MicroSurgical Suture Device for Targeted Neurovascular Hemostasis with Integrated Hotwire Flow Sensor and Nitinol Actuator

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Abstract

The advancement of minimally invasive surgical techniques necessitates the development of innovative tools capable of precise manipulation and control at micro-scale dimensions. This project introduces a groundbreaking surgical microgripping suture, designed to address blood vessel hemorrhaging, particularly in delicate and complex procedures such as brain and circulatory surgeries and prolonged subarachnoid microhemorrhaging. The device, on the scale of 100μm, integrates hot-wire anemometers and a nitinol shape-memory actuated overhanging gripper to ensure rapid, reliable, and controlled hemostasis. The microsuture device operates using nitinol-based shape memory actuation with integrated fluid anemometers. The nitinol gripper provides precise manipulation of blood vessels, ensuring secure occlusion and minimizing potential vessel damage. The joule-heating hotwire anemometer enables the detection of local blood flow changes, a critical component for real-time feedback to ensure immediate response during hemorrhage control. Additionally, the design incorporates a thin harness disconnect mechanism on the back, which allows for easy and safe detachment of the suture once hemostasis is achieved, reducing surgical time and improving patient outcomes.
The device's micro-scale precision and responsive actuation make it particularly suitable for neurovascular and ophthalmic surgeries, where the margin for error is minimal and the consequences of uncontrolled bleeding are severe. Model-driven analysis demonstrates the microgripping suture's efficacy in rapidly achieving hemostasis, showcasing its potential to significantly enhance surgical precision, safety, and efficiency. By addressing the challenges associated with micro-scale blood vessel manipulation, this innovation stands as a significant step forward in the field of minimally invasive surgery, paving the way for improved surgical outcomes and patient recovery.

Keywords: microhemorrhage, hemostasis, shape-memory, joule-heating

1. Introduction

Minimally invasive surgical techniques have revolutionized the field of surgery by offering patients less traumatic procedures, shorter recovery times, and reduced risk of complications. This paradigm shift has, however, highlighted the need for innovative tools capable of precise manipulation and control at micro-scale dimensions, particularly in delicate and complex procedures such as neurovascular and ophthalmic surgeries. Achieving effective hemostasis at such small scales presents a formidable challenge, as existing methods often fall short in providing the required precision and responsiveness.

Current methods for achieving hemostasis in microvascular surgeries predominantly rely on fine suturing techniques and the application of various coagulation agents. While these methods have proven effective at larger scales, they face limitations when dealing with micro-scale blood vessels. The delicate nature of neurovascular and ophthalmic tissues demands a higher level of precision and control than conventional techniques can provide. Existing tools often struggle to achieve the required level of occlusion in these small vessels, and their response time to changes in blood flow is often inadequate. Hemostasis, the process of stopping bleeding, is a fundamental aspect of surgical procedures. In neurovascular surgery, the traditional methods of achieving hemostasis include mechanical methods (such as sutures and clips), thermal methods (like electrocautery), and chemical agents (such as fibrin sealants). Each of these methods has its advantages and limitations, particularly when operating at micro-scale levels.

In contrast, the microgripping suture introduced in this paper leverages the remarkable properties of nitinol shape memory actuation to provide precise manipulation of blood vessels. Nitinol's ability to undergo reversible phase transitions in response to temperature changes allows for controlled and repeatable gripping and releasing of vessels, ensuring secure occlusion without causing vessel damage. Additionally, the integration of joule-heating hotwire anemometers adds a critical dimension of real-time feedback by detecting local blood flow changes. This feedback loop enables the device to respond immediately during hemorrhage control, further enhancing its effectiveness.

2. Principle of Design

The hot wire based flow sensor utilizes the convective heat loss from a single thin wire to determine the flow crossing over it in a specific direction. The wire, which is made of poly silicon, has a temperature-dependent resistance and serves as both a heater and a sensor. An external source supplies a current to the on MEMS circuit that heats the wire through the aluminum lead. The circuit itself is controlled temperature (CT), which is generally more responsive and sensitive to changes compared to constant current circuit. This is a necessity as the flow from the vessels has acute changes that need to be monitored for the effectiveness of the MEMS device. When the fluid flows over the wire, the wire cools down and its resistance decreases. This change in resistance is detected by a negative feedback circuit that consists of a Wheatstone bridge and an operational amplifier.The circuit adjusts the heating power to maintain the wire temperature at a constant level (Wang 2022). The power consumption required to keep the wire temperature constant is proportional to the fluid flow velocity. Therefore, by monitoring the power consumption, the flow velocity can be determined (Wang 2022). This technique is known as hot-wire anemometry and it is widely used for various applications, such as biomedical, microfluidics, and energy-efficient building. The hot wire based flow sensor can be fabricated using CMOS-MEMS technology, which enables low-cost miniaturized devices with high integration capabilities. By reducing the thickness and width of the wire to nanoscale, the heat conduction loss can be greatly suppressed, while the response time of the sensor can be significantly improved. The nanoscale hot-wire flow sensor exhibits an ultrafast response time of 30 μs, a wide flow range of 0–30 m/s, and a cut-off frequency of 21 kHz under the CT mode (Buchner 2006).

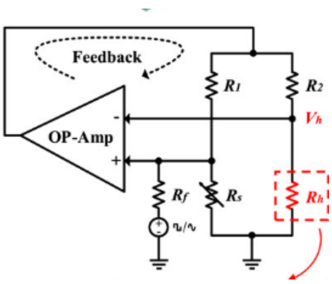

Figure 1: CT Hot-Wire Control Circuit (Wang 2022)

To connect the resistor circuit on the MEMS device to the rest of the CT control circuit, a surgical harness is utilized. These types of harnesses generally stay connected to the device while moving within the body. This functionality is further utilized to reduce the need for complex circuitry on top of the MEMS device, reducing cost and making the process efficient and harness reusable for future connections. In addition to housing the circuit, the harness creates the flow sensor to microgripper connection. Once the desired flow is detected, current is sent directly to the connected wire on the Nitinol microgripper, heating it up and allowing it to clamp shut.

Nitinol, a nickel-titanium alloy, is renowned for its shape-memory and superelastic properties, making it a highly suitable material for microsurgical tools. The shape-memory effect in nitinol is a result of its ability to return to a predetermined shape when heated above its transformation temperature. This unique property arises from the alloy's crystallographic phase transformation between martensite and austenite phases(see Figure 2). The microstructure of thin film nitinol, including its grain size and the presence of precipitations, significantly influences its phase transformation process and associated temperatures.

The transformation temperature and the stress behavior of thin nitinol films, crucial for their shape memory and superelasticity, are determined by their microstructure, which can be controlled through composition and post-heat treatment processes. We control heat treatment and alloying processes to generate a m-a phase transition temperature under the 100c threshold of blood boiling, but maintain hysteresis in a-m phase transition to constrain the operating regime of the suture within the superelastic austenite phase(see Figure 7).

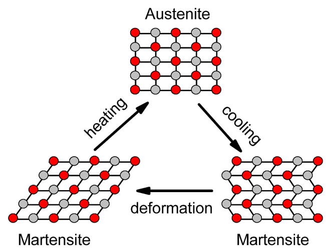

Figure 2: Nitinol Crystallographic Cycle - SmartWire

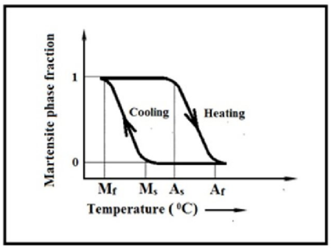

Figure 3: Nitinol Hysteresis Cycle - Taha 2015

3. Fabrication

The hot-wire flow sensor and Micro gripper in our project would be fabricated through a CMOS-MEMS integrated process. The hot-wire flow sensor is fabricated first. Figure 1 shows the cross-section of the fabrication process of the hot-wire flow sensor.

Initiating the process, we use a silicon wafer as a substrate and then deposit a layer of thermal oxide (.25 um) on top of the silicon wafer (Figure 4). This layer serves as an etch stop for the DRIE release etch later, preventing undercutting and allowing for the connection to the harness being made to the silicon below it.

Subsequently, we deposit a low-stress LPCVD nitride (.25 um) on top of the oxide (Figure 4). This layer is excellent for high-temperature electrical passivation and liquid applications. This is especially important as the device will be moving within the body and blood.

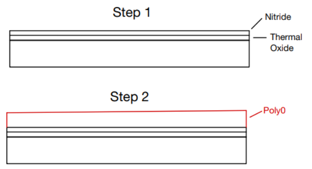

Figure 4: Step 1:Deposition of Thermal Oxide (.25 um) and Nitride (.25 um LPCVD). Step 2: Polysilicon Deposition (2 um).

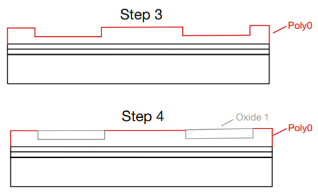

Figure 5: Step 3: Dry etch of polysilicon to make square shape. Step 4: Oxide deposition as sacrificial layer (.75 um).

Moving forward, we proceed with a 2 um polysilicon deposition (Figure 4) (Science 2023). We then perform dry etching on the polysilicon to get a square shape to allow for evenly distributed flow in the area of the hot-wire. Following this, we deposit a .75 um oxide layer (Figure 5). This layer is sacrificial and will be removed later in an HF solution.

Next in line, we deposit a .76 um thin film of polysilicon using LPCVD (Figure 6). This layer is used as the wire. We decided to go with polysilicon as the wire material as its large resistivity, compatibility with high-temperature fabrication processes, and high thermal sensitivity, allow for accurate and sensitive flow measurements. After the poly has been deposited it is etched to the appropriate shape, covering the area above the oxide. Then the oxide is removed using an HF solution to release the wire.

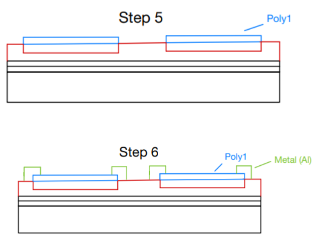

Figure 6: Step 5: Deposit Poly to make up the structure of the wire. Remove oxide using HF solution. Step 6: Deposit aluminum to tab wire (.5 um).

Subsequent to this, we deposit a .5 um metal layer (Aluminum) on the ends of the wire (Figure 6) (Science 2023). This layer is used to tab the wire and connect it to the rest of the circuit.

During this step the first layer wire connection to the surgical harness is left open using poly wiring. This allows the flow sensor to be connected to the surgical harness afterwards before the start of the operation.

Then, we proceed with a 1.5 um polysilicon deposition on the backend of the MEMS device. This layer is used as supports for the Nitinol Microgripper and does not go over the wire or metal but is only over the 2 um polysilicon shown in (Figure 7) (Science 2023).

In this step the second connection is left open ontoop of the 3rd polysilicon layer. This connection will connect the harness directly to the nitinol microgripper.

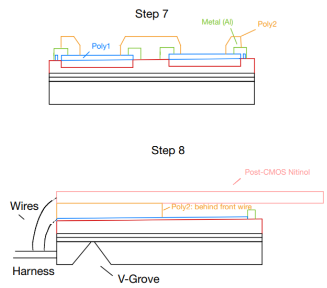

Figure 7: Step 7: Deposit Poly to make supports for Nitinol Micro gripper (1.5 um). Step 8: Side View. DRIE etch to create V-Groove. Top wire showcases connection to Nitinol and bottom to the ire that runs to the hotwire

Finally, we perform Deep Reactive Ion Etching (DRIE) from the bottom, creating a V-Groove up to the thermal oxide boundary layer (Figure 7). In this step, the thermal oxide on the backside is used as a hard mask during the DRIE process, and the buried oxide layer of the silicon wafer acts as an etching stop. This allows the V-grove that would later be snapped off to be made. Figure 7 also showcases the wiring of the harness, with it directly being connected to Nitinol at the top and to the poly wire running along the back end at the bottom. This second wire is seperate from the hotwire but is connected to the hotwire with the metal layer. The final step of the fabrication process is the Post-CMOS sputter deposition of Nitinol shown on top of the MEMS structure.

The sputter-deposition technique has emerged as the preferred method for producing thin film nitinol due to its precise constituent controllability and consistency in film quality. This technique involves the use of dense plasma of Ar+ gas, which provides consistent production of high-quality thin film nitinol with the desired ratio of nickel to titanium. Key factors affecting the sputter-deposited thin film nitinol's characteristics include the distance between the target and substrate, Ar+ gas pressure, translation and rotation of the substrate during deposition, composition of the target material, temperature of the sputtering chamber, and the sputtering rate and time (Shayan 2015). In the fabrication of thin film nitinol, controlling the composition of the alloy is crucial for achieving the desired material properties. Sputtering from multiple targets, as opposed to a single nitinol target, offers a significant advantage in this respect. This alternative technique allows for the use of elemental targets (i.e., pure nickel and pure titanium) or nitinol alloy targets with varying compositional ratios of nickel and titanium. The key benefit of this approach is the ability to precisely control compositional variations by altering the power ratio of the targets and adjusting geometry parameters. This precise control of alloy composition is particularly important in the context of the microgripping suture device, where the material's properties at the micro-scale are critical to its performance and effectiveness in surgical applications.

It has been found that low Ar+ gas pressure is beneficial for achieving good shape memory effects in thin film nitinol, as high pressure can lead to a porous structure and poor mechanical properties. Additionally, the sputter-deposition process has been refined to address challenges like the fast oxidation of titanium during sputtering and the difference in sputtering yields of titanium and nickel.

4. Simulation Results

The nitinol alloy clamp, in its heat-treated Martensitic phase, is very plastic, undergoing mostly permanent deformation. Kept below 6% strain, the subsequent reheating and Martensitic Strain. Kept below 6%, the crystallography is entirely reconstituted when heated above the complete phase transformation temperature(See Figure 7 for reference) A Finite Element Analysis was performed on the suture system to study the clamp forced opening strain. As shown in Figure 9, the martensitic phase maintains roughly 4% engineering strain, and so can endure full closure when resistively heated. Figure 8 displays the stress field and deformation of the device under full vascular hemostasis stress in the 10-50μm range (10-25kPa).

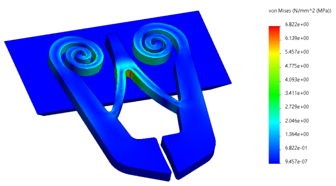

Figure 8: Microsuture Stress Field in Clamped State

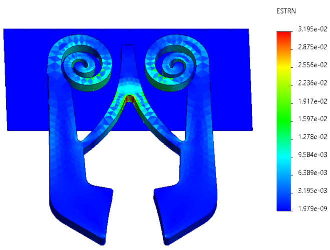

Figure 9: Microsuture Pre-Strain in Martensitic Phase. Strain below 6%

The Hotwire analytical model: is developed in accordance with the specs in Figure 10 (Wnag 2022). Crossflow equations are drawn from A Heat Transfer Textbook, and is as follows. (Lienhard 2020)
Crossflow Model:

$$\overline{\mathrm{Nu}}_D = 0.3 + \frac{0.62\,\mathrm{Re}_D^{1/2}\,\mathrm{Pr}^{1/3}}{[1 + (0.4/\mathrm{Pr})^{2/3}]^{1/4}} \left[1 + \left(\frac{\mathrm{Re}_D}{282,000}\right)^{5/8}\right]^{4/5} \quad (1)$$

The resistance and heat transfer models are used to generate power generation and convective heat transfer terms that are implemented for validation in Figure 11. As evidenced by the temperature range and geometry in the image, the hotwire loses significant temperature to conduction through the edges, at this length. A future study may involve the wire temperature consistency as a function of wire length, accounting for the space claim trade-off of the device itself, as it relates to minimally invasive surgical procedures.

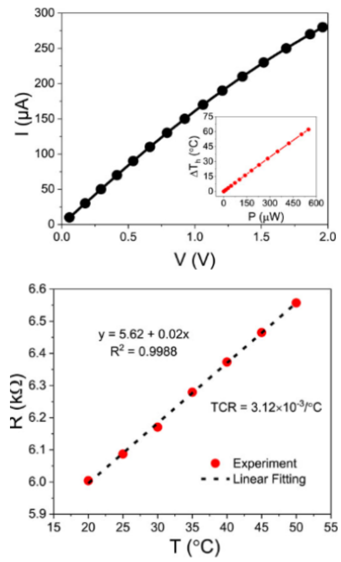

Figure 10: Hotwire Temperature vs Resistance and Resulting Power - Wang 2022

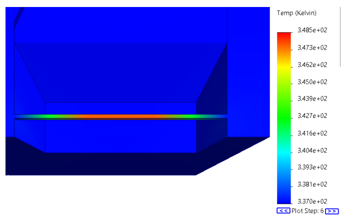

Figure 11: Hotwire Thermal FEA at 200μW Joule Heating, 0.5m/s Crossflow

5. Conclusion

In conclusion, this paper presents a novel microsurgical suture device, leveraging advanced fabrication techniques and materials to address critical challenges in neurovascular hemostasis. Its design incorporates a hotwire flow sensor and a Nitinol actuator, optimized for precise control and responsiveness in micro-scale surgical environments. The device's efficacy is demonstrated through model-driven analysis, showcasing its potential to enhance surgical precision, safety, and efficiency. This innovation marks a significant advancement in minimally invasive surgery, offering improved outcomes and patient recovery.

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