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Optical contact force monitoring sensor for cardiac ablation catheters

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ABSTRACT

Modern lifestyles can lead to various lifestyle diseases that have become the most threatening health issues to humans. In particular, heart disease is the leading global cause of death. To diagnose heart disease, cardiac catheterization is frequently conducted. The contact force between the tip of the catheter and tissue is very critical because it determines the success or failure of the procedure. In this work, an optical sensor composed of transparent, flexible, and stretchable PDMS layers forming an air cavity was developed and evaluated. The reflectance of the sensor varied with external applied force depending upon the gap between elastomeric layers placed on the catheter tip. The fabricated sensor showed very low minimum resolution (<0.1 gF), which is desired for the application. A wider dynamic range than that of the present sensor (0–0.6 gF), which is inadequate for the practical application, can be achieved by optimizing the thickness of the flexible layers.

1. Introduction

As humans live longer and worldwide development accompanying civilization, industrialization, mechanization, and automation continues, lifestyle diseases have arisen as the greatest threats to human health. Lifestyle diseases are mostly caused by bad diet and lifestyle, such as eating junk foods and high cholesterol, drug abuse, smoking, alcohol drinking, and lack of exercise [1,2]. These diseases include obesity, diabetes, heart diseases, chronic obstructive pulmonary diseases, cancers, chronic liver diseases, arthritis, osteoporosis, and stroke. According to one report, 9 of the 20 leading causes of global death of 2012 were lifestyle diseases, including ischemic heart disease, lower respiratory infections, stroke, and chronic obstructive pulmonary disease [3]. Among these diseases, ischemic heart disease was top of list and its impact as a cause of global death is still increasing [3,4]. Heart diseases can be diagnosed as arrhythmias using an electrocardiogram (ECG) and treated in diverse ways such as medications, ablation, defibrillation, and implantation of devices (e.g., pacemakers) [5]. Cardiac catheterization, which destroys abnormal tissues by radiofrequency ablation, is a nonsurgical approach with a low risk of complications and short convalescence, and the number of ablation procedures has constantly increased over

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the last 10 years [6,7]. Although catheter ablation procedure shows a very high success rate (>90%), there is still uncertainty due to the *in vivo* remote control without actual vision.

Real-time contact force monitoring technology has become a significant issue to minimize the risk and provide necessary information to physicians, such as the contact force between the catheter tip and tissue during the ablation procedure. With this technology, a safe, efficient, and satisfactory procedure can be ensured [8]. Peirs et al. could achieve a contact force resolution up to 0.01 N with a 5-mm diameter catheter tip that contained three optical fibers within a metal spring [9]. Polygerinos et al. modified a 7-Fr commercial catheter, simulated on the flexible polymer structure and designed spring structures, and tested them with both axial and lateral forces [10–12]. More sophisticated microelectromechanical system (MEMS)-based miniature force sensors had been applied to the catheters [13–15]. However, the sensor structures and fabrication processes are very complicated and cumbersome, resulting in high cost and low effectiveness. Therefore, in the present study we proposed an optical sensing element structure with consideration of ease of fabrication and user friendly operation.

It is well known that optical principles can be adopted to avoid electromagnetic interference (EMI) produced by integrated electronic devices such as RF electrodes, impedance sensors, and temperature sensors. As an example, a typical optical force sensor application is a tactile/touch sensor. In the past, many research groups have studied transparent and flexible optical tactile sensing films using microwave waveguides and dielectric cavities array [16–20]. This sensor technology is very promising and fascinating because high sensitivity, light weight, and flexibility can be achieved due to the easy fabrication process and cheap polymer materials. We adopted optical tactile sensor technology for this work with necessary modifications to meet specific requirements for application in a cardiac ablation catheter.

2. Design considerations

2.1. Working principle

In the reflectance probe, the reflected intensity decreases with reduced distance from the end-face of the probe to the reflecting surface for near field. This characteristic is useful for monitoring the external force when altering the distance to the reflecting surface, which can be realized with a typical diaphragm configuration. A flexible diaphragm consisting of elastomer layers is very susceptible to minute deflections caused by external forces due to the mechanical properties of elastomers. Fresnel reflection, or dielectric reflection, occurs at the surface of a freestanding elastomer layer that is deflected by external forces and air. Consequently, the intensity of the reflected light decreases with higher external force, which produces more deflection.

2.2. Sensor design

According to the working principle, we designed a structure composed of three flexible and stretchable polymer layers (top layer, spacer, and bottom layer) to form an air cavity and a proper air-polymer interface as shown in Fig. 1. The thicknesses of the layers can be optimized based on material properties and desired sensing range. The flexible layer assembly was placed on the end-face of the reflectance probe to form the force sensor; hence, the diameter of the flexible layers was determined by the diameter of the reflectance probe end-face. Accordingly, the thicknesses of the flexible layers were set to 100 μm while the sensor and the cavity diameters were set to 5.0 mm and 2.5 mm, respectively.

3. Experimental details

3.1. Sensor fabrication

PDMS (polydimethylsiloxane) was selected as the flexible and stretchable polymer for the sensor structure due to its ease of handling and well-known properties. PDMS (SYLGARD® 184 Silicone Elastomer Kit, Dow Corning) liquid mixture was prepared by homogeneously mixing the base and the curing agent with 10:1 wt ratio and degassing. The 100-μm thick base layers were fabricated by spin-coating onto 4″ Si wafer at 1000 rpm for 30 s, followed by thermal curing (100 °C, 15 min). The base layers were transferred onto PET films. One of these films was punched with a 2.5-mm hole puncher to form more than 20 cavities per layer. Two base layers and one punched layer were permanently bonded using oxygen plasma and heat treatment. Finally, the bonded layer was punched with a 5.0-mm hole puncher with respect to the preformed cavities. The fabricated sensor point was placed onto the end-face of the reflectance probe (R600-8-UVVIS-SR, StellarNet Inc.) by natural adhesion.

3.2. Evaluation system set up

The instruments and their set up are shown in Fig. 2. The apparatus consists of five components: LED, load cell, linear stage, photodetector, and PC. An exact external force was induced by adjusting displacement of the sensor fixed on the linear stage (UTS50CC, Newport) controlled by the motion controller (ESP301, Newport). The applied force was measured by a load cell (R04, MARK-10) and monitored by a force indicator (7i, MARK-10). Light source for the sensor was a 660-nm