POLYPYRROLE DRIVEN CATHETER

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ABSTRACT

An optical fiber 2D scanner and positioner intended for in-vivo imaging application is presented. The design is a catheter coated with conducting polymer actuators and equipped with an optical fiber. Conducting polymer actuators (here polypyrrole) enables both positioning of the catheter to the desired region to be visualized and 2D scanning of the optical fiber. The optical fiber is connected to an optical coherence tomography (OCT) imaging system which performs high resolution depth resolved imaging. OCT depth imaging combined with the 2D scanning of the fiber will result in a complete high resolution 3D image. This technique enables detection and monitoring of changes in tissues, which is useful for assessment of vascular disease, cancer tissue progression, and surgical guidance.

Initial prototypes of the active catheter have been constructed and tested. In these devices a commercial catheter is coated with polypyrrole, which is laser micromachined into electrodes. These polypyrrole electrodes are electrochemically activated, leading to bending of the catheter. The catheter is able to achieve a radius of curvature of 10 mm, which is similar to the curvature achieved in wire guided catheters used at present. The catheter scans at frequencies of up to 10 Hz, but lifetime is short at this frequency. The primary challenge is to demonstrate high speed with reasonable lifetime. An electromechanical model of the active catheter suggests means of achieving high speed actuation and sufficient cycle life.

\textbf{Keywords:} Polypyrrole actuator, Catheter, Optical coherence tomography, In-vivo imaging.
INTRODUCTION

Catheterization is a common medical procedure, in which a hollow tube (i.e. the catheter) is inserted into body cavities to provide a channel for fluid passage or an entry for a medical device. Catheters as fluid channels may be used to drain urine from the urinary bladder and administrate the intravenous fluids and medication directly into the body. Catheters are also used to direct a medical tool to a particular part of the body for minimally invasive surgical procedures. In angioplasty, for instance, catheters are employed to guide a therapeutic device to open a blockage inside a blood vessel [1].

The conventional method of handling a catheter involves inserting it into the body passively by employing push/pull control mechanisms that are outside the body, where a wire configured to be pushed or pulled along a longitudinal axis to bend the catheter tip [2]. Limitations of the current catheter and guidewire designs include long procedural times, and risk of lumen or vessel wall damage, both as a result of slow and inexact guidance. These issues become more critical when dealing with narrow and complex passages such as blood vessels of the brain and tertiary bronchi of the lung [1]. Therefore, advanced active catheter designs with controllable features are required in order to enhance the performance of these devices during minimally invasive medical procedures. Various active catheters driven by different methods have been suggested, however no active catheters are in wide spread use. Micromotors mounted on catheters had been reported for ultrasonography [3,4], but they feature a relatively large size (diameter of 1.9 mm [4]) and expensive fabrication processes. Shape memory alloy (SMA) and Shape Memory Polymers (SMP) actuators have been used for steerable endoscopes [5-11]. Although these types of actuators are potentially able to provide a large degree of bending, their slow response, high operating temperature and the possibility of electrical current leakage limit their applications [9]. Controllable catheters utilizing hydraulic mechanisms have also been developed, where the catheter position is controlled by varying the size of inflatable balloons mounted on its tip using electrothermally controlled microvalves [2]. This mechanism is cumbersome and controlling the microvalves is slow; hence not suitable for many applications [1]. Ionic Polymer Composites (IPMC) actuator has been also suggested to design active catheters [12-14]. These actuators can generate large displacements at relatively low voltages (<10 V) and moderate speed; however, their manufacturing process is often relatively expensive and additional energy is usually consumed for holding the actuator in a position. Conducting polymer actuators have shown attractive properties, which make them promising to be employed extensively in active catheter applications. Some of the characteristics include low actuation voltage, ease of fabrication, relatively high strain, and biocompatibility.

In this paper a conducting polymer actuated catheter for minimally invasive intervention inside arteries is designed and demonstrated. The design is composed of two active catheters optimized for two distinct applications (shown in Figure 1). One active catheter, “scanner”, is responsible for scanning an optical fiber over a distance of 1 mm, with a relatively high speed to provide forward viewing images from an artery lesion. The second catheter, the “positioner”, is then actively bent to reach the target lesion and guide a wire to navigate through the lesion, while the first fiber optic mounted catheter is monitoring the procedure in real time. Real time forward viewing is done by a technique called optical coherence
tomography (OCT) which performs depth resolved imaging by sending wide band near infrared light into tissue and observing the backscattered light interferometrically [15]. OCT depth imaging combined with the conducting polymer based scanning catheter shown in Figure 1 (which provides planar 2D scanning of the optical fiber), will result in a complete high resolution 3D image. This technique can serve as an important diagnostic adjunct, enabling the detection and the monitoring of changes in tissues, therefore is useful for assessment of vascular disease and cancer tissue progression [15], and surgical guidance. Each active catheter is encapsulated within a biomaterial structure containing an ionic electrolyte. Polypyrrole electrodes coated on the catheters are used as the conducting polymer based active elements and electrochemically actuated inside the ionic electrolyte using voltage changes of <1 V per polymer electrode. A lens is embedded at the end of the encapsulation tube containing the imaging catheter, which can amplify the angular scanning range (see Figure 1).

![Fig.1: Schematic of the final encapsulated device](image)

**EXPERIMENTS**

Mechanism of actuation

The conducting polymer, in this work polypyrrole, is electronically conductive. It is also porous, enabling ion insertion. Application of a voltage to the polymer in an electrolyte alters the charging of the polymer. The electronic charging occurs throughout the volume of the polymer, and is balanced by the insertion of ions from the electrolyte. This charging process is associated with changes in volume, where increase in volume generally occurs when ions are inserted into the polymer matrix. Figure 2 illustrates the mechanism of the dimensional change as a result of the electrochemical activation. As shown in the figure a substrate (here a catheter) coated with conducting polymer electrodes on both sides is in an electrolyte solution containing mobile negative ions and large immobile positive ions. An alternating voltage is applied across the two polymer electrodes resulting in charging and discharging of the polymer electrodes. During charging the mobile negative ions enter the polymer from the electrolyte, therefore expand the structure. During discharging they exit the polymer to the electrolyte and contract it. Expansion on one side and contraction on the other side induces a stress gradient on the polymer/catheter interfaces and causes the whole structure to bend in one direction. Alternating expansion and contraction will result in the movement of the catheter in 2 directions inside the electrolyte solution. Coating the catheter with four polymer electrodes enables actuation in 2 dimensions.
The amount of dimensional change “strain” $\varepsilon$, is proportional to the amount of ion insertion and equivalently the charge per unit volume, $\rho$, via the relationship:

$$\varepsilon = \alpha \rho$$

(1)

$\alpha$ is an empirically determined strain to volumetric charge ratio [24-26]. The rate of actuation of polypyrrole is proportional to the rate of ion insertion, and hence to the current. The current can be limited by the both ionic and electronic resistivities, diffusion coefficients, and the capacitance of the electrodes. For a long device the total polymer resistance along the length of the catheter, $R_{ppy}$, can significantly limit the rate [26], with the predicted time constant being $\tau = R_{ppy} C = \frac{C V^2}{\sigma e}$ [26], where $\sigma e$ is the electronic conductivity of the polymer, and $C_v$ is the polymer volumetric capacitance. For a thick device the ionic resistance through the thickness, $t_p$, is the rate limiting factor, with the time constant of $\tau = \frac{t_p^2}{D}$ [26], where $D$ is the effective diffusion coefficient. An electrochemical model was developed which uses the above factors to design optimum devices for both the positioner and the scanner catheters [21, 22, 23].

**Fabrication**

The catheter used in this experiment was a Micro Therapeutics Inc. (Irvine, CA) Ultraflow™ HPC, with inner and outer diameters of 0.28 mm and 0.5 mm respectively. Polypyrrole deposition on the catheter was done in two steps. First a thin layer of polymer was deposited using electroless deposition by chemical polymerization of pyrrole monomer in the presence of oxidizing agent [16]. Then polypyrrole films are electrochemically grown from a solution of 0.06 M pyrrole monomer [www.aldrich.com] and 0.05 M tetraethylammonium hexafluorophosphate [www.aldrich.com] and 1 % vol distilled water in propylene carbonate, following the procedure of Yamaura [17]. Polypyrrole is deposited galvanostatically on to the catheter at the current density of 1.25 A/m² and at temperatures between -30 °C and -45 °C with a rate of ~1.3 μm/hr. The resulting polymer is in the doped or oxidized state with the doping level in as-grown polypyrrole of approximately one charge per three monomers [18]. Polymer coating was then divided into 4 electrodes using laser ablation (Figure 3) [19].
**Experimental Catheter Actuation**

According to the developed model a thickness of > 40 μm is required to achieve the large degree of bending (i.e. the requirement for the positioner catheter). The model, however, suggests that a polymer thickness of ~ 10 μm results in maximum tip displacement at high actuation rate (i.e. the requirement for scanner catheter). Therefore the positioner catheter was coated with 40 μm thick polypyrrole and the scanner catheter was coated with 10 μm thick polymer, and their performances were tested separately. Both catheters are actuated inside an aqueous solution of sodium hexafluorophosphate (NaPF₆) which has been previously shown to produce relatively large strains [27].

**Positioner Catheter**

The polymer coated positioner catheter was actuated inside an aqueous solution of NaPF₆ by applying a step potential of -0.8 to +0.8 V versus Ag/AgCl reference electrode and a bending radius of 9.76 mm was achieved in 30 seconds. This is similar to the curvature achieved in wire guided catheters used at present [22]. Figure 4 illustrates the positioner catheter bending.

**Fig. 4.** Positioner catheter tip at two states: initial, bent.

The scanner catheter with 4 polymer electrodes was also tested in the same electrolyte (AQ-NaPF₆) by applying potential across the two facing polymer electrodes. Note that two potential sources are used (see Figure 5); one applies an alternating voltage across the two facing electrodes with relatively high frequency which causes the catheter to move back and forth in y direction relatively quickly; the other source simultaneously applies a potential with a slower frequency to the second polymer electrode pairs resulting in x direction actuation.
The primary demonstration of the scanner was performed with a speed of 0.1 Hz in x direction and 1 Hz in y direction. Figure 6 shows a view of the scanner tip at initial and final positions with the arrows showing the route of the scanning.

In order to achieve real time OCT imaging the scanner catheter requires scanning an optical fibre in 2 dimensions with high speed (10-30 Hz). The scanning speed of 10 Hz was achieved in one dimension by applying a high actuation potential (10 V), however the number of scanning cycles was limited due to short polymer lifetime at high actuation voltages. An electromechanical model was used to study the feasibility of achieving high speed actuation (10 Hz – 30 Hz) appropriate for OCT imaging. The detailed description of the model can be found in our previous work in [21]. According to our model, electrochemical characteristics of the conducting polymer such as electronic conductivity, ionic conductivity and electrochemical strain need to be improved to achieve the desired catheter scanning speed (i.e. 30 Hz) for real time imaging [21,23]. Table 1 illustrated the current values of these parameters and the model suggested values for obtaining 30 Hz actuation over a distance of 1mm. The catheter length of 35 mm was considered in this calculation (defined by our collaborators in medicine). Table 1 also contains recommendations for achieving the required electrochemical characteristics.
<table>
<thead>
<tr>
<th>Parameters</th>
<th>Current value</th>
<th>Required value</th>
<th>Recommendations [21]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic conductivity</td>
<td>$0.4 \times 10^4 \text{ S/m}$</td>
<td>$5 \times 10^4 \text{ S/m}$</td>
<td>- Add a metal coating</td>
</tr>
<tr>
<td>Ionic conductivity</td>
<td>$1.8 \times 10^{-3} \text{ S/m}$</td>
<td>$9 \times 10^{-3} \text{ S/m}$</td>
<td>- Increase polymer porosity</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- Use fast mobile ions</td>
</tr>
<tr>
<td>Electrochemical strain</td>
<td>2%</td>
<td>4%</td>
<td>- Use larger mobile ions</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Mechanical amplification</td>
</tr>
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<td></td>
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<td>- Actuate in resonance</td>
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Table 1. Electrochemical parameters of the polypyrrole driven catheter; current values, model suggested value for achieving 30 Hz actuation and recommendations for improving the mentioned parameters.

CONCLUSION

Two polypyrrole based active catheters were designed and fabricated for imaging and maneuvering applications inside artery. One active catheter, “scanner”, is responsible for scanning an optical fiber within a distance of 1 mm in two dimensions, with a relatively high speed to provide forward viewing images from an artery lesion. The second catheter, the “positioner”, is then actively bent to reach the target lesion and guide a wire to navigate through the lesion, while the first fiber optic mounted catheter is monitoring the procedure in real time using optical coherence tomography (OCT). The bending of the positioner catheter using polypyrrole actuators was demonstrated in an aqueous solution of NaPF$_6$ by applying a square potential of ±0.8 V across the two polymer electrodes and a bending radius of 9.76 mm was achieved in 30 seconds. The scanner catheter was also tested and a 2-D motion with a speed of 1 Hz in y direction and 0.1 Hz in x direction was achieved. A fast actuation of 10 Hz was also tested and a total tip displacement of 1 mm was achieved using over-potential actuation, which degraded the polymer within few cycles. The primary challenge to achieving an effective polypyrrole driven scanner catheter for real time OCT imaging is to demonstrate high speed with reasonable lifetime. According to a developed model mechanical amplification along with the polymer electrochemical properties’ improvement will result in a high speed scanner catheter suitable for real time imaging applications.

REFERENCES

21. Shoa Tina, Madden John D., Munce Nigel R., Yang Victor XD., (Accepted in Sep 2009), Analytical modeling of conducting polymer driven catheter, Polymer international, in press.


