brain activities (Berger et al., 2001; Kim et al., 2010a); light-emitting sutures for accelerated wound healing and transducers of blood oxygenation and perfusion, waterproof micro-LEDs and proximity-sensor on surgical gloves to monitor distance from a proximal object, and illuminated plasmonic crystals and thin, refractive-index monitors on flexible tubing for intravenous delivery systems to monitor dosage of nutrition and medicines (Viventi et al., 2010a); conformal bio-interfaced silicon electronics for mapping cardiac electrophysiology (Baek et al., 2008; Kim et al., 2012a; Kim et al., 2011; Viventi et al., 2010b) and brain activities *in vivo* (Viventi et al., 2011); multifunctional balloon catheters for cardiac ablation therapy (Kim et al., 2012a; Kim et al., 2011); and epidermal electronics for the measurement of electrical activities produced by the heart (EKG), brain (EEG) and skeletal muscles (EMG) (Kim et al., 2011).

Kim et al. (2012a) demonstrated integrated stretchable electronics and tactile sensors on cardiac balloon catheters that were used to detect circumferential contact between the balloon surface and endocardial tissue during ablation treatment. These arrays of tactile sensors can help reduce dependence on intraprocedural X-ray and radioactive contrast agents, which are typically employed by physicians to help assess mechanical contact between balloon catheters and endocardial tissue. Tactile sensors on balloons provide a safe quantitative alternative to X-ray imaging during cardiac ablation procedures. In addition to assessing

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mechanical contact, there are several other sensing modalities, including electrocardiograms, temperature, and pH mapping, which can be measured with stretchable electronics on balloons.

Mapping physiological parameters at specific anatomical targets, like the heart as well as other internal organs, requires that the flexible sensors, actuators and substrates of balloon catheters all fold down to their minimal geometric profile in order to allow safe insertion and routing through small arteries and veins. The balloons must therefore repeatedly transition from their original inflated state (shown in Fig. 1a), to fully deflated state (Fig. 1b). In their deflated state, the balloon substrate forms three 'clover-shaped lobes' (Figs. 1c and 1d), driven by a pressure mismatch between inside (~vacuum) and outside of the balloon (pressure ~1 atm). Three lobes occur most frequently, though four lobes have also been observed before. The lobes are far apart and have essentially no interactions. Through controlled inflation the balloon catheter then can be configured to match requirements on size and shape for its interaction with the tissue, where contact occurs in a soft, conformal manner, capable of accommodating complex, curvilinear and time dynamic surfaces in a completely non-destructive manner.

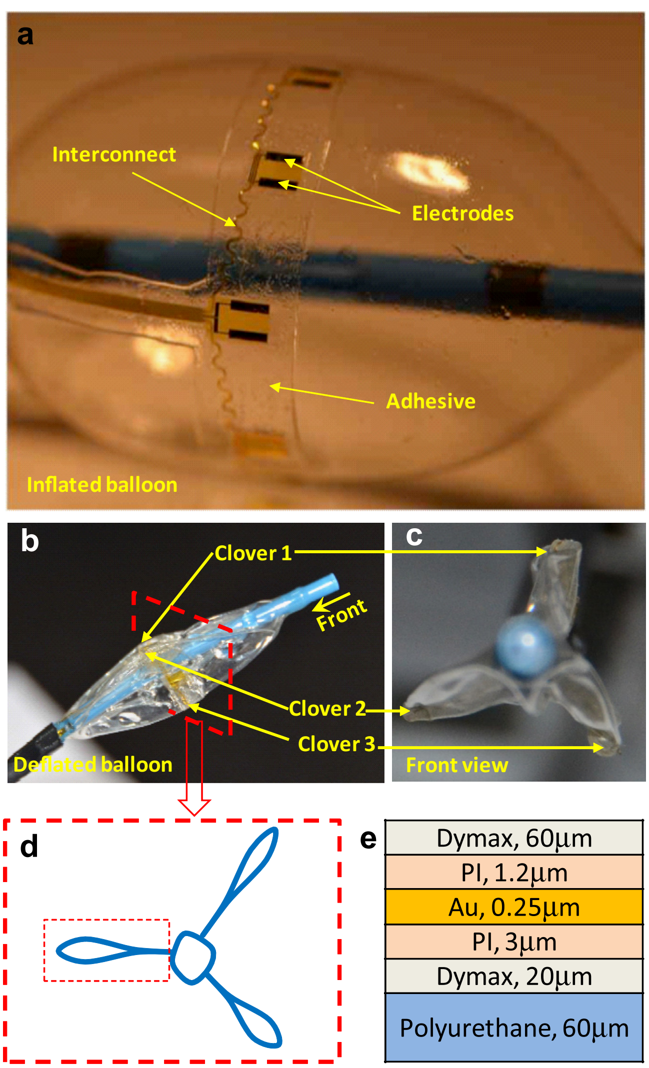

Fig. 1. (a) Inflated balloon catheter; (b) deflated balloon catheter; (c) a view of the deflated balloon catheter along its axial direction; (d) a schematic illustration of uniform 'clover' patterns for the deflated balloon catheter; (e) a representative cross section of interconnects on the balloon catheter.

The balloon catheter undergoes extreme mechanical deformation during the inflation and deflation. It is important to ensure that the maximum strains in the microelectrodes and interconnects integrated on the balloon catheter are well below their fracture limit. An analytic mechanics model for the inflation and deflation of balloon catheter is established in Section 2. It is validated by the finite element analysis (FEA) that accounts for details of the microelectrodes, interconnects and balloon catheter. Application of the analytic model to the design of stretchable electronics for high-efficacy ablation is discussed in Section 3. The effect of initial radius of the inflated balloon catheter is also discussed in Section 3, together with the numerical results obtained from FEA.

2. Analytic model

As shown in Fig. 1a, the microelectrodes and interconnects are printed on a Dymax adhesive, which is attached to the balloon catheter around its equator. The polyurethane balloon catheter is 60 µm thick. Fig. 1e shows a representative cross section of interconnects on the balloon catheter, with a 20-µm-thick Dymax layer as the adhesive and a 60-µm-thick Dymax layer as the encapsulation, on top of the PI/Au/PI microelectrode. The microelectrodes are printed in pairs (Fig. 1a), and have the cross section similar to Fig. 1e but without the 60-µm-thick Dymax encapsulation and 1.2-µm-thick PI layer to expose Au. Within the pair of microelectrodes the Au layer is removed, which leaves only the 20-µm-thick Dymax adhesive and 4.2-µm-thick PI layer. Beyond the pair of microelectrodes there is only 80-µm-thick Dymax layer (60-µm encapsulation +20-µm adhesive).

As to be discussed in Section 3, these cross sections, together with 60-µm-thick balloon catheter, have similar bending stiffness. Therefore they can be approximated by a uniform beam with the effective thickness h and effective bending stiffness EI (per unit width) to be given in Section 3. As shown in Fig. 2a, each lobe is modeled as a beam, subject to external pressure p and bent to the shape of a "tennis racket", similar to the experiments (Fig. 1c). This deformation mechanism is similar to the collapse (Elliott et al., 2004; Pugno, 2010) and self-folding (Buehler, 2006; Buehler et al., 2004; Falvo et al., 1997; Zhou et al., 2007) of carbon nanotubes, though the latter is driven by Van der Waals force. The initial radius of the fully inflated balloon catheter (~10 mm) is much larger than the bend radius (~0.2 mm) of "tennis racket" such that the initial curvature of beam is neglected and is considered initially flat. These approximations of uniform, initially flat beam are validated by FEA in Section 3.

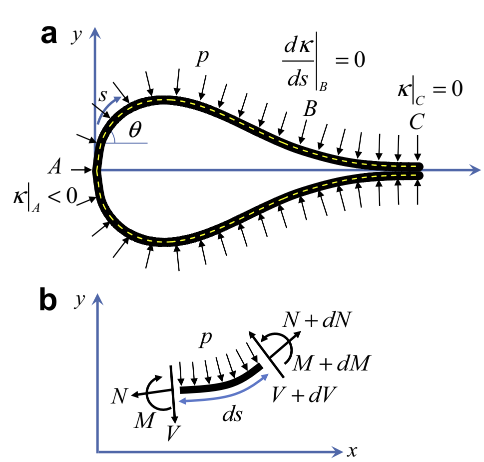

Fig. 2. (a) A schematic diagram of a beam bent to the shape of a "tennis racket" under the external pressure p; (b) illustration of axial and shear forces, bending moment and external pressure.