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DESIGN AND CONTROL STRATEGY OF TIP MANIPULATION FOR SHAPE MEMORY ALLOY ACTUATED STEERABLE NEEDLE

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ABSTRACT

In a minimally invasive percutaneous process like biopsy, brachytherapy, and tissue ablation, the inner soft tissue is accessed through surgical needle-puncture of the skin. This process reduces tissue damage and risk of infection and improves patient recovery time. However, its effectiveness depends on the needle's ability to travel on a curved path, avoid obstacles, and maintain high targeting accuracy. Conventional needles are passive and have limited steerability and trajectory correction capability. This has motivated researchers to develop actuation mechanisms in the needles to make them active. In this study, an innovative active steerable needle with a single shape memory alloy (SMA) wire actuator is designed, fabricated, and tested for maneuver. A closed-loop Proportional Integral Derivative (PID) controller with position feedback is developed to control needle tip deflection in air and tissue-mimicking gels. The needle tip is deflected up to 5.75 mm in the air. The tip deflection is increased to 15 mm for a 100 mm insertion into the tissue-mimicking gels to utilize additional bending caused by an unbalanced moment generated in the needle. Results show that needle tip deflection control has an average root mean square error (RMSE) of 0.72 mm in the air and 1.26 mm in the tissue-mimicking gel. The low targeting error with the SMA actuated needle, and the designed control system would increase the efficacy of the percutaneous procedures. The needle tracking performance would next be tested in biological tissues.

Keywords: steerable needle, shape memory alloy, actuator, PID controller

1. INTRODUCTION

In a minimally invasive surgery, a surgical tool is inserted through a small incision in the skin. Its tip is attempted to reach the target region in the soft tissue inside a human body. The effectiveness of percutaneous interventional procedures depends heavily on the accuracy of the surgical needle tip reaching the target tissue inside the body. Conventional surgical needles are flexible bevel tip needles. Reaching the target in a single attempt with these needles is difficult because of the needle deflection and tissue movement. As a result, surgeons typically make multiple passes to try to reach closer to the target. Sometimes, the surgeon must insert the needle in a curved path to bypass obstacles like critical blood vessels and nerves in front of the target. The asymmetrical tip geometry in bevel tip needles creates an unbalanced force to cause bending during insertion. The needle is rotated and applied with a moment at the base to change the direction and magnitude of flexural bending during tissue insertion. However, these steering strategies with conventional needles cannot increase needle targeting accuracy but can increase tissue shear and tear, causing increased tissue damage.

To reach the target with high accuracy in one pass and to bypass any obstacles, it is desirable to make the needle tip travel in a defined curved trajectory. It is also desirable to control the needle tip motion along the curved trajectory to ensure that the needle tip reaches the target as accurately as possible. The active steerable needles can overcome the limitation of bending curvature found in conventional passive needles by installing actuation mechanisms. These mechanisms could be activated by electrical, thermal, mechanical, magnetic, or hydraulic energy. Current research in active needles can be categorized into four unique designs: pre-curved stylet actuated needle, tendon actuated active cannula, programmable bevel, and SMA wire actuated needles [1]. In an SMA wire actuated active needle, a prestrained wire actuator attached to two ends in a needle is heated to raise its temperature above the actuation temperature and cause contraction. The contraction upon heating occurs because the wire remembers its initial unstretched length due to the property called the shape memory effect. Other properties like super-elasticity, high power-to-weight ratio, and biocompatibility have made SMA wire a suitable candidate for the actuator in the active needles. The SMA wire contraction causes needle tip deflection, which can be used for steering the needle towards the target while being inserted into a tissue. SMA actuated needle can bend with varying curvature, unlike a pre-curved stylet needle that can actuate only with fixed curvature. It has fewer components, unlike a programable bevel tip needle, so manufacturing on a clinically applicable scale is feasible. The actuation in SMA actuated needle applies only on the portion of the needle where the actuator is installed and is uncoupled with flexural rigidity of the entire needle body, unlike the tendon-actuated needle.

Ryu et al. [2] proposed an active needle with an SMA wire actuator, activated by infrared radiation through silica optical fiber. The needle also used optical fibers for sensing SMA wire temperature and needle bending curvature feedback to control the insertion maneuver according to Auricchio algorithm-based elastic model. Ayvali et al. [3] designed a steerable cannula with three bending sections near the tip connected by SMA actuators and applied pulse width modulation (PWM) control using visual position and temperature feedback. Joseph et al. [4] developed SMA actuated flexible needle and compared the needle tip trajectory tracking performance using electromagnetic (EM) position sensor, vision, and ultrasound (US) feedback and concluded that the EM sensor was the best in terms of achieving smaller RMSE. They also used adaptive PID with sliding mode controller (APID-SMC) to improve controller performance in SMA actuated needle. Ruiz et al. [5] also used the EM position sensor feedback system to develop PID and PID-P^3 control systems to control needle deflection in air and water.

In our previous work [6], we presented an SMA wire-actuated active steerable needle design consisting of a bendable tip region. The needle was composed of an active stainless-steel stylet and compliant PTFE collet. A computational study was performed on the SMA actuation and corresponding needle tip deflection with stationary analysis applying the built-in "Lagoudas model" in COMSOL Multiphysics. The simulation showed that the needle tip would deflect up to 6 mm when the temperature of the SMA wire was raised to 90 °C and would induce stress in the SMA lower than the yield strength. Similarly, the prototype needle was tested for tip deflection during insertion in the air and the tissue-mimicking gel.

In this study, the SMA wire actuated active steerable needle design is improved and tested for steerability and control. The current needle prototype has a 2.60 mm outer diameter compared to 3.25 mm in our previous work. The study presents 2D needle steering with 3D-based work as future scope. The needle design allows the stylet to rotate inside the collet during tissue insertion and change the bending direction to all 360° regions without shearing the tissue (Fig. 1). Thus, this work focuses on performing real-time coordinated position control of the improved design of the SMA actuated active steerable needle. First, the needle tip deflection control in air is tested for static setpoint displacement and dynamic trajectory tracking. This is followed by testing the needle for trajectory tracking inside a tissue-mimicking gel. The paper's outline is as follows: Section 2 elaborates on the materials and methods involved in our work. Section 3 discusses the experimental results obtained. Finally, conclusions are presented in section 4.

2. MATERIALS AND METHODS

This section is divided into three subsections; where the first subsection explains the design of the SMA actuated active steerable needle and details the components used in the design and prototype fabrication. In the second subsection, a controller design for the needle tip deflection control in the air medium is studied. Static target tracking and dynamic trajectory tracking are performed for needle tip deflection in the air. In the third section, the SMA actuated active steerable needle prototype is inserted into polyvinyl chloride (PVC) tissue-mimicking gel of two different stiffness with the control system to track a predefined trajectory.

2.1 Design of The SMA Actuated Steerable Needle

The SMA wire actuated active needle is composed of stainless-steel stylet and PTFE tube collet. The stylet is machined near the tip region to install a single SMA actuator, as shown in Fig. 1. The diameter of the stylet is 1.30 mm. In the bending region near the tip, the stylet is machined to cut a slot 0.90 mm deep from the surface. An SMA wire with crimped ends is attached to the two ends of the slot. One of the two ends is made electrically conductive to the stylet body while the other is insulated. This allowed using the stylet body as one terminal and the insulated end of SMA wire as a second terminal for the power supply. The assembly is inserted into a PTFE tube collet for completing the active needle prototype fabrication. The finished diameter of the active needle prototype after adding the PTFE tube collet is 2.60 mm.

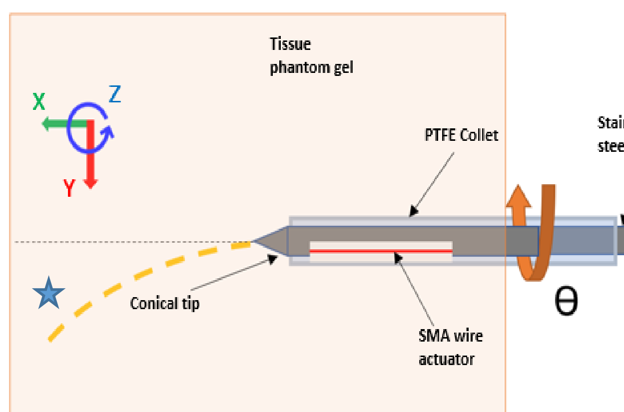

Figure 1: Tip Region of Active Needle Showing Stylet, Collet, and SMA Wire Actuator. Yellow Dashed Line Represents Imaginary Deflected Shape of Needle After SMA Wire Actuation

A 70°C activation nitinol wire with a diameter of 0.25 mm, and a length of 27 mm at a prestrained state is used as the SMA wire actuator. These dimensions are chosen based on our previous work [6]. The SMA wire ends are fixed to the ends of the slot at the bending region of the stylet. When an electric power supply heats the SMA wire, its temperature rises above the actuation temperature, causing it to contract due to the shape memory effect. The SMA actuator can achieve a 6 mm needle tip deflection in the air at a temperature of 90º C which prevents the temperature on the outer surface of the PTFE collet from being more than 50º C. This prevents tissue damage due to SMA heating. The contraction of the SMA wire causes the needle tip region to bend. This process reverses, and the wire returns to the prestrained state (allowing the needle to be straight in a low viscous medium like air) when the wire cools. To repeat the bending action, the actuator is heated again by resuming the electric power. A PWM power is applied to the SMA wire for heating actuation, but deactivation is achieved by self-cooling. Some properties of SMA wire derived from the Manufacturer's Datasheet are presented in Table 1.

Table 1: Properties of SMA (Nitinol) Wire Actuator

Property	Value
Martensite start temperature	56°C
Martensite finish temperature	48°C
Austenite start temperature	70°C
Austenite finish temperature	90°C
Calibration stress level	172 MPa
Yield strength in the austenite phase	345 MPa
Maximum Transformation Strain	4.5%
Young's modulus of the austenite phase	90 GPa
Young's modulus of the martensite phase	32.5 GPa
Poisson's ratio	0.33
Density	6450 kg/m^2

The prototype of the SMA actuated active steerable needle is shown in Fig. 2. The active steerable needle is designed to be used in a robotic needle insertion system, as shown in Fig. 3. The active steerable needle has 3 DOFs: 1. needle tip deflection in the Y direction (controlled by SMA actuation), 2. needle insertion in the X direction (controlled by Nema 23 stepper motor operating a linear unislide), and 3. needle stylet rotation (controlled by Nema 14 stepper motor for stylet rotation). For this study, the stylet angle is kept fixed; thus, displacements are controlled only in the XY (horizontal) plane. An EM position sensor is attached to the needle tip for feedback. The robotic active needle insertion system also allows for measuring SMA wire temperature, and power consumed using a NI cDAQ data acquisition system. The PWM power is fed to the SMA wire using the PWM MOSFET switch, which is operated by the digital PWM pin of Arduino Uno. Power is derived from a BK Precision Switching Mode DC power supply to heat the SMA wire and thus actuate the needle tip deflection.

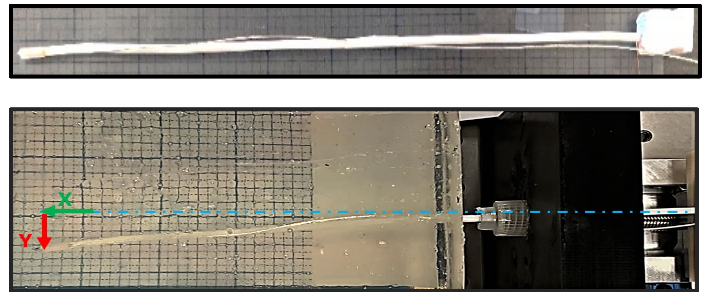

Figure 2: SMA Actuated Active Needle Prototype of Diameter 2.60 mm and Length 200 mm (Top). Active Needle Inserted into Tissue-mimicking Gel (Bottom)

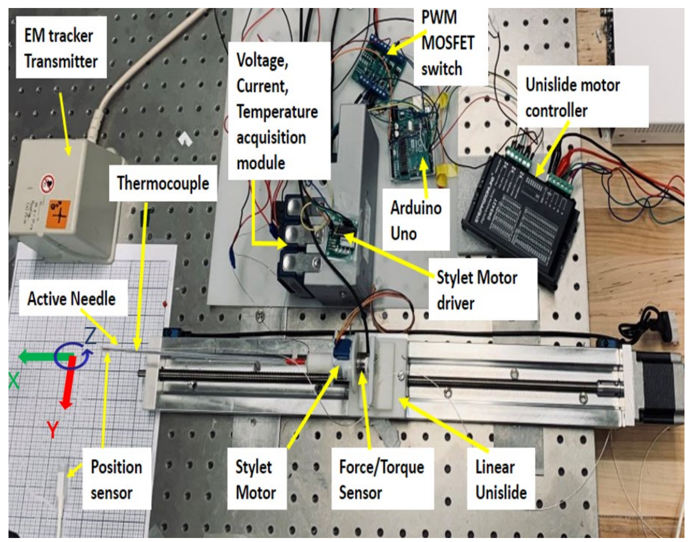

Figure 3: Active Needle Setup in Linear Unislide for Robotic Insertion

2.2 Control of Needle Tip Deflection in Air

The EM position sensor data in x and y coordinates are acquired in LabVIEW, which is converted into the absolute displacement of the needle tip. A PID function in LabVIEW is inputted with the error computed from setpoint displacement and measured displacement of the needle tip. The PID gains are manually tuned, and the control output on each iteration is fed to the Digital Arduino pin using the LINX add-on for LabVIEW to establish communication between LabVIEW and Arduino. The peak current across the SMA wire is limited to 0.7 Amp according to the manufacturer's recommendation to prevent the overheating of the SMA wire. Thus, real-time control of needle tip displacement is obtained based on position feedback. The schematic of the control system for needle tip displacement based on resistive heating of SMA wire is shown in Fig. 4. The needle prototype and the controller are tested for a static displacement of 5 mm as well as a sinusoidal displacement of 5.75 mm. The results of the needle tracking performance are discussed in the results and discussion section.

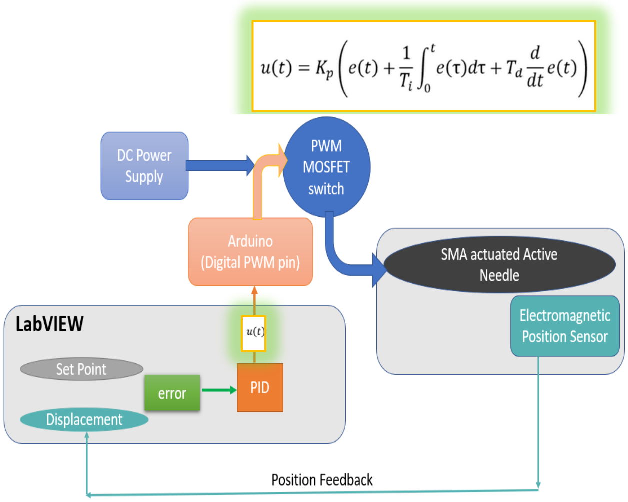

Figure 4: Schematic of the PID Controller Using LabVIEW and Arduino for Needle Tip Deflection. u(t): Input in the Form of PWM Current Duty Cycle, K_p: Overall Gain, e(t): Error Between Desired and Actual Displacement, T_i: Integral Time, and T_d: Derivative Time

2.3 Control of Needle Tip Trajectory Tracking in Tissue-mimicking Gel

In addition to an SMA actuated needle tip deflection control in the air, a trajectory control in homogenous PVC tissue-mimicking gel of 10 kPa and 20 kPa stiffness is tested for the needle and the controller. A trajectory for the needle tip displacement in the XY plane is created using the waypoint trajectory generation function in MATLAB. The tissue-mimicking gel induces additional needle deflection, which sustains even after deactivating the SMA wire. Thus, smaller actuation is sufficient to achieve a larger deflection for the 100 mm tissue insertion depth than in the air.

The multi-input multi-output (MIMO) PID controller is designed to control needle tip deflection by PWM duty cycle and insertion depth by a linear unislide motion, which is activated using Arduino Uno LINX interface in LabVIEW. The PID time step and the loop iteration time in LabVIEW are set to 25 milliseconds such that at each iteration, the data point (x, y) of the desired trajectory is applied as a setpoint for the PID controller. The tracking performance of the needle to the planned trajectory inside the tissue-mimicking gel is explained in the results and discussion section.

3. RESULTS AND DISCUSSION.

Step response of the needle tip deflection of 5 mm in the air in the XY (horizontal) plane is shown in Fig. 5. The result indicates that the needle achieves the set displacement at about 10 seconds and remains steady for almost 100 seconds. The fluctuation in the static target is due to noise in the position data acquired and small vibration that could not be controlled in the air at the static target. The RMSE is 0.73 mm, and the RMS control used is 0.39 Watt.

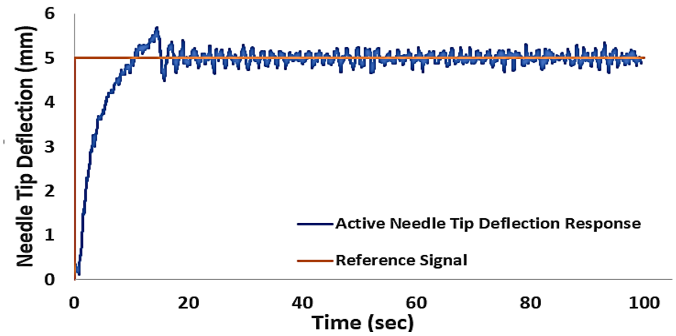

Figure 5: Active Needle Tip Deflection Step Response in Air for 5 mm Setpoint

Similarly, the needle prototype and the controller performance are tested for dynamic target tracking in the air, resulting in a smoother response, as shown by sinusoidal signal tracking in Fig. 6. The sinusoidal signal applied to the needle tip deflection had a small amplitude of 2.25 mm at an offset of 3.5 mm, and a slow period of 40 seconds. The slow and small trajectory tracking is applied because a gradual change in the needle tip deflection is desirable during tissue insertion to reduce the tissue damage and increase accuracy. The results show that the trajectory tracking in the air is smooth, except for a slight phase lag between the input signal and the measured output position. The RMSE is 0.71 mm, and the RMS control used is 0.39 Watt.

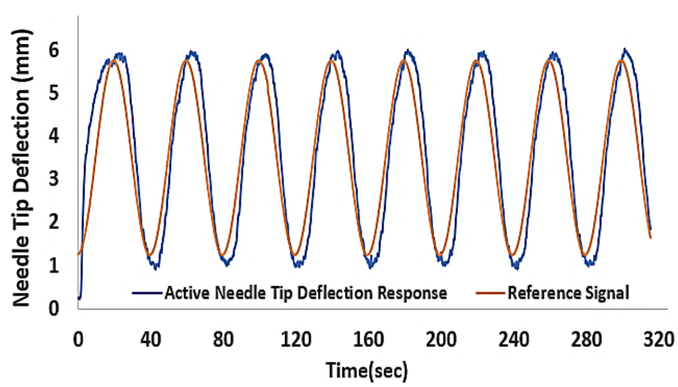

Figure 6: Active Needle Tip Deflection for Sinusoidal Input Signal in Air (1.25 mm to 5.75 mm Displacement with a Period of 40 Seconds)

Next, the active steerable needle is inserted into tissue-mimicking gels of two different stiffness applying the PID controller to track the desired trajectory. The desired trajectory is developed such that the deflection is only planned in the positive Y-axis after the initial insertion depth of 20 mm along the X-axis without deflection (refer to Fig. 1 and Fig. 3). Preliminary results show that the controller can track the needle tip trajectory inside a 10 KPa stiffness tissue gel (Fig. 7) with an RMSE of 1.52 mm. Similarly, the needle insertion in a 20 KPa stiffness tissue-mimicking gel showed an RMSE of 1 mm (Fig. 8).

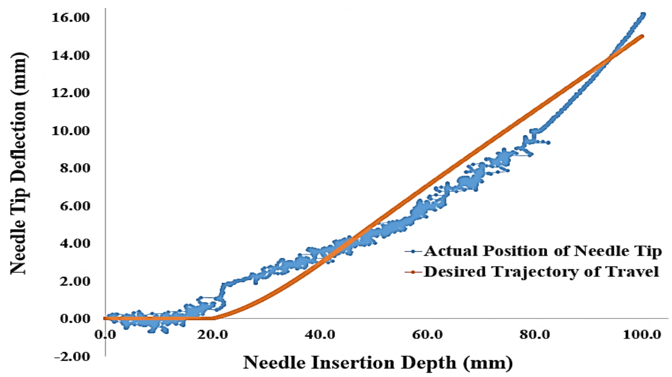

Figure 7: Active Needle Tip Tracking the Desired Trajectory Inside a 10 KPa Stiffness Tissue -mimicking Gel (Insertion Duration: 125 Seconds)

As the tissue stiffness increases, the needle deflection increases upon further insertion along the X-axis even when the controller stops the actuation along the Y-axis. This is because of the needle's inability to become straight on stiffer tissue medium. Similarly, the unbalanced force developed in the curved portion of the needle brought in by earlier actuation keeps adding to the error. Without the addition of stylet rotation, the only way for the needle to get back to the planned trajectory after the deflection overshoot is by allowing the curved portion of the needle to become straight, relying entirely on the needle's flexural rigidity. This is not achieved in stiffer tissues. A 180^0 degree needle rotation could be added to correct this error.

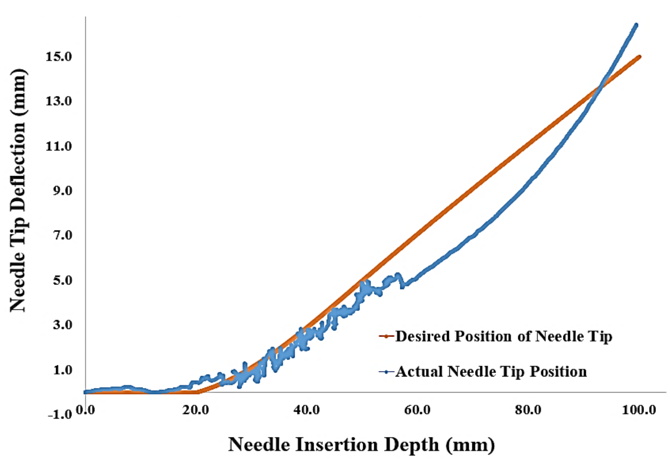

Figure 8: Active Needle Tip Tracking the Desired Trajectory Inside a 20 KPa Stiffness Tissue-mimicking Gel (Insertion Duration: 125 Seconds)

4. CONCLUSION

This study presents an improved design of the SMA actuated active steerable needle that was introduced in our previous work [6] and proposes a control strategy based on tip manipulation. The outer diameter of the active needle prototype is 2.60 mm. The needle design is simple, uses a single SMA wire actuator, and can be further reduced in diameter with advanced manufacturing techniques to a clinically applicable size of 2.11 mm (14 gauge). The PTFE polymer collet provides thermal and electrical insulation to the tissue from the SMA wire actuator. The control system used in this study is a basic PID controller, which has been tuned manually and can control needle tip motion in the desired path in air and tissue medium with small errors. In future work, the rotation of stylet will be added to the current design to perform more complex path tracking and robust error correction. Further study would introduce the needle steering in biological tissues to establish its applicability.

ACKNOWLEDGEMENTS

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