Manufacturing PA Innovation Program

Additive Manufacturing Method for Smart Surgical Needles

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RESEARCH OBJECTIVE

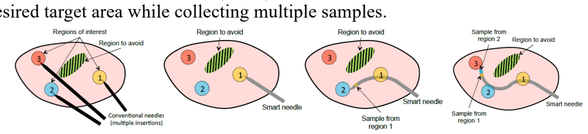
This project aims to develop advanced manufacturing method that is suitable to integrate actuating and/or sensing elements to surgical devices, which will enable in-situ monitoring and active control of such medical devices. Specifically, this work focuses on surgical needles containing Nitinol shape memory alloy (SMA) wires. The objectives are:

1) Design and manufacturing SMA-containing needles;
2) Characterization of mechanical response of smart needles; and
3) Development and evaluation of scale-up manufacturing methods

It is expected that successful completion of this project will demonstrate the functionality of smart needles, and find a pathway towards development of design and manufacturing method(s) suitable for commercial production.

MOTIVATION

Surgical needles are widely used in various medical procedures. The lack of active control makes maneuvering the needles a challenging task. Introduction of active control elements, such SMA wires, in surgical needles can enhance their maneuverability and increase the precision. The schematic shown below demonstrates that a flexible (smart) needle can avoid obstacles to reach the desired target area while collecting multiple samples.



APPROACH

Overview

This project is planned to be carried out in two stages. In the current first stage, we focus on laboratory exploration and demonstration at Temple University. Faculty members and student researchers are working on device design, prototype fabrication, mechanical testing, and finite element analysis. Industrial partners are informed about the progress through periodical discussions. The second state will focus on development of manufacturing technologies suitable for large-scale fabrication through collaboration between the university team and the industrial partners.

Prototype Manufacturing using 3D Printed Mold

The initial effort in development of manufacturing method involved selection of polymer materials. Potential materials should possess sufficient flexibility which when combined with metal components, and good binding and insulating behavior.

Figure 1 illustrate the fabrication process of a prototype needle through infusion of a silicone based polymer. In this process, Nitinol SMA wires were first fixed onto thin metal bars (as a surrogate of a surgical needle) using collars (Fig. 1a). Lead wires were also attached. Meanwhile, a mold was fabricated using 3D printing (Fig. 1b). The needle with SMA wire was then placed in the mold (Fig. 1c) and the polymer was introduced by an infusion process. After curing, the needle was removed from the mold (Fig. 1d).

In this process, 3D printing was used to manufacturing the mold. The goal is to fabricate the polymer layer on the metal components in a mold-free manner, which could be achieved through additive manufacturing utilizing laser-induced polymerization.

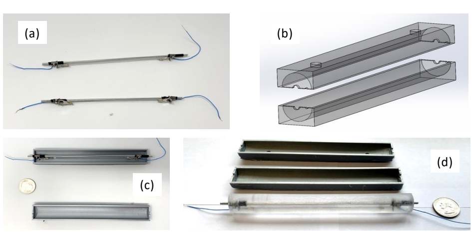


Fig. 1 Fabrication process of a prototype smart needle using polymer infusion.

Future Work

Future laboratory work will include research on polymer materials, development of manufacturing process, and testing and analysis. Collaboration between the university team and the industrial partners will involve evaluation and modification of manufacturing methods for potential commercial production.

Prototype Manufacturing in PVC Tube

Figure 2 illustrates the fabrication process of a prototype needle through infusion of a silicone based polymer into a polyvinyl chloride (PVC) tube. In this process, the needle with SMA wire was placed into a soft PVC tube and the polymer was directly injected and cured in the tube. Two 3D printed plugs (Fig. 2a) were used to hold the needle and they were removed after curing (Fig. 2b).

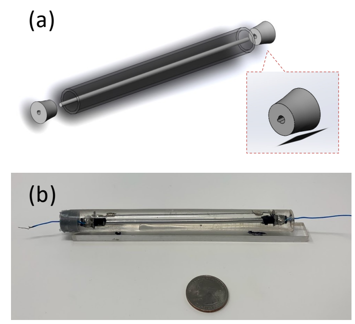


Fig. 2 Schematic (a) and prototype needle (b) fabricated by injection of silicone into a PVC tube.

Testing of Prototype Needles

The prototype of nitinol wire actuated smart needle was tested for deflection using a setup as shown in Fig 3. A 300 µm diameter nitinol wire (SMA) obtained from Dynalloy, Inc with recommended pull force of 1280 grams when heated above the phase transition temperature of 70°C was used as actuator. The pull force comes from property of nitinol wire to contract (3-5%) when heated to austenite phase from martensite phase. The contraction of SMA causes bending of the needle. When the power supply is removed, the needle goes back to original position due stiffness of needle and phase reversal in Nitinol. The recommended current for heating was 1500 mA for one second. Since the polymer coating absorbed heat, the deflection test was conducted by Joules heating of Nitinol with 1600 mA current for 12 sec until the maximum deflection was obtained as shown in Fig. 4.

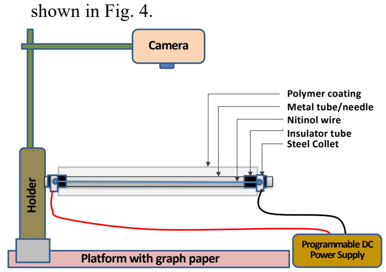


Fig. 3 Schematic of SMA actuated needle deflection test setup.

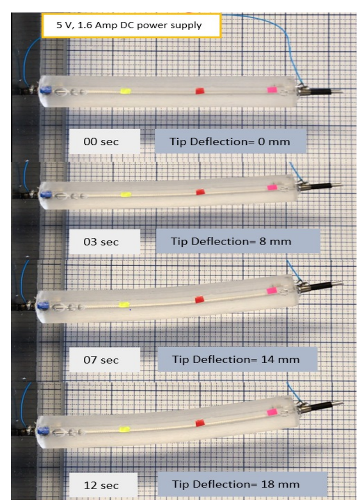


Fig. 4 Deflection result of prototype needle.

IMPACT ON PA

Pennsylvania, one of the most populous states in the US, has multiple cities serving as national and regional medical hubs. Medical device sector is a high value-added industry. Investment in research and manufacturing of medical devices has great potential to create high-paying jobs in the state. This project aims to develop next generation medical needles which could be widely used. The partnership between Temple University and the industrial partners will give PA based companies the advantage to access the developed technologies. Meanwhile, graduate and undergraduate students participated in this project will have opportunities to work within an industrial environment and join the PA workforce after graduation.

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