UC Riverside UCR Honors Capstones 2023-2024

Title

SHAPE MEMORY ALLOY CARDIAC CATHETER WITH ELASTICALLY DRIVEN RECOVERY FORCE

Permalink

<https://escholarship.org/uc/item/14x718x7>

Author

Oda, Keiju M

Publication Date

2024-07-24

SHAPE MEMORY ALLOY CARDIAC CATHETER WITH ELASTICALLY DRIVEN RECOVERY FORCE

By Keiju Michael Oda

A capstone project submitted for Graduation with University Honors

May 10, 2024

University Honors University of California, Riverside

Approved

Dr. Jun Sheng Mechanical Engineering

Dr. Richard Cardullo, Howard H Hays Jr. Chair University Honors

ABSTRACT

Shape memory alloys (SMA), such as nitinol, have great potential as smart actuation materials when implemented in cardiac catheters. The muscle-like flexibility of nitinol makes SMA catheters particularly useful when negotiating delicate environments such as vasculatures and heart chambers, and the compliant nature of nitinol minimizes damage to surrounding tissues. These characteristics are an invaluable attribute for a catheter being used in procedures such as radiofrequency ablation. Despite such an advantage, constructing a catheter with nitinol presents one primary challenge: creating a robust mechanism capable of bidirectional movement with minimal rigid components. To accomplish this challenge, the catheter presented in this report leverages a single nitinol wire alongside elastic material to enable bidirectional steering. Nitinol's shape memory properties are harnessed by training the wire into a 3D curve, with the elastic serving as an antagonistic recovery force. The implementation of an elastic recovery force in conjunction with nitinol wire is novel, so multiple engineering tests were conducted to validate the catheter's design and determine its capabilities. These tests included surface temperature evaluation and bend angle measurements, where the effect of different currents on the catheter's surface temperature and range of motion were characterized. Additionally, a fatigue test was executed where the change in the catheter's bend angle over a period of 150 cycles was used to examine the catheter's useful life. In future works, the diameter of the catheter will be further decreased, and the implementation of functionalities such as a working channel, micro camera, or feedback control steering system will be introduced, with the eventual goal of producing a functioning surgical tool.

 \mathfrak{D}

ACKNOWLEDGMENTS

Dr. Jun Sheng,

I would like to express my gratitude for your invaluable support, guidance, feedback, and mentorship throughout my undergraduate research experience at RaMS Lab. Your commitment to your students is clear, and I appreciate the freedom and autonomy you have allowed me to have while exploring different design solutions throughout the catheter project. Working in the RaMS Lab has inspired me to pursue a Master's degree and has even shaped my eventual career path as I begin to seek out internships and jobs within the medical devices field. Thank you for believing in my potential and guiding me toward a successful capstone project. I am grateful to have worked under your supervision and appreciate the lessons and experiences I have gained from our collaboration.

Vinesh Manian,

I would like to extend my appreciation for your contributions, dedication, and collaboration throughout our research project. Your commitment has been commendable since I joined the project more than 2 years ago, and while our objectives within the project have varied, you have been indispensable in the successful execution and completion of fabricating, testing, and analyzing our actuator. I am grateful for the many discussions, brainstorming sessions, and constructive feedback that we shared during our collaboration. Your enthusiasm, passion, and dedication continuously inspire and motivate me to strive for excellence.

> Research reported in this publication was partially supported by: *The UC Riverside Undergraduate Education Mini-Grant Program*

I. INTRODUCTION

Futuristic smart materials such as nitinol, a type of shape memory alloy (SMA), have the unique ability to remember an old configuration. This allows nitinol wires to transform back to their trained shape when gently heated. By using this muscle-like mobility, advanced actuators can be fabricated to assist in medical procedures such as endoscopy, intravascular lithotripsy, and cardiac ablation. In previous works, Sheng et al. demonstrated a steerable cardiac catheter consisting of rigid bending modules linked with nitinol wire [1]. This design achieved 5 degrees of freedom but consisted of a complex assembly process that caused out-of-plane bending. To improve upon their catheter and achieve an actuator capable of in-plane bidirectional steering with a completely compliant design, the steering module is reconfigured to employ a single nitinol wire with parallel strands and an elastic antagonistic recovery force. The bidirectional steering and compliant characteristics of the presented catheter allow it to be used as an actively controlled catheter that, in addition to a significant maneuverability advantage over passive catheters, also mitigates the chances of internal damage. While the use of nitinol to achieve one direction of steering is trivial, the novel implementation of an elastic band allows for the unique bidirectional steering characteristics needed for superior control within the intricate vasculature of the human heart.

II. DESIGN METHODOLOGY

In starting this project, background knowledge of nitinol and existing steerable catheters was crucial for understanding how to maximize nitinol's shape memory effect and identify potential improvements in surgical catheters. This knowledge enabled the evaluation of various actuation methods used in current designs to understand the strengths and limitations of existing technologies. The following evaluation resulted in the concept of an elastic antagonistic recovery force, which had the potential to provide enhanced precision, mobility, and overall performance in comparison to other actuation methods. Significant trial and error in experimenting with SMA training configurations, cross-sectional geometries, and pre-tension were required to achieve the desired steering characteristics.

A. SMA Characterization

Shape memory alloy, or SMA, is a classification given to certain metals that can retain the memory of a trained shape. Some of these alloys include Cu-Al-Ni, Cu-Zn-Al, Au-Cd, Mn-Cu, and Ni-Mn-Ga, though an alloy of nickel and titanium, called nitinol, is the most widely used SMA [2]. Nitinol contains approximately 55% nickel and 45% titanium (though the true ratio depends on the manufacturer) and can take the form of wires, tubes, or plates. Additionally, other additives and the ratio of the alloy's elements can be manipulated to achieve superelasticity. To leverage the shape memory effect, the nitinol must be fixed into place and then heated in the range of 400-550˚C depending on alloy composition, material thickness, and the manufacture recommendations [3]. This high heat phase of the training process achieves the austenite face-centered-cubic crystal structure that 'resets' the previous training shape and gives the metal its new configuration. Following the high heat phase is a quench in water to lock in the newly trained shape in a separate form called martensite [4]. The nitinol can then be deformed to any shape, and with gentle heat activation (generally 40-80˚C but may differ per manufacture alloy composition), it can be made to transform back to its trained shape.

B. Existing Steerable Catheters

Coinciding with SMA's rise in popularity are a diverse range of surgical actuators demonstrating the advantages of compliant mechanisms leveraging different actuation methods such as tendon-driven, magnetic, and the shape memory effect. One tendon-driven design by Chitalia et al. presents a robotic endoscopic tool with two degrees of freedom for use in minimally invasive surgeries [5]. The body of this catheter is made from a nitinol tube with specific grooves and channels machined into it to accommodate a superelastic tendon wire. The design, presented by Chitalia et al., offers bidirectional steering with a working channel to allow different surgical tools to be inserted inside the actuator. However, the materials required by this design are expensive, and the nature of tendon-driven actuators prevents steering from being decoupled between each steering link. Despite each steering link having its own tendon, every other link's tendon wire must be fastened to some part of the actuator, thus when a steering link is activated, the bending causes inactive tendons fastened to the active link to be pulled on, coupling each link with the others. With the SMA actuation mechanism presented in this report, each steering module is independent, allowing for more precision in the catheter's steering characteristics.

Magnetically steerable catheters, or MSCs, are another type of maneuverable surgical catheter that employs two primary methods that leverage magnets to actuate within a body. The first method involves moving permanent magnets, or other mobile magnetic devices, outside of the patient to steer the catheter, while the second method uses an MRI as the magnetic source to influence the catheter's direction. In accordance with the first steering method, Mohanraj et. al. use Helmholtz coils laying on either side of a patient's leg to induce a magnetic force on their MSC [6]. These coils control the catheter's movement by attracting a ring-shaped magnet that is

7

integrated into the catheter's tip, a unique design feature that enables a working channel within the catheter. Mohanraj et. al. display a clinical application of this external setup consisting of Helmholtz coils, a feeding mechanism, and a control box. Though Mohanraj et. al. demonstrate a functioning design, its primary disadvantage is its inability to be used in wider sections of the body due to the Helmholtz coils. The second implementation of MSCs, analyzed by Limpabandhu et al., uses an MRI machine to steer the MSC [7]. This method is made possible by magnetic resonance coils, which are deflected by magnetic forces generated by an MRI machine. While this method eliminates the specialized setup required to use permanent magnets, an MRI machine is still required to steer the catheter. Additionally, MSCs are currently limited in how small they can be based on the magnet, or magnetic material, found in the steerable tip. The smaller the MSCs are, the greater the external magnetic force is required to be, otherwise the MSC must be closer to the surface of the patient, limiting use cases.

Figure 1. Previous work by Sheng et. al. from which this project expands on [1]

An example of a surgical catheter using nitinol and the shape memory effect is in previous works by Sheng et al., where a bidirectionally steering catheter was developed utilizing 3D printed components and SMA wire (Figure 1) [1]. Sheng et al. achieved five degrees of

freedom by utilizing multiple steering modules linked with nitinol wire to control the steerable tip. The fabrication of each steering module was complex, necessitating three assembly jigs and the use of nichrome wire, a delicate and difficult material to work with. Additionally, a high degree of precision is required when installing the nitinol wire to minimize out-of-plane bending, however, some out-of-plane bending is inevitable as perfect alignment is impossible with the method presented by Sheng et al. Serving as the basis for this capstone project, the goal is to improve upon the design from Sheng et al. by fully integrating compliant materials into the catheter, implement a novel elastic antagonistic recovery force, and employ a single nitinol wire trained into a 3D curve.

C. Project Design

Achieving the desired steering characteristics proved to be a significant challenge requiring many different designs and iterations. The crux of this challenge lies in the need for an antagonistic recovery force to oppose the nitinol's transition from its resting state back to its trained position. Early on in the design process, the catheter's silicone substrate was intended to act as the antagonistic force. Silicone was cast in a curved mold in hopes that the stiffness of the cured silicone would be hard enough to return to the original casted shape after the catheter's actuation, yet soft enough to allow the nitinol to be heated into its trained position. Though the silicone's compliant nature made it a suitable substrate for the catheter, it was not stiff enough to revert back to the original casted shape. The failure of this design motivated a much stronger recovery force, manifested in the concept of using pre-tensioned elastic material. This method implements a section of an elastic band that is fastened to two end caps which are then stretched across the silicone mold prior to casting. By isolating the recovery force mechanism from the

substrate, the amount of recovery force can be adjusted without affecting the stiffness of the silicone. This method's ability to control the amount of pretension is a significant advantage over varying the stiffness of the silicone and is the reason the current design implements an elastic band.

Figure 2. Evolution of nitinol training shapes: (a) Arbitrary pre-activation shape, (b) Pre-trained straight, (c) 2D curve, (d) 3D curve

The other design parameter adjusted to achieve bidirectional steering was the training shape of the nitinol wire. Before the wire is gently heated up, the nitinol starts in any arbitrary shape (Figure 2a) before being transformed into the trained configuration (Figure 2b-d). Initially, pre-trained straight wires were used to prove the concept of the elastic antagonist force (Figure 2b). Using pre-trained wires accelerated the fabrication process enabling precise adjustment of pretension without the need to retrain the nitinol. However, once the pretension was adjusted, the single straight trained wire was switched to a curved trained wire to enable the full range of the desired movement. This second wire, pictured in Figure 2c, was trained in a 2D curve and was intended to actuate past the 0˚ mark. However, because the wire was a single strand and did not have any support keeping it oriented within the catheter, it rotated about itself when the catheter was actuated. The force required to oppose the rubber band was far greater than the friction keeping the wire from rotating within the silicone, causing the curve to realign itself with the rubber band. To prevent the wire from rotating internally, a new 3D curve training pattern was implemented. This new shape still utilizes one nitinol wire but takes the form of two 2D curves stacked on top of each other, resulting in parallel strands of nitinol trained in identical arcs (Figure 2d). Along with preventing internal rotations seen in the 2D curve shape, the parallel strands of wire increase the actuator's ability to oppose the recovery force, making actuation faster.

III. PHYSICAL PROTOTYPE

The fabrication of the physical prototype was split into two distinct parts: SMA training and actuator assembly. Both parts required a high level of attention to detail, as the small size of the catheter amplified any fabrication errors resulting in poor steering characteristics. The design and fabrication processes were entirely iterative, taking many months to test different cross-sectional geometries, end cap designs, pretensions, SMA training patterns and procedures, wire gauges, and silicone densities. Throughout this process, numerous techniques, procedures, and jigs were developed to help ensure the alignment of each component and consistent replication of each actuator.

A. SMA Fabrication

Figure 3. Training jig to final form of the two layered training shape (3D curve)

In preparation for training the SMA, a metal jig was fabricated to anchor the nitinol wire during the training process. This jig, made from a 3 mm thick plate of steel, improves upon the previous training jig with the addition of a circular array of holes meant to accommodate the 3D curve described in the previous section. These holes were bored at a diameter of 2.5 mm to allow an M3 tap to add threads to each hole, a change from the previous use of nuts and bolts on the old training jig, which simplified fabrication but sacrificed the ability to tighten each side of the jig individually. With the addition of threaded holes, the SMA was anchored to each side of the jig independently, allowing 'two-layer' training shapes to be achieved (Figure 3). This two-layer concept is key to bidirectional steering as the parallel strands of nitinol wire help mitigate any twisting within the silicone substrate. After fastening the wire, the whole assembly is placed inside a 500°C laboratory oven for 20 minutes, with a subsequent quench in ice water. This procedure retrains the nitinol wire into the fastened position and is critical to achieving bidirectional steering.

B. Catheter Fabrication

Figure 4. End cap/pretension assembly and implementation

Though simple in appearance, assembly of the catheter requires meticulous attention to detail due to its small size amplifying any off-center compression or wire-twisting fabrication errors. Assembly begins by slicing the elastic band at a shallow angle such that the pointed tip fits through the end cap's rectangular hole. Two end caps are then threaded onto the elastic with the twin holes on the convex side of the band's natural curvature. Next, an overhand knot is tied on the distal side of the elastic band, from which 24 mm (or the desired pretension length) is measured (Figure 4a). After securing a second knot, the two end caps stretch over the primary mold, and with the tensioned elastic in place, a piece of trained nitinol wire is added to the actuator, (Figure 4b-c).

Figure 5. 3D printed wire straightening jig

To flatten the wire from its curved training state, a wire straightening jig is implemented to mitigate either end of the wire twisting prior to installation, (Figure 5). However, negligence at this stage can still cause the wire to twist, resulting in the catheter bending out of plane. Once the elastic band and SMA are centered within the mold, a 2.4 gram batch of a 1A:1B ratio of Smooth-On Dragon Skin^{TM} 10 is thoroughly mixed in a syringe. The plunger of the syringe is then inserted, and with the tip of the syringe blocked, the plunger is drawn, creating a vacuum to pop any bubbles incorporated during the mixing process. Degassing the silicone is a useful step, as these bubbles can cause surface defects and a heterogeneous substrate that may adversely affect the elastic's adhesion to the silicone or cause non-uniform bending. Subsequently, the silicone is poured into the prepared mold and is ready to be taken out after 5 hours of curing. Though not necessary, a layer of superglue should be added to reinforce the area where the nitinol touches the end caps. Without such protection, extensive heating may damage the 3D printed end caps. After taking the catheter out of the mold, the silicone is adhered to the nitinol wire, but actuating the device 3-6 times will loosen this bond, resulting in the maximum steering range.

Figure 6. Fully encapsulated actuator with soldered magnetic wire leads

If a more refined product is desired, a second phase of silicone casting in addition to the soldering of magnetic wire leads to the SMA wire can be performed. The second phase of casting involves the same silicone mixing and degassing procedure with the utilization of two-part molds to cover up each bare end of the actuator (Figure 6).

C. Fabrication Outcomes

Figure 7. Catheter actuation: (a) Resting, (b) Halfway through steering range, (c) Complete steering range

With the implementation of the 3D curve and the appropriate elastic pretension, the catheter was able to achieve a full range of movement. At rest, the elastic experiences the least amount of tension and exhibits a 90˚ bend (Figure 7a). As the catheter is actuated, the nitinol is gently heated and transformed back to its 3D curve configuration causing, the elastic to be put in partial tension as it resists the nitinol's movement; however, the nitinol's shape memory effect overcomes the recovery force (Figure 7b). Once the nitinol has reached its original training configuration, the elastic is at its maximum tension (Figure 7c), thus, if this angle is desired, the current must be constantly flowing since the moment the nitinol begins to cool, the elastic recovery force will take over and return the catheter back to the resting position.

Figure 8. Actuator characteristics: (a) Expected bending motion, (b) Axial twisting and out-of-plane bending

In making multiple actuators of the final design, an unusual axial twisting motion in some of the actuators was revealed, hypothesized to be caused by misalignment of the nitinol wire strands, off-balance elastic compression, and a vertical rectangular cross-section. While the catheter is expected to bend along one plane, Figure 8 demonstrates the unwanted out-of-plane bending caused by the axial twisting seen in some catheters. This is a unique occurrence only found in actuators with two strands of nitinol, indicating a link between the 3D curve training shape and the unusual bending motion. Past designs implementing a single strand of nitinol did not suffer from these unusual mobility characteristics, motivating the belief that the 3D curve nitinol configuration was allowing for new fabrication errors, which contributed to the twisting.

Figure 9. Twisting wire strands potentially contributing to the unwanted steering characteristics

Another contributing factor to the unwanted steering behaviors is the twisting of one or both strands; this twisting bends the actuator in the average direction of the two strands, inconsistent with the original training shape. Both strands of nitinol must have their arc aligned with the steering plane prior to installation. This fabrication error is easy to make, as manipulating the SMA for sanding, wire coiling, soldering, or threading through the end caps may result in unintentionally twisting one or both of the strands (Figure 9). Additionally, fastening the wire to the straightening jig can cause the end to twist when the screw is tightened. To remedy these problems, washers were used when fastening the SMA to the straightening jig, and markings indicating the correct orientation of the SMA strands were made on top of the wire such that any twisting could be detected before pouring the silicone into the mold.

Figure 10. End cap misalignment fabrication error

While likely not the sole reason for the out-of-plane steering, another potential cause may be the misalignment of the elastic band. This can occur when the elastic is threaded through the endcaps and stretched over the first mold, decreasing the diameter of the elastic band and causing play in the hole where the band can shift side to side; even if the elastic band is perfectly spaced

in the middle of the endcap, the end caps themselves might be misaligned relative to the first mold (Figure 10). Failing to fix these spacing issues will cause the elastic band to compress the actuator off-center, such that during the actuator's return to its resting state, the actuator will bend towards the side with more tension instead of straight down the middle. These spacing issues were not apparent in past actuator iterations as the cross-section was a horizontal rectangle. This cross-section changed to a vertical rectangle when the width of the catheter was contracted to decrease the actuator's diameter when it was redesigned to accept the 3D curve nitinol. The unintended consequence was that the reduced amount of material along the width of the catheter encouraged out-of-plane bending as less force was required to bend the catheter width-wise (out-of-plane) than height-wise (in-plane). The geometry was quickly updated, and with more attention directed to the orientation of the nitinol strands, the unusual out-of-plane steering was eliminated.

IV. CATHETER CHARACTERIZATION

Demonstrating the actuator's validity for use as a cardiac catheter motivated the performance of surface temperature, fatigue, and bend angle engineering tests. These tests were chosen to help characterize the actuator's operating surface temperature, longevity, and mobility, in turn indicating the catheter's relevance for use in the human body. The surface temperature test was performed first to learn what maximum amperage resulted in a 2˚C buffer below the threshold surface temperature of 44˚C. The resulting amperage was then used in the fatigue test, where 150 cycles were run. After analyzing the degradation of the bend angle over time, the plateau in the bend angle was determined, in turn influencing how long the actuator was fatigued before the bend angle test.

A. Surface Temperature Test

To perform the surface temperature test, an actuator was fabricated with a temperature sensor fixed on the surface of its distal end. The temperature sensor, with a known resistance of 1Ω, is made of material that changes electrical resistance at a predictable rate, allowing an Arduino to interpret the analog data coming from the sensor and calculate the actuator's surface temperature. While the Arduino continuously recorded temperature data, seven trials, each conducted in 37˚C water to simulate the approximate internal body conditions, were run at different currents, ranging from 2.500 amps to 3.100 amps, in 0.100 amp increments. Each trial started with the actuator in its resting position, at which point the current was supplied to the actuator; the actuator was then held at the specific amperage until the surface temperature reading plateaued. The purpose of these trials was to find the maximum amperage that resulted in a surface temperature of 42˚C, a benchmark chosen for the catheter as the internal tissue can be heated to 44˚C before tissue is harmed [8]; a 2˚C discrepancy exists as a buffer before tissue damage occurs.

Figure 11. Surface temperature test data

By executing the surface temperature test, the threshold temperature of 42˚C was reached with a maximum amperage of 2.800 amps. Aggregating the data from the seven trials produced the Surface Temperature vs. Time graph displayed in Figure 11. Using this reference, the average temperature for the lowest amperage, 2.500 amps, was 40.2˚C while the corresponding temperature for the highest tested amperage, 3.100 amps, was 43.7˚C. The maximum amperage before the threshold temperature was reached was 2.800 amps, achieving a surface temperature of 41.7˚C. Having determined the maximum appropriate current, each subsequent test was then run at 2,800 amps.

B. Fatigue Evaluation

Figure 12. TinkerCAD circuit simulation and the physical implementation of the simulated circuit

Using the maximum amperage determined by the surface temperature test, a series of fatigue cycles were run to determine how many cycles it would take for the change in the actuator's bend angle to stabilize. This test was much more involved than the surface temperature test as it required its own programmable electrical circuit to throttle the current on and off throughout the 150 fatigue cycles. An Arduino microcontroller was implemented for its 'programmability' enabling features such as the ability to count the number of cycles, display the

test trial, change the maximum number of fatigue cycles, and precisely control the amount of time the catheter was live and at rest (Figure 12). In light of the results from the surface temperature test, the circuit was required to handle 2.800 amps, which an Arduino is not solely capable of. To get around this issue, a digital signal was sent by the microcontroller to a MOSFET transistor's base pin, allowing current from a power supply (attached to the collector pin of the transistor) to flow through the emitter pin, completing the circuit and actuating the catheter. While the microcontroller served as the brain of the fatigue circuit, the MOSFET sat at the core of the electrical hardware, acting as a check valve for the current flowing through to the actuator. Once this circuit had been set up, the digital pin was programmed to send an 'on' signal for 15 seconds, followed by a period of 20 seconds off; this on-off period constituted one fatigue cycle.

Fatigue Test: Returning Angle (Elastic Fatigue)

Figure 13. Fatigue of the returning bend angle (elastic fatigue)

Fatigue Test: Extending Angle (Nitinol Fatigue)

Extending Angle - (Nitinol Fatigue) \blacksquare -110 + 0.298x + -9.37E-04x^2

Figure 14. Fatigue of the extending bend angle (nitinol fatigue)

After performing the fatigue test, the rate of change of the bend angle over time was characterized in the graphs displayed in Figures 13-14. Pictured are red and blue data lines representing the measured bend angle after every three cycles; the angles were measured using a digital protractor tool in Kinovea, a free sport analyst software. Note that the angle convention chosen for the catheter at rest is 90˚, while the catheter extending past the vertical is said to be 0˚ or less. Observing the returning angle fatigue data shows a close to linear decrease in the actuator's resting position, while the extending fatigue data shows a nonlinear decrease in the maximum bend angle. By assuming a linear decrease, the average loss in the returning and extending bend angles are -0.06° and -0.15° for every cycle throughout a test period of 150 cycles. While there is no well-defined plateau where the rate of change of the actuator's bend angle levels out, at approximately the 100th cycle, the curve following the bend angle seems to become flatter, resulting in the prescribed fatigue period for the bend angle test to be 100 cycles.

C. Bend Angle Characterization

Characterizing the actuator's steering required an initial fatigue procedure before the bend angle test commenced. Fatiguing the catheter prior to data collection ensured the accuracy of the results by omitting the time period where the catheter's bend angle dramatically decreased with every actuation. A plateau in the catheter's bending characteristics was seen during the fatigue test, thus motivating the decision to subject the catheter to 100 cycles; this was carried out at 2.800 amps per the results of the surface temperature test. Conducting the bend angle test started with the actuator at rest in 37°C water and consisted of slowly increasing through different amperages to find what value resulted in -90˚, -60˚, -30˚, 0˚, 30˚, 60˚, and 90˚ of bending.

Current vs. Bend Angle

Figure 15. Fatigue of the extending bend angle (nitinol fatigue)

The results in Figure 15 illustrate the three trials conducted to reach seven target angles and the corresponding currents required to achieve each angle. While the data collected is fairly consistent through each trial, an anomaly exists in Trial 2, where the actuator did not fully return to the 90˚ position. The current to achieve 30˚ was similar to the currents needed in trials 1 and 3, yet once the actuator hit 47.3˚ in trial 2, it was unable to bend past this mark even with no current and sufficient cooling time (the cooling time deemed sufficient was 20 seconds, the same amount of time given during the fatigue test for the catheter to cool completely and return to the resting position). An additional 5 minutes were given for the actuator to return to the resting position, but it never progressed past 47.3˚. Despite this anomaly, a third trial was run the following day, with the same actuator, and a full range of bending was seen. Excluding this outlier data point and averaging out the different angles and currents results in an association between the two (Figure 16). Strictly using the currents outlined in Figure 16 to achieve the respective angle would result in a very slow catheter. Instead, a control system should be implemented to administer a high current, say 2.800 amps, where the current is then reduced to the amperages outlined in Figure 16 as the desired angle is approached. The challenge with such a system is finding a way to reliably determine the catheter's bend angle without empirically measuring the catheter itself.

Figure 16. Fatigue of the extending and returning bend angles

V. CONCLUSION

The cardiac catheter presented in this report utilizes an innovative elastic recovery force to achieve bidirectional steering with a single length of nitinol wire. This design, based on previous work by Sheng et al., underwent multiple development phases, including refining the recovery force mechanism, training the nitinol, and adjusting the cross-sectional geometry and fabrication procedures. The primary challenge was the successful implementation of the elastic recovery force, which involved fastening the elastic, adjusting pretension, and ensuring proper alignment. Additionally, significant work in training the nitinol was required, resulting in a two-layered 3D curve configuration that achieved the desired steering characteristics. Throughout the majority of the project, fabrication was tedious yet straightforward, though with the implementation of the 3D curve training pattern, axial twisting and out-of-plane bending began to occur, requiring further rigor and attention to detail during assembly. With an adjusted fabrication procedure, the unwanted twisting and bending were resolved, and the characterization of the actuator commenced. The first test assessed the catheter's surface temperature to ensure safe operation within the human body, establishing 2.800 amps as the maximum usable current. This current was then used in 150 fatigue cycles to observe changes in the actuator's bend angle. By the 100th cycle, the bend angle started to stabilize, motivating further testing of the catheter's steering accuracy. The following bend angle tests involved varying the supply current to achieve specific angles. The data demonstrated a strong correlation between target angles and currents, showcasing the catheter's precise steering capabilities and potential for surgical applications. In conclusion, the SMA surgical catheter outlined in this report presents a promising alternative to existing steerable catheters. Future research should focus on refining the design and fabrication process to improve consistency in replicating actuators with similar steering and fatigue

characteristics. Further downsizing the actuator's diameter to approximately 5 mm will expand its use in various surgical applications. Additionally, demonstrating the catheter's functionality in a phantom model is essential to validating its design for operating room use. By continuing to leverage the unique properties of smart materials such as nitinol, medical procedures can benefit from innovative, minimally invasive solutions.

REFERENCES

[1] J. Sheng, X. Wang, T. -M. L. Dickfeld and J. P. Desai, "Towards the Development of a Steerable and MRI-Compatible Cardiac Catheter for Atrial Fibrillation Treatment," in IEEE Robotics and Automation Letters, vol. 3, no. 4, pp. 4038-4045, Oct. 2018, doi: 10.1109/LRA.2018.2861011.

[2] I. Chopra and J. Sirohi, "Shape Memory Alloys (SMAs)," in *Smart Structures Theory*, vol. 35, United States: Cambridge University Press, 2013, pp. 194–304. doi: 10.1017/CBO9781139025164.004.

[3] H. B. Gilbert and R. J. Webster, "Rapid, Reliable Shape Setting of Superelastic Nitinol for Prototyping Robots," in *IEEE Robotics and Automation Letters*, vol. 1, no. 1, pp. 98-105, Jan. 2016, doi: 10.1109/LRA.2015.2507706.

[4] J. J. Li, "Ferroelectrics/Piezoelectrics, Multiferroics, and Shape Memory Alloys" in *Marks' Standard Handbook for Mechanical Engineers, 12th edition*, The McGraw-Hill Companies, Inc., 2018.

[5] Y. Chitalia, S. Jeong, K. K. Yamamoto, J. J. Chern and J. P. Desai, "Modeling and Control of a 2-DoF Meso-Scale Continuum Robotic Tool for Pediatric Neurosurgery," in IEEE Transactions on Robotics, vol. 37, no. 2, pp. 520-531, April 2021, doi: 10.1109/TRO.2020.3031270.

[6] T. G. Mohanraj, J. Song, M. R. Rajebi, L. Zhou and F. Alambeigi, "A Kirigami-Based Magnetically Steerable Robotic Catheter for Treatment of Peripheral Artery Disease," *2022 9th IEEE RAS/EMBS International Conference for Biomedical Robotics and Biomechatronics (BioRob)*, Seoul, Korea, Republic of, 2022, pp. 1-6, doi: 10.1109/BioRob52689.2022.9925350.

[7] C. Limpabandhu, Y. Hu, H. Ren, W. Song, Z.T. Ho Tse, "Magnetically Steerable Catheters: State of the Art Review," in Proc Inst Mech Eng H., pp. 297-308, Mar. 2023, doi: 10.1177/09544119221148799. Epub 2023 Jan 27. PMID: 36704957; PMCID: PMC10052423.

[8] B.B. Ong, N. Milne, "Injury, Fatal and Nonfatal: Burns and Scalds," in *Encyclopedia of Forensic and Legal Medicine (Second Edition)*, pp. 173-181, 2016, doi: 10.1016/B978-0-12-800034-2.00220-2.