Conducting Polymer Based Active Catheter for Minimally Invasive Interventions inside Arteries

Tina Shoa, John D. Madden, Niloofar Fekri, Nigel R. Munce, Victor XD. Yang

Abstract— **An active catheter intended for controllable intravascular maneuvers is presented and initial experimental results are shown. A commercial catheter is coated with polypyrrole and laser micromachined into electrodes, which are electrochemically activated, leading to bending of the catheter. The catheter's electro-chemo-mechanical properties are theoretically modeled to design the first prototype device, and used to predict an optimal polypyrrole thickness for the desired degree of bending within ~30 seconds. We compared the experimental result of catheter bending to the theoretical model with estimated electrochemical strain, showing reasonable agreement. Finally, we used the model to design an encapsulated catheter with polypyrrole actuation for improved intravascular compatibility and performance.**

I. Introduction

CONDUCTING polymer (CP) actuators are a class of "artificial muscle" actuators, with particular characteristics which are advantageous for minimally invasive surgical and diagnostic tools. Some of the characteristics include low actuation voltage (<2 V), ease of fabrication, relatively high strain (typically 2% or greater), and biocompatibility [1]. One of the interesting applications of these types of actuators is to convert passive catheters into active ones, hence providing controllable catheter manipulation inside the body [2]. Catheters are extensively used in many medical procedures such as angiography, stent deployment, intravascular ultrasound, coiling of cerebral aneurysms, and treatment of thromboembolic diseases. Catheters can be used to provide a channel for fluid passage or an entry for a medical device. In angioplasty and stenting, for instance, catheters are employed to guide a therapeutic device to open a blockage inside a vessel. Traditionally, guide wires manipulated external to the patient are used for guidance of the catheter by combinations of push-pull and torque motions [3]. Limitations of the current catheter and guidewire designs include long procedural time, lumen or vessel wall damage, and the subsequent medical complications. 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.

Recently, advanced catheter designs exploit active tip bending for more controllable and efficient minimally invasive medical procedures. Although various active catheters driven by shaped memory alloys (SMA) [4-7], piezoelectric materials and MEMS based devices [8, 9] have been presented, no active catheters are in wide spread use.

Conducting polymer actuators have shown attractive properties, which make them promising to be employed extensively in active catheter application. IPMC (ionic polymer metal composites), another type of artificial muscle actuators, has been used in steerable catheters [10-12]. These actuators can generate large displacements at relatively low voltages (<10 V) and are typically faster than conducting polymers; however, their manufacturing process is often relatively expensive, stresses are smaller and unlike conducting polymers, additional energy is usually consumed to hold the actuator in place. Conducting polymers offer higher stiffness than IPMCs, an attribute which is often important in catheter design [13]. Their efficiency can be higher as maintaining deflection does not require energy expenditure.

In this paper we investigate the feasibility of producing small radius of bending curvature using polypyrrole actuators in order to maneuver a catheter through highly curved vessels. The goal is to access the lesions in narrow and curved blood vessels where a conventional guide wire cannot reach. In our approach a catheter with an active tip is inserted into the vessel using conventional guidewire/catheter insertion techniques. The catheter tip is then bent actively to access the lesion. A flexible wire is subsequently inserted through the lumen of the catheter to navigate through the lesion (See Fig. 1). The whole process is monitored using x-ray angiography from the outside and intravascular imaging from the inside simultaneously. The same catheter can be used to inject the radio opaque x-ray contrast agents.

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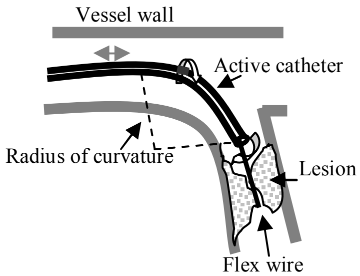


Fig. 1. Schematic of the device

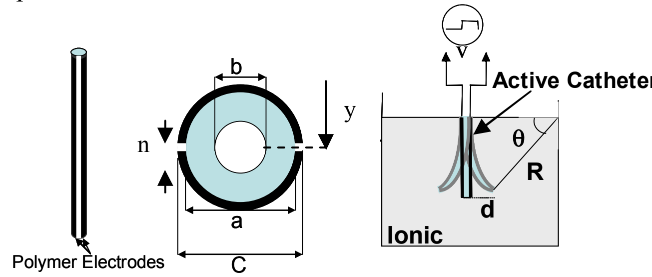
The catheter used to demonstrate the bending is Micro Therapeutics Inc. (Irvine, CA) Ultraflow^{TM} HPC (0.5 mm OD/0.28 mm ID), which is a neurointerventional catheter with a thin, flexible tip that allows maneuvering through narrow and curved arteries. The tip of this catheter is coated with conducting polymer. Coating the flexible tip of the catheter with polypyrrole actuator substantially increases the stiffness at the tip providing a sufficient axial rigidity to prevent the catheter from buckling during insertion and yet enabling passage through highly curved regions (Fig. 1).

Using our initial design, which is similar to a design suggested by Mazzoldi and De Rossi [2], we demonstrate that the polymer can provide sufficient force and displacement to achieve the desired bending. We have achieved a minimum radius of curvature of 9.8 mm in 30 s, which is sufficient for maneuvering through most vessels' branches (e.g. the smallest radius of curvature of the left anterior descending coronary artery is 10 mm [14]). The results of our experiments and modeling are presented here, and a new encapsulated design is suggested which should be able to be used *in-vivo* to achieve the desired bending in a reasonable time.

II. ELECTRO-CHEMO-MECHANICAL MODELING

The polypyrrole coated catheter is a trilayer structure, where two polypyrrole layers are the electromechanically active materials. Fig. 2a shows schematics of the structure which consists of a flexible tube (i.e. catheter) with inner and outer diameters of b=0.28 mm and a=0.5 mm. The coated polypyrrole is divided into two segments that run the length of the tip. As shown in Fig. 2b, application of a voltage between opposing halves in an electrolyte leads to deflection of the catheter towards one side or the other, depending on polarity. The goal is to achieve a 10 mm radius of curvature in less than 30 s.

When a positive potential is applied across the two polypyrrole electrodes inside an aqueous solution of $NaPF_6$ salt, the polypyrrole film on one side is oxidized and the one on the other side is simultaneously reduced. During oxidation mobile negative ions enter the polymer from a surrounding electrolyte to balance charge. In this case positive ions are considered to be too large to be transported within the polymer. The insertion of anions from the electrolyte generates a stress tending to expand the polymer and produces a bending moment. The process reverses itself upon reduction.



(a) (b)

Fig 2. (a) Schematics of the polymer coated catheter modeled as a trilayer, (b) Actuation of the trilayer by applying voltage inside an electrolyte

Equation 1 describes the stress generated, σ, within the oxidized polypyrrole;

$$\sigma = \frac{yE_p}{R} - E_p\varepsilon \qquad (1)$$

where E_p is the Young's modulus of the polypyrrole, R is the radius of curvature; y is the distance from the center of the trilayer structure and ε is the polypyrrole active strain that would occur in response to ion flux under no load. To first order the strain is proportional to the number of ions per unit volume inserted, and equivalently the charge per unit volume, ρ, via the relationship;

$$\varepsilon = \alpha\rho\,. \qquad (4)$$

α is an empirically determined strain to volumetric charge ratio [15-17]. In the same way, polypyrrole contraction occurs during the reduction process because anions leaving the polymer cause a stress gradient opposite to the one described for the oxidation process (see Fig. 3). The net torque leads to a bending of the structure which is opposed by the stresses induced in the catheter walls. Considering the force and torque balance to achieve zero bending moment [18] at the tip of the structure (i.e. cantilever beam condition), and assuming that the electrodes wrap around the catheter almost completely, the radius of curvature of the trilayer structure "R" and the total time of actuation "τ" are found to be:

$$R = \frac{3}{32}\pi\frac{Eb^4 - E_p(a+2t_p)^4 - Ea^4 + E_p a^4}{E_p\varepsilon\left[(a\,)^3 - (a+2t_p)^3\right]} \quad (2) \quad \text{and} \quad \tau = \frac{t_p^2}{D}, \ (3)$$

Here a and b are the outer and inner diameters of the catheter, t_p represents the thickness and of the polypyrrole electrodes, E and E_p are the Young's moduli of the catheter and the polymer respectively. τ represents the time of ion diffusion through the thickness of the polymer, which is also the catheter bending time. D is the effective diffusion coefficient of ions and was estimated to be 5.5×10^{-11} m^2/s from the experiment. The Young's modulus of an electrochemically grown polypyrrole film and a commercially available catheter were measured to be 300 and 75 MPa respectively. The free polypyrrole strain, ε, was measured to be ~ 0.8% during actuation of films between ±0.2 V, increasing to 4% at ±0.8 V vs. Ag/AgCl reference electrodes in aqueous 1 M $NaPF_6$ electrolyte.

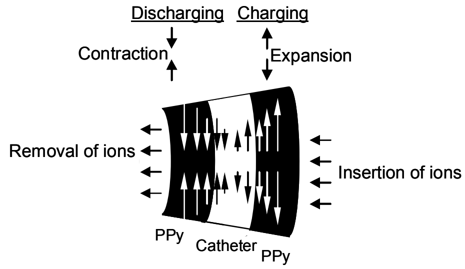


Fig. 3. Stress distribution upon insertion and removal of ions from the polypyrrole layer.

II. Experimental Catheter Step Response

The response of the actuator to a step input of voltage was measured to determine the minimum radius of curvature achieved using the initial design and compared with model predictions. According to the model a thickness of > 40 µm is required to achieve the minimum radius of curvature on the Ultraflow™ HPC catheter used in this experiment. Electroless deposition was first used to deposit an initial layer of polypyrrole, onto which 40 µm thick polypyrrole (doped with PF_6) was electrodeposited. The polymer coating was then divided into two electrodes as shown in Fig. 4.

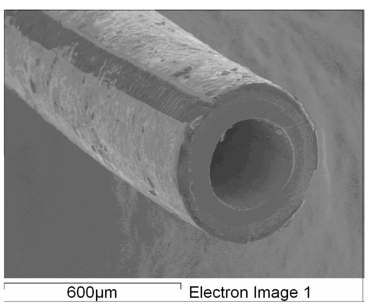


Fig. 4. a) SEM image of the catheter coated with polypyrrole and micromachined into two polymer electrodes.

The analytical model of Equation 2 is compared to experimental results to verify that it provides a reasonable description of the response, and then is used to predict conditions under which small radius of curvature can be achieved. In this experiment a radius of curvature of R= 16.8 mm was obtained in about 32 s by applying step potential of ±0.5 V to the polymer electrodes versus Ag/AgCl reference. Fig.5 shows the initial and final positions of the catheter.

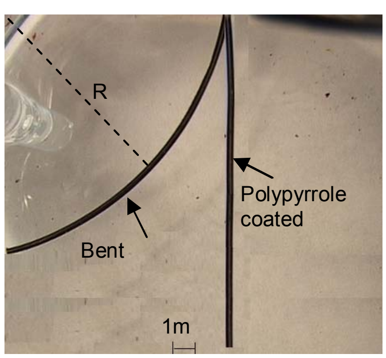


Fig.5. Experimental result showing the catheter at two states: initial, bent.

A. Curvature improvement

Curvature can be increased by applying a higher voltage. According to Equation 2 the radius of curvature, R, is inversely proportional to the polymer electrochemically induced strain. As was mentioned, strain is proportional to the number of charges per unit volume inserted. In steady state the polymer behaves like a capacitor or battery and a capacitive model works quite well, where charge density is expressed in terms of applied voltage, V, and the volumetric capacitance of the polymer, C_v [21]. Hence strain can be written as $\varepsilon = \alpha\rho = \alpha C_v V$. α was estimated (by measuring the amount of charge transferred) to be 3.6×10^{-11} C/m^3 and C_v to be 0.3×10^9 F/ m^3. We increased the voltage, V, in order to increase the strain (see Fig. 6) and decrease the radius of curvature. Further increases in voltage were found to lead to larger strains, but shorter lifetimes, and were thus avoided [19].

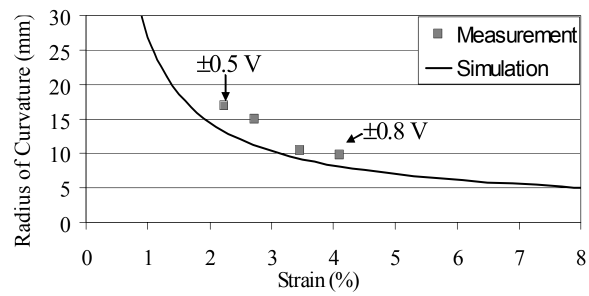
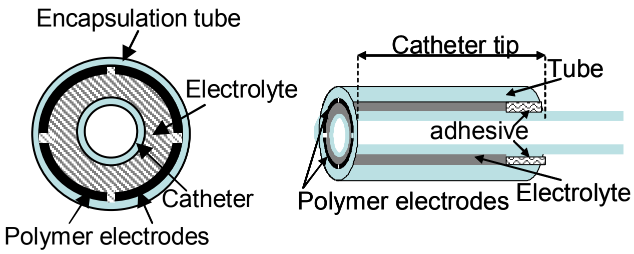


Fig. 6. Experimental and simulated bending radius versus strain for 40 µm thick polymer

Fig. 6 shows the experimental and model-predicted values of radius of curvature for different strains obtained using 40 µm thick polymer layers on the catheter shown in Fig. 2. The model is an extension of Equation 2 in which the width of the spacing between polypyorrole electrodes, 100 µm, is also taken into account. As shown in this figure, a radius of curvature of R=9.8 mm was achieved by applying ±0.8 V across the two polymer electrodes. According to Equation 3, the time needed for ions to diffuse through 40 µm thick polymer is ~ 30 s which is in close agreement with the measured value 32 s for total time of bending.

III. PROPOSED DESIGN

The presented results indicate that the desired degree of bending is achievable using polypyrrole actuators and our initial prototype served as a "proof of concept". However, electrochemical actuation of this device involves using electrolytes and electrical currents which in most medical applications mandate encapsulation. A more practical design is presented in Fig. 7, where the active catheter is encapsulated inside a tube. Four polypyrrole actuators are considered in this design to provide bending moment in two directions. The tube is slit into quadrants and polypyrrole is deposited on the inside surfaces. The catheter coated with a gel electrolyte is then embedded in the center of the tube lumen. A medical adhesive such as Dymax "CTH" UV curable catheter bonding adhesive will be used to attach the quadrants together and the central catheter to the tube wall, creating a completely encapsulated device that can be bent in either of two directions. The model was modified for the proposed geometry and suggested the following parameters in order to achieve the bending radius of 10 mm: tube Young's modulus of 20 MPa with an outer and inner diameter of 1mm and 0.8 mm respectively, electrolyte gel Young's modulus of 1MPa with a thickness of 0.3 mm, catheter tip with a Young's modulus of 75 MPa and an outer and inner diameter of 0.5mm and 0.28 mm respectively (Ultraflow^{TM} HPC). According to the model prediction a minimum bending radius of 10 mm can be achieved in ~ 30 s with a polymer electrode thickness of 40 μm capable of generating an electrochemical strain of 4%.



(a) (b)

Fig. 7. Encapsulated design for active catheterization application: a) cross section view, b) side view.

IV. CONCLUSION

Conducting polymer actuators are good candidates for use in active catheters due to their biocompatibility, low cost, large strain, low actuation voltage and ease of fabrication. In addition these actuators offer high rigidity, which is often important in catheter design.

In this paper the bending of a catheter using polypyrrole actuators is demonstrated. The device was electrochemically actuated in an aqueous solution of $NaPF_6$ by applying a step potential of between -0.8 V to +0.8 V and a bending radius of 9.8 mm was achieved in 30 seconds. The predicted bending radius shows relatively good agreement with experiment.

Since electrochemical actuation of these devices involves using ionic electrolytes, encapsulation is often required. An encapsulated design is proposed in this paper. The encapsulated design is predicted to provide 10 mm of bending radius. Although this design is mainly focused on cardiac catheterization, the concept can be extended to design active elements for other catheterizations and endoscope procedures.

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