Characterization of optically actuated MRI-compatible active needles for medical interventions

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ABSTRACT

The development of a Magnetic Resonance Imaging (MRI) compatible optically-actuated active needle for guided percutaneous surgery and biopsy procedures is described. Electrically passive MRI-compatible actuation in the small diameter needle is provided by non-magnetic materials including a shape memory alloy (SMA) subject to precise fiber laser operation that can be from a remote (e.g., MRI control room) location. Characterization and optimization of the needle is facilitated using optical fiber Bragg grating (FBG) temperature sensors arrays. Active bending of the needle during insertion allows the needle to be accurately guided to even relatively small targets in an organ while avoiding obstacles and overcoming undesirable deviations away from the planned path due to unforeseen or unknowable tissue interactions. This feature makes the needle especially suitable for use in image-guided surgical procedures (ranging from MRI to CT and ultrasound) when accurate targeting is imperative for good treatment outcomes. Such interventions include reaching small tumors in biopsies, delineating freezing areas in, for example, cryosurgery and improving the accuracy of seed placement in brachytherapy. Particularly relevant are prostate procedures, which may be subject to pubic arch interference. Combining diagnostic imaging and actuation assisted biopsy into one treatment can obviate the need for a second exam for guided biopsy, shorten overall procedure times (thus increasing operating room efficiencies), address healthcare reimbursement constraints and, most importantly, improve patient comfort and clinical outcomes.

Keywords: Fiber Optic Sensors; SMA Actuators; Biopsy Needles; Cryoprobes; FBG Temperature Sensors

ABSTRACT FOR ONLINE OR PRINTED PROGRAMS (100 WORDS)

The development of a Magnetic Resonance Imaging (MRI)-compatible optically-actuated active needle for guided percutaneous surgery and biopsy procedures is described. MRI-compatible actuation in the small diameter needle is provided by an electrically passive design based on non-magnetic materials including a shape memory alloy (SMA). Optimization of the needle is facilitated using optical fiber Bragg grating sensor arrays for characterization of the actuation efficiency.

1. INTRODUCTION

Currently, experimental image-guided medical procedures and operations are performed with a variety of passive steering approaches, wherein the steering is accomplished by twisting and rotating the needle base during insertion to compensate for needle deflections in the tissue. The needles used in these passive approaches often exploit tip asymmetry, flexible shafts, and/or a variety of curved needle designs, in order to generate bending forces along the length of the needle. Significant research has been carried out using, for example, bevel-tip needles[1, 2], pre-strained needles[3], and curved concentric tubes with variable stiffness[4]. A limited selection of pre-curved passive needles also are commercially available, typically in 18-gauge and larger calibers. In providing better path predictability, however, passive steering generally requires complex trajectory planning algorithms, utilizing programmable robots with advanced software. Several groups have implemented image-guided computer technology and robotic assistance to improve the accuracy of needle insertions. These approaches automatically align the needle with the target, based on a known target location in three dimensions[1]. Although these advanced guidance systems provide greater needle dexterity and improved accuracy, they are often unable to make adjustments whenever the inevitable path errors arise. Correcting a trajectory in the face of these path errors requires knowledge of needle-tissue forces; however, in predicting these forces, all passive approaches implicitly assume that the tissue properties are homogeneous, which is not necessarily so.

In addition, robotic devices based on automated needle-target alignment often must rely on effectively immobilized target tissue; they may not be able to anticipate and correct rapidly enough for deviations from a straight needle trajectory. To date, robotic needle steering approaches are still wrestling with control, complexity, and cost issues, which so far have prevented more widespread clinical adoption.

An active system that could provide for the direct dynamic control of needle deflection, even without having to resort to complex robotic path planning, would be highly desirable. In particular, the use of controllable actuation from the proximal end would give physicians the ability to manipulate the needle tip in real time, thereby providing a capability for rapid needle reorientation, even without full robotic guidance. The key to the success of all active steering approaches is compatibility with advanced imaging methods, which would allow for the image feedback and simultaneous needle observation required for fast and precise targeting and for trajectory correction. Commonly used imaging systems include Ultrasound (US), Computed Tomography (CT), and Magnetic Resonance Imaging (MRI).

Herein, we describe a Magnetic Resonance Imaging (MRI)-compatible optically-actuated active needle based on a shape memory alloy (SMA) for guided percutaneous surgery and biopsy procedures. Active bending of the needle during insertion allows the needle to be accurately guided to even relatively small targets in an organ while overcoming undesirable deviations away from the planned path due to unforeseen or unknowable tissue interactions. This feature makes the needle especially suitable for use in image-guided surgical procedures when accurate targeting is imperative for good treatment outcomes. Such interventions include reaching small tumors in biopsies, delineating freezing areas in, for example, prostate cryosurgery and improving the accuracy of seed placement in brachytherapy. Combining diagnostic imaging and biopsy into one treatment obviates the need for a second exam for guided biopsy, shortens the overall procedure time (thus increasing operating room efficiencies), addresses healthcare reimbursement constraints and, most importantly, improves patient comfort and clinical outcome. A key impact of this innovation to image assisted surgery is to add a steering degree of freedom in an MRI compatible disposable 18 gauge needle and producing predictable deflection of the distal end without resorting to electrical or magnetic means. The optically actuated SMA approach represents a potential breakthrough that could lead to a class of needles that provide optimal routing to tumors, shorten procedure times and are safer and more controllable than passive beveled-tip needles available today. The Fiber Optic (FO) delivery technology lends itself well to additional sensing functionalities leading to a single multifunctional fiber-instrumented needle adaptable to a large variety of medical interventions.

The innovation in the proposed concept is the needle stylet design, which uses fiber optically delivered infrared (IR) laser radiation to efficiently heat an internal force-inducing part (e.g., actuator) made from a shape memory alloy (SMA), thereby producing predictable deflection of the distal end without resorting to electrical or magnetic means, which would require electrical wiring. The absence of conductive or magnetic materials makes the needle MRI compatible, immune to fields generated by MRI devices, and less prone to cause artifacts in the imaging system. Use of a flexible fiber optic (FO) distributed light-delivery system results in a miniaturized (< 1.5 mm diameter), steerable needle system comprised of low cost components compatible with the practical issues of disposability and reimbursement. Compared with techniques that manipulate the needle at the base, such as rotation and translation, active tip bending is a more effective means of targeting and compensating for tissue resistance. As the requirements for complex trajectory planning are reduced, positional sensitivity is increased, and greater control can be exerted by the surgeon. We believe that the optically actuated SMA (pre)product developed in this work represents a breakthrough in interventional surgery that will lead to a class of manipulatable needles that offer better patient outcomes, while being only moderately higher in cost than beveled-tip needles available today. An added and important benefit is that this innovative flexible needle offers an more certain path to commercialization and clinical approval as contrasted to more complex techniques based on fully robotic, cable driven systems that are unique to specific procedures. Downstream, the FO needle product can be interfaced to additional FO mediated functionalities such as shape[5] or curvature and force sensing, potentially leading to a single multi-functional fiber-instrumented needle (e.g., the smart needle) adaptable to a large variety of medical interventions under real-time MRI guidance. Alternatively, the simplicity and cost effectiveness of an active needle with controlled bending and unbending could also make it attractive for applications that rely on imaging modalities other than MRI, including US and computed tomography CT. Finally, there is good reason to believe it will ultimately be possible to develop thinner needles that are optimized for applications requiring 18- or 20-gauge needles capable of reaching the deepest organ and tumor targets.

2. ACTIVE NEEDLE DESIGN

A biopsy needle is composed of two main parts: an inner stylet and an outer cannula or sheath. During biopsy, the two elements are inserted together to reach the biopsy site. Then, the inner stylet is removed, leaving the hollow sleeve in place. This allows a probe to be inserted to perform biopsy or other interventions. For our device initially proposed in Ryu et al., [6, 7], the active element is the inner stylet initially inserted with the cannula, as indicated in Figure 2, which shows the active needle stylet. The main design features include:

- An active bending element composed of a 250 µm diameter NiTi SMA wire located near the tip
- A superelastic NiTi tube with a set of slits making the element uni-directionally flexible
- A multi-lumen PTFE (teflon) core placed inside the tube
- A soft outer sheath made of PTFE or surgical-grade silicon
- Two optical fibers inserted into the dedicated lumens of the PTFE tube used for light delivery as a way of heating the SMA
- Two single mode optical fibers with embedded FBGs than can be used to sense temperature

In this design, NiTi, well-known for its MR- and bio-compatibility, is the only metallic material used. Figure 1 shows the needle design in (a) transverse and (b) longitudinal cross sections. As shown in the longitudinal view, each end of the SMA wire is anchored by threading it through two holes. Wire-EDM machined grooves on the needle tip portion distribute the high recovery stresses and allow the wire be clamped firmly and flat.

The Figure 2 inset shows the two lumens cored to accommodate the two optical fibers used for the SMA wire heating (blue), a lumen (green) used to embed a FBG fiber as temperature sensor fiber 1, and a larger lumen further away from the wire (purple) used to embed a FBG fiber as temperature sensor fiber 2.

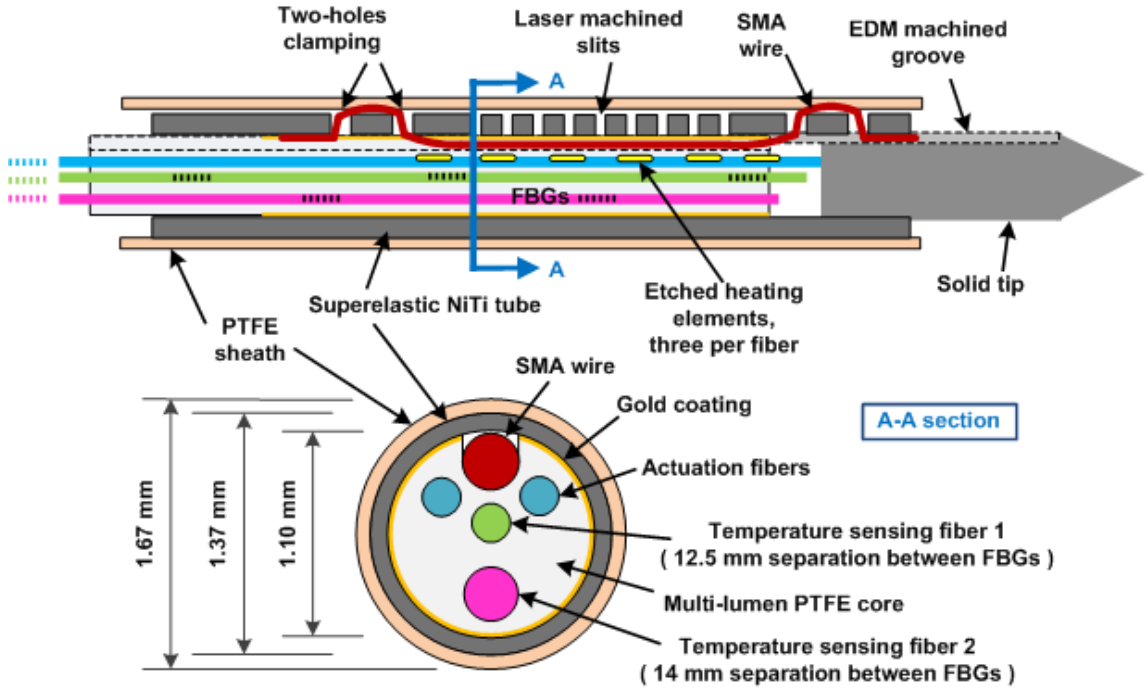

Figure 1: Single-wire design [6, 7] with following features: PTFE sheath – 1.67 mm OD (16G); Superelastic NiTi tube - 1.37 mm OD (18G); Multi-lumen PTFE core – 1.10 mm OD; Gold coating; SMA NiTi wire – 0.25 mm OD; Actuation fiber lumens (blue) – 0.15 mm OD; Temperature sensing fiber lumen (green) – 0.15 mm OD; Temperature sensing fiber 2 lumen – 0.25 mm OD

Note that temperature sensing fiber 1 being located near both the SMA wire and the neutral axis should measure temperature of SMA wire with minimal strain effects – however, in practice, the pressing of the wire at the clamp point resulted in a small strain for this tight fitting fiber. On the other hand the larger off-axis lumen allowed the fiber in to slide avoiding the off-axis strain effect due to curvature. The core material PTFE is largely IR-transparent and has adequate mechanical stiffness to support the SMA wire and maintain alignment of the fibers, keeping them parallel to the axis.

3. SMA OPERATION

The needle operates when the SMA wire contracts in the austenite start to austenite finish region shown in the schematic of Figure 2, which shows schematically the hysteresis curves for typical SMA, indicating the transition temperatures between the various material phases. In initial proof-of-concept experiments, we used Flexinol wires had a austenite transition start temperature, A_s, of 70°C and an austenite transition finish temperature, A_f, of 90°C. A key objective of our work has been to obtain wires with transition temperatures close to body temperature. In particular, lower transition temperature wires would allow achieving higher bending with lower laser input power, and correspondingly less risk of potential collateral damage to surrounding tissue due to excess heat. On the other hand if the transition temperature is too low, as in some commercial wires with A_s, of 20°C that we obtained, then body contact will induce contraction and bending of the needle. Thus our objective was to obtain wires with A_s, in the region 35°C. As we discuss elsewhere, tensioning the wire and annealing are key ingredients used to tune the transition temperatures. This paper focuses on the thermal characterization during operation.

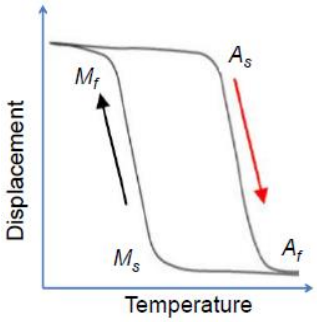

Figure 2: SMA parameter definition: schematic of displacement versus temperature, showing the following key temperatures: 1. Martensite Finish (M_f), 2. Martensite Start (M_s), 3. Austenite Start (A_s), 4. Austenite Finish (A_f).

4. NEEDLE CHARACTERIZATION USING FBG TEMPERATURE ARRAYS

In work to date, we have demonstrated the optical actuation concept and initiated an optimization path to achieve operation at body temperature. Critical to this optimization is characterization of the SMA performance as a function of optical power and resulting wire temperature.

FBG arrays provide multiple electromagnetic-interference-immune harsh-environment-tolerant systems [8, 9] along small diameter optical "nerves" and a basis for multi-point temperature sensing. In this section, we describe multi-point temperature (and strain) sensing results obtained using two optical fiber arrays with four FBG sensors along each array.

To date, several wires with different transition temperatures have been tried. In the following, we present some example results. The optical part of the needle characterization setup is shown in Figure 3.

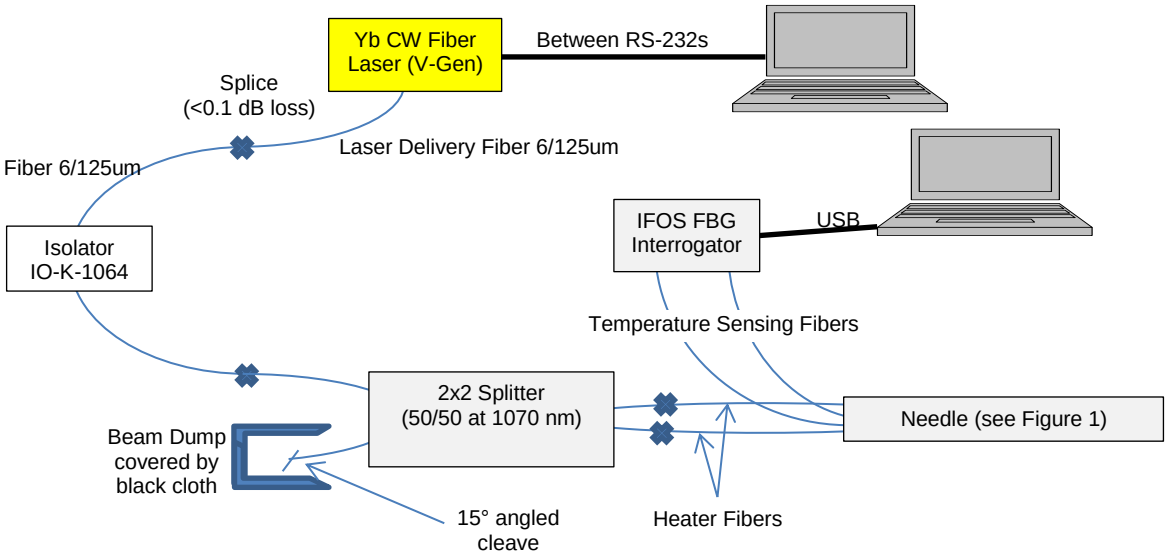

Figure 3: Functional optical characterization setup (not to scale).

In the following tests, the needle was inserted and retracted from a tissue phantom matching the mechanical properties of the human prostate. The following graph shows FBG wavelength shift in picometers for needle activation during insertion over a period of 12 seconds (from t=4 to t=16 seconds), following which the needle cooled, and then between t= 58 and 70 seconds the needle was retracted.

Note that, if temperature is the only effect then a wavelength shift of approximately 10 pm corresponds to 1°C. On the other hand, when strain is the only effect, then a wavelength shift of 1.2 pm corresponds to a strain change of 1 microstrain. In Figure 4, the wavelength shifts for sensors 1 to 4 and sensor 4 in array 2 are due almost completely to temperature effects. On the other hand, sensors 1 to 3 in the tight-fitting fiber array 2 also see strain effects due to the SMA wire pressing on the fiber in the clamping region (left clamp in Figure 1). Indeed, the strain signature is particularly pronounced at t = 58 seconds, when the needle retraction begins.

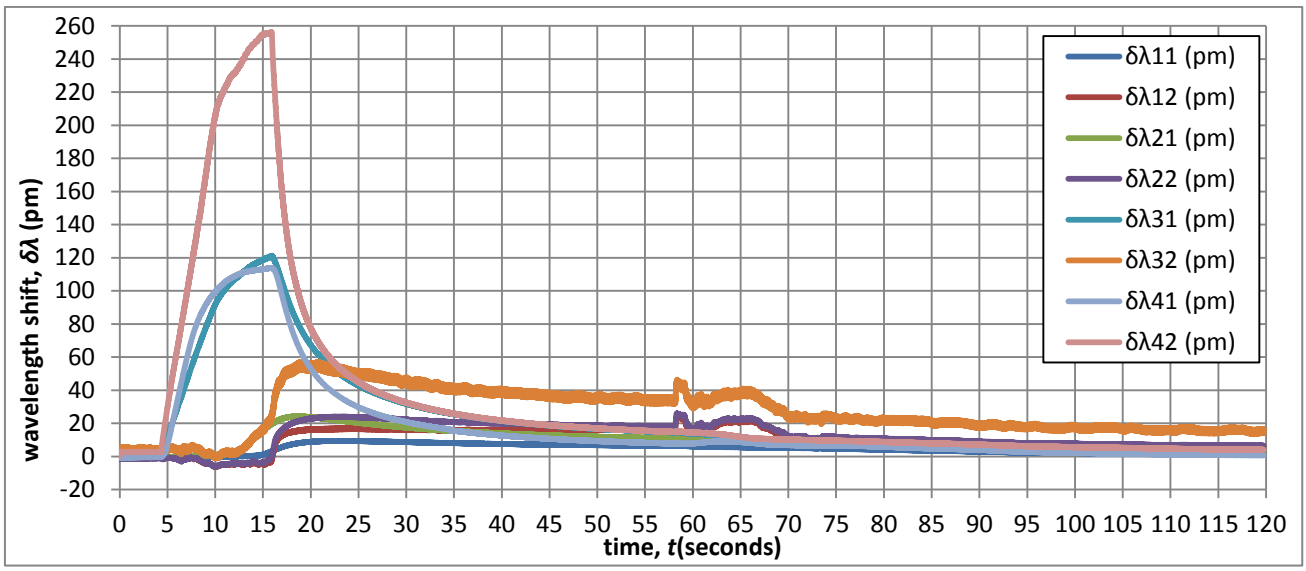

Figure 4: Needle based on "lower-temperature" SMA wire with 0.3 W of optical power applied for 12 seconds: Wavelength shift for the FBG sensors in arrays 1 and 2. The shifts for sensors 1 to 4 and sensor 4 in array 2 are due to temperature effects only. Sensors 1 to 3 in array 2 also see strain effects due to the SMA wire pressing on them in the clamping region.

In Figure 5, we plot, following the appropriate conversion, the temperature of the five sensors for which strain effects are thought to be negligible.

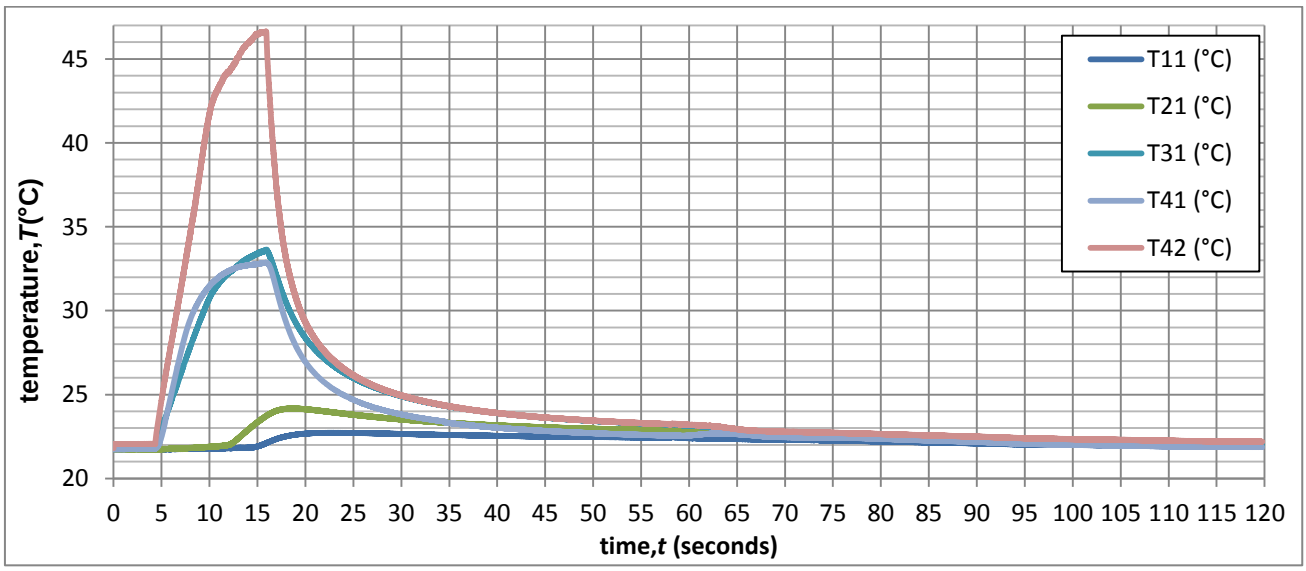

Figure 5: Needle based on "lower-temperature" SMA wire with 0.3 W of optical power applied for 12 seconds: Temperature for sensors 1 to 4 and sensor 4 in array 2, for which the wavelength changes are due to temperature effects. Note that we used the same temperature sensing arrays as we used in Reference [10] together with the calibration provided therein.

Work is currently ongoing to optimize the SMA wire so as to achieve maximum contraction within 5 to 10°C above body temperature (i.e., at temperature such as shown Figure 5).

Note that in our previous work, higher powers and larger temperatures were required for activation, e.g., see Figure 6 in which 0.5 W of optical power was used raising the temperature by approximately 55°C to 75°C.

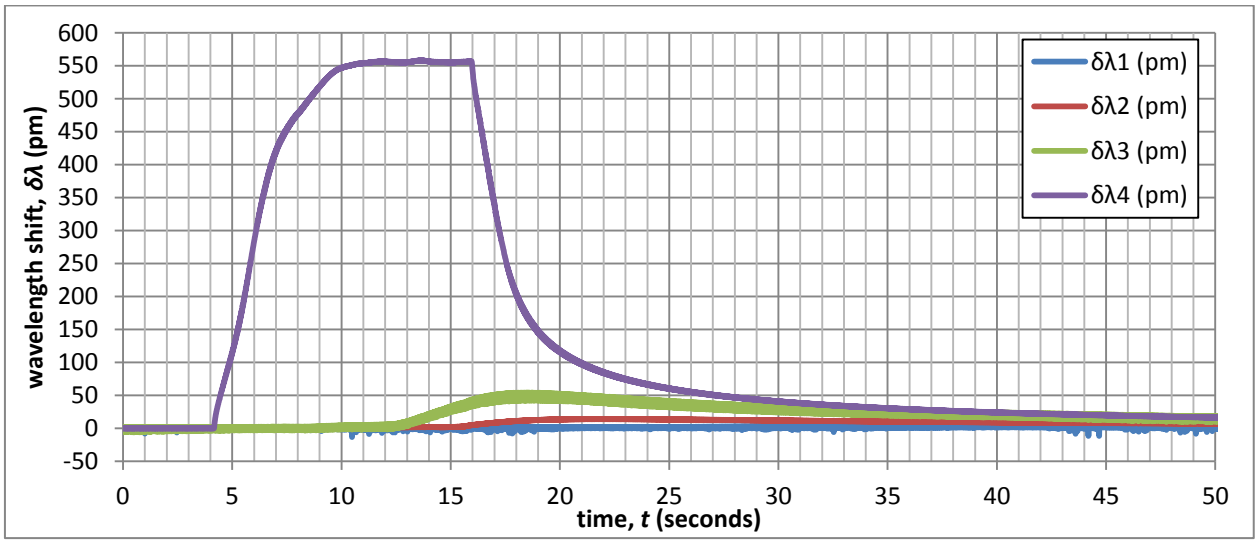

Figure 6: Needle based on "Flexinol" SMA wire with 0.5 W of optical power applied for 12 seconds from t = 4 to 16 s.

5. CONCLUSIONS

An optically steerable needle was demonstrated for use in image assisted biopsies and surgeries. A distributed optical activation method was devised using side-etched optical fibers to heat a single SMA wire contained within a slender, gold-coated multi-lumen super-elastic NiTi tube within the needle. Tip bending of over 15° in air and 7.4° in phantoms simulating the prostate's mechanical properties were achieved with just 0.8W optical power within 5 seconds within a prostate tissue phantom with only 1°C temperature increase within the phantom in the absence of any perfusion cooling. This represents a significant technical achievement and efficiency in speed and optical power conversion to SMA actuation and needle bend control. The clinical significance of the effort was established by employing a simple retract-reinsert strategy wherein the deflection angle resulted in a trajectory deviation of 3 mm within 60 mm insertion, an average length for reaching the prostate. Finally, tests were conducted to determine the temperature profile both inside the needle and outside it at the tissue boundary, using a thermal phantom that approximates the prostate's thermal properties. In the final device, we expect to use an SMA requiring heating to only 45°C. Even with high inner channel temperatures for the preliminary SMA, the temperature measured in the phantom was only 1°C above ambient 2 mm away from the needle. This is a conservative figure as real tissue that is perfused with blood is likely to cool to a temperature below 45°C, indicating that risks of temperature shock to the tissue and collateral damage from excessive heat can be readily mitigated. Considering our initial results were obtained using SMA wire with As ~ 70°C austenite transition temperature, the proposed design should be more than adequate for future active needles using a lower temperature (e.g., As ~ 35°C) SMA wire, even at optical powers exceeding 1 W for fast operation. However, initial indications are that sufficient tip deflection is achievable using the appropriate body temperature wire even with several hundred mW.

In the basic design employed, bending is accomplished by the SMA actuator working against the stiffness of the outer tube, which has a stress-dependent material property. Therefore, it is not necessary to have an antagonistic pair of actuators as in many other SMA applications. The single actuator/spring return design also reduces the size and complexity of the needle bending mechanism, and allows it to be incorporated inside a slender needle. This is a key attribute of the developed needle design. Depending on the application and whether or not additional fiber optic sensing is incorporated inside the needle, the design may be extended to even thinner needles of 18 or 20-gauge, making this a breakthrough in actuator technology for challenging percutaneous interventions. Additional needle manipulation dexterity can be obtained by coupling the needle with e.g., base rotation that is already employed in pioneering medical robotic systems.

Specific areas of development for a follow on program would include: (1) Selection, sourcing and optimization of low temperature SMA wires; (2) Needle design development, addressing control of laser power versus time, bending/unbending control tolerances, flexible tube and sheath optimization, insertion speed algorithms and integration with temperature/ curvature sensing to prepare for tissue studies including under MRI; (3) Design validation in tissue phantoms; (4) Ex vivo studies of needle deflection in tissue to establish key pre-clinical efficacy and safety parameters, steerability characteristics, functionality under MRI and comparison to passive needle steering; (5) Investigation of practical/clinical aspects essential to successfully introduce the new active needle to end customers, including surgical/radiological interventionists and medical device manufactures. This will involve providing samples for end user tests to gather further insight from potential customers and to develop cost models suitable for the transition of the technology to commercial markets in collaboration with our medical device partners that has the responsibility for device approval by the FDA.

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