Mighten C. Yip
Dalio Institute of Cardiovascular Imaging,
New York-Presbyterian Hospital & Weill Cornell Medicine,
New York, NY 10065;
Department of Radiology,
Weill Cornell Medicine,
New York, NY 10065
e-mail: mighteny@gatech.edu

Seyedhamidreza Alaie
Department of Mechanical and Aerospace Engineering,
New Mexico State University,
Las Cruces, NM 88003
e-mail: alaie@nmsu.edu

Eva A. Romito
Dalio Institute of Cardiovascular Imaging,
New York-Presbyterian Hospital & Weill Cornell Medicine,
New York, NY 10065;
Department of Radiology,
Weill Cornell Medicine,
New York, NY 10065
e-mail: evajrz24@gmail.com

Tejas Doshi
Dalio Institute of Cardiovascular Imaging,
New York-Presbyterian Hospital & Weill Cornell Medicine,
New York, NY 10065;
Department of Radiology,
Weill Cornell Medicine,
New York, NY 10065
e-mail: tejasjdoshi45@gmail.com

Amir Ali Amiri Moghadam
Dalio Institute of Cardiovascular Imaging,
New York-Presbyterian Hospital & Weill Cornell Medicine,
New York, NY 10065;
Department of Radiology,
Weill Cornell Medicine,
New York, NY 10065
e-mail: aamirimo@kennesaw.edu

Bobak Mosadegh[1]
Dalio Institute of Cardiovascular Imaging,
New York-Presbyterian Hospital & Weill Cornell Medicine,
New York, NY 10065;
Department of Radiology,
Weill Cornell Medicine,
New York, NY 10065
e-mail: bom2008@med.cornell.edu

Low-Cost and Rapid Shaping of Nitinol for Medical Device Prototyping

This paper describes the methodology for rapid prototyping of nitinol structures by heat setting. Nitinol is a shape memory alloy commonly used in implantable medical devices. The proposed technique, based on 3D printing, can be used to effectively iterate multiple nitinol designs for different types of medical devices. We describe a rapid and low-cost process of ceramic replica molding of standard 3D printed parts to create high-temperature resistant fixtures, suitable for heat setting of nitinol. The technique represents a low cost (<\$20 materials per fixture) and rapid (as quickly as 16 h for a volume less than 1.25×10^5 mm^3) method for shaping nitinol, a technique that typically is costly, labor intensive, and requires specialized equipment. Our method satisfies a need for cost-effective, rapid prototyping of nitinol for implantable medical devices, and we show an example set of shaped nitinol wires, clips, and stents. This method is straightforward and can be easily applied by researchers to rapidly iterate medical device designs.
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[1]Corresponding authors.
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Simon Dunham[1]
Dalio Institute of Cardiovascular Imaging,
New York-Presbyterian Hospital & Weill Cornell Medicine,
New York, NY 10065;
Department of Radiology,
Weill Cornell Medicine,
New York, NY 10065
e-mail: sid2012@med.cornell.edu

1 Introduction

Rapid prototyping constitutes a set of technologies designed to create three-dimensional (3D) objects based on computer-aided design (CAD). Specifically for medical device prototyping, methods that allow for rapid iteration of designs are challenging because of the complexity of processing common medical grade materials, especially nitinol. The following techniques are all effective for traditional rapid prototyping, but none of them allow for direct shaping of nitinol prototypes. Methods such as 3D printing [1], CNC milling [2], and replica molding [3] facilitate rapid fabrication and iteration of designs and prototypes [1,4]. Thus, we present a method that integrates these conventional techniques with ceramic replica molding and heat setting to demonstrate the prototyping of stent frames and wire components.

Nitinol is uniquely suited for minimally invasive medical implants because it meets the following criteria: (1) devices must be biocompatible and/or hemocompatible [5,6]; (2) materials must undergo dramatic deformations in order to be catheterized [7]; (3) for most implants, long-term durability is a consideration [6]. As a result, research and development of medical implants are cost intensive.

Nitinol is a highly unique, elastic shape memory alloy, which when processed properly, exhibits superelasticity by virtue of its unique structure and associated phase transitions. As a result, it exhibits much higher fracture toughness, elastic strain, and strain to failure compared to other highly rigid materials [8,9]. Furthermore, nitinol is biocompatible and hemocompatible [5,10,11]. Because of these distinctive properties, it is used in a variety of medical applications, such as cardiovascular implants, orthopedics, and orthodontics [5,12]. Nitinol is also widely used in the automotive and aerospace industries (e.g., in RF antennas) and shape memory alloy actuators [8]. Although nitinol has a large number of applications, its manufacturing and processing are costly and time-consuming [13]. While there are commercial services for the research and development of implantable nitinol devices, they can be slow and costly, often limiting the ability of researchers to create novel prototypes.

Nitinol raw materials are fabricated through vacuum melting or sputtering [14–16]. Vacuum melting is most suitable for bulk wires, tubes, and sheets. Alternatively, sputtering allows for thin film deposition (typically <30 μm), however, it is a very expensive process [16]. Almost all final nitinol components can be fabricated by laser cutting and/or subsequently heat setting of either wire, tube, or sheet [17]. Heat setting requires nitinol components to be held in their desired geometry while being annealed at ~550 °C [17]. As the nitinol components undergo phase changes associated with temperature change, they exert high stresses (200–800 MPa) that become the primary challenge for fixtures to accommodate [17–19]. Therefore, production of a metallic fixture, that is strong enough to confine nitinol and stable at high temperature, is required. Some fixtures are manufactured using conventional machining, but this requires skilled labor and access to specialized facilities depending on part complexity. Alternatively, CNC machining provides more flexibility but requires maintenance [20]. In addition, other reports involve manual and time-intensive methods that do not provide the precision or efficiency of 2D/3D CAD [21]. In a previous study, Utela et al. were able to heat set nitinol wire by using a metal 3D printer which contributes not only to high upfront costs but uses instrumentation not currently widely accessible [22].

Additive manufacturing of nitinol has recently attracted interest from the academic community. Selective laser melting and laser directed energy deposition have been among the techniques that explore this [23]. While these techniques offer rapid prototyping of complex 3D structures within a short period of time, they have limitations on the resolution of structures and their upfront equipment cost. Moreover, techniques such as conventional combustion sintering [24] can also produce nitinol structures with a lower cost within a short period of time; however, the structures lack a smooth surface that is desirable for some applications, e.g., medical device implants. Metal injection molding [23,24] also offers a cost-effective technique however, it is more suitable for mass production compared to rapid prototyping of a few samples. On the other hand, other machining techniques such as electrical discharge machining, water jet machining, and laser cutting techniques feature excellent precision, but they are rather costly due to their subtractive nature and expensive equipment. These and conventional methods make it difficult to explore the effect of designs and design choices either for early prototyping or for research. As a result, innovation in this type of biomedical implant is limited and devices tend to utilize less innovative designs. The goal of these methods is to allow researchers and inventors to explore more innovative designs in more controlled experiments at early stages in the design process.

For these reasons, most research papers that attempt to optimize nitinol geometries for medical applications focus primarily on mechanical modeling and finite element analysis [25,26]. While this is a critical stage in the design process, it is also important to fabricate prototypes and understand their complex interactions with actual tissue, which can be much more difficult to simulate. Here, we present a method to allow for rapid and inexpensive fabrication of a variety of nitinol structures and present their basic assessment in cadaveric heart models.

2 Materials and Methods

The workflow for rapid heat setting of nitinol is described in Fig. 1. First, a polymeric template is 3D printed based on the design, followed by casting an intermediate silicone mold, and finally casting an inverse ceramic replica. This method was selected over directly molding the ceramic on the 3D printed part because, for many of the geometries explored, 3D printed materials (Veroclear and TangoPlus) lacked sufficient elasticity to demold ceramic replicas. Improved mechanical properties of silicone should allow this complication to be avoided.

Using this approach, we can create a variety of nitinol wire geometries based on precise CAD designs: a helix with varying pitch, a conical spiral, an oval wire, and a Z-stent model. The latter two geometries are demonstrated because of their relevance to septal occluders and stent grafts [5,7,25,27,28]. Both applications have been investigated extensively via simulation, but in vitro studies have been primarily limited to those that utilize commercial

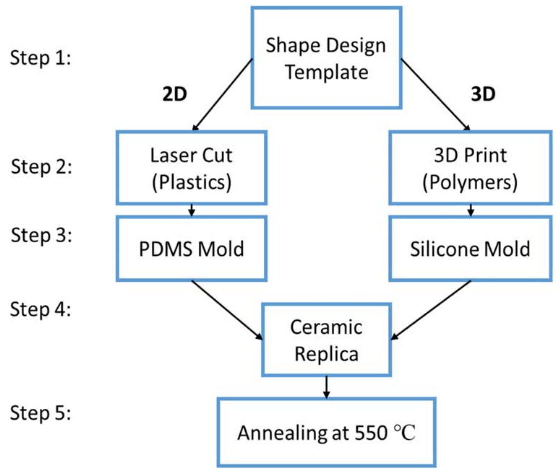

Fig. 1 Alternative workflows for achieving 2D and 3D nitinol features—(left) laser cutting polymeric sheets, using them for casting silicone molds, casting ceramic mandrels for rapid prototyping of nitinol wires, and (right) 3D printing polymeric molds, using them for casting silicone molds, using the mold for casting ceramic mandrels for rapid prototyping of 3D nitinol structures

medical devices [26,29,30]. The approaches described here illustrate a rapid and low-cost solution for evaluating these classes of implants.

2.1 Nitinol Wires. The nitinol wires (55% Ni, 45% Ti) used during testing had a diameter of 0.014" (Fort Wayne Metals, Fort Wayne, IN, USA) and 0.016" (Tegra Medical, Franklin, MA, USA). When winding nitinol into shapes with a higher bend radius, smaller diameter nitinol wires were used because of their compliance.

2.2 Experimental Design. CAD software was used to design the molds for the 2D and 3D nitinol shapes (AUTOCAD for 2D designs, SOLIDWORKS for 3D designs). Molds were designed with 3D grooves to accommodate the nitinol wire. The size and shape were selected to constrain the nitinol during heat setting (e.g., Fig. 2(*c*)). For 2D patterns, they were cut using a CO_2 laser (Universal Laser Systems VLS2.30, Scottsdale, AZ, USA). A single line defined a groove for nitinol to be placed in. In SOLIDWORKS, the grooves were formed in the 3D fixture with an elliptical cross section with an opening of 0.5 mm and a depth of 1.0 mm. This allowed the nitinol wires (0.014" and 0.016" diameter) to be secured.

Several factors were considered when choosing the appropriate silicone intermediate molds (Sylgard 184 and Dragonskin 20). Silicones can be used for either 2D or 3D method and the user should consider the importance of mechanics. Sylgard is stiffer and will maintain greater groove fidelity. Dragonskin is more flexible and will allow for more complex geometries where Sylgard would be too brittle to demold.

After the 2D template patterns were created, they were inverted in silicone (Sylgard 184; cured at 100 °C for 60 min). Then, the ceramic replica was molded over the pattern cut in acrylic. The nitinol wire was carefully threaded into the 2D ceramic pattern using a glass slide and subsequently heat set in a kiln at 550 °C for 7 min (Evenheat Kiln, Inc. Kingpin 88). Upon removal from the kiln, the assembly was quenched in an ice bath and allowed to cool at room temperature for 10 min. For 3D shapes, the designed molds were 3D printed (Stratasys Objet260 Connex, Veroclear) and then inverted in the silicone intermediate mold (Dragonskin 20; cured at 60 °C for 30 min). The patterns of the molds were designed such that outward radial forces kept the wire in place; however, for more complex geometries multi-part molds could be utilized to maintain the wire geometry. Additionally, using the 0.014" nitinol wire, we were able to create a Z-stent pattern that can be molded into different bend radii or circumferences.

For testing stent designs of laser cut nitinol tubes [7,29], we received nitinol stents produced in a similar fashion from Laserage™. Then, the rapid prototyping method was performed on the tines of the mitral valve stent, in order to show its applicability toward in situ experimentation for medical device prototyping. We ensured that the stent design of the nitinol tube was held in its desired geometry by using a fixture clamp that held the required nitinol components in their desired geometry.

2.3 Rapid Heat Setting Protocol

2.3.1 Polymer Template. For 2D shapes, the template designs for heat setting were sketched via CAD (AUTOCAD) and designed to laser cut onto 0.125" thick acrylic (McMaster-Carr) plates. The laser cutter (Universal Laser Systems at 100% power level and 25% speed, resolution of 10 μm) cut for eight passes to ensure that the cut properly went through all the acrylic plates (see Fig. 2(*a*)). Afterward, the plate was washed with isopropyl alcohol.

The template designs for 3D shapes were created via CAD and 3D printed (resolution of 50 μm). The 3D-printed templates were then boiled in water in a pressure cooker for 2 h and dried (Fig. 3(*a*)). This process reduces the residues of uncured polymers on the surface of the template parts—critical for the subsequent steps.

2.3.2 Silicone Intermediate Mold. Polydimethylsiloxane (PDMS) intermediate molds were created from the cut acrylic. First, repeated once, the acrylic parts were sprayed with Pattern Release 202 (Miapoxy) and then dried in a 60 °C oven for 30 s to ensure proper separation between the PDMS and molds. For the 2D parts, they were molded by pouring the silicone (Dow Corning, Sylgard 184) under vacuum impregnation desiccator onto the laser cut acrylic. Once the PDMS was free of air bubbles, it was baked in a 100 °C oven for an hour (see Fig. 2(*b*)).

For the 3D shapes, repeated once, the parts were sprayed with Pattern Release 202 (Miapoxy) and then dried in a 60 °C oven for

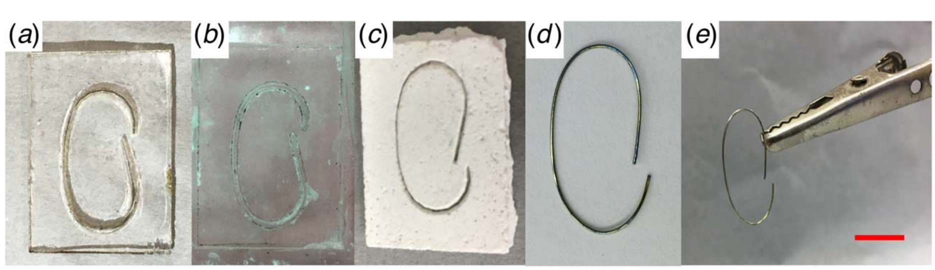

Fig. 2 Procedures for 2D nitinol shaping: (*a*) laser cutting on acrylic, (*b*) PDMS mold of the cut acrylic, (*c*) ceramic mold of the PDMS, (*d*) nitinol wire shape after kiln firing process, and (*e*) nitinol wire pre-bending

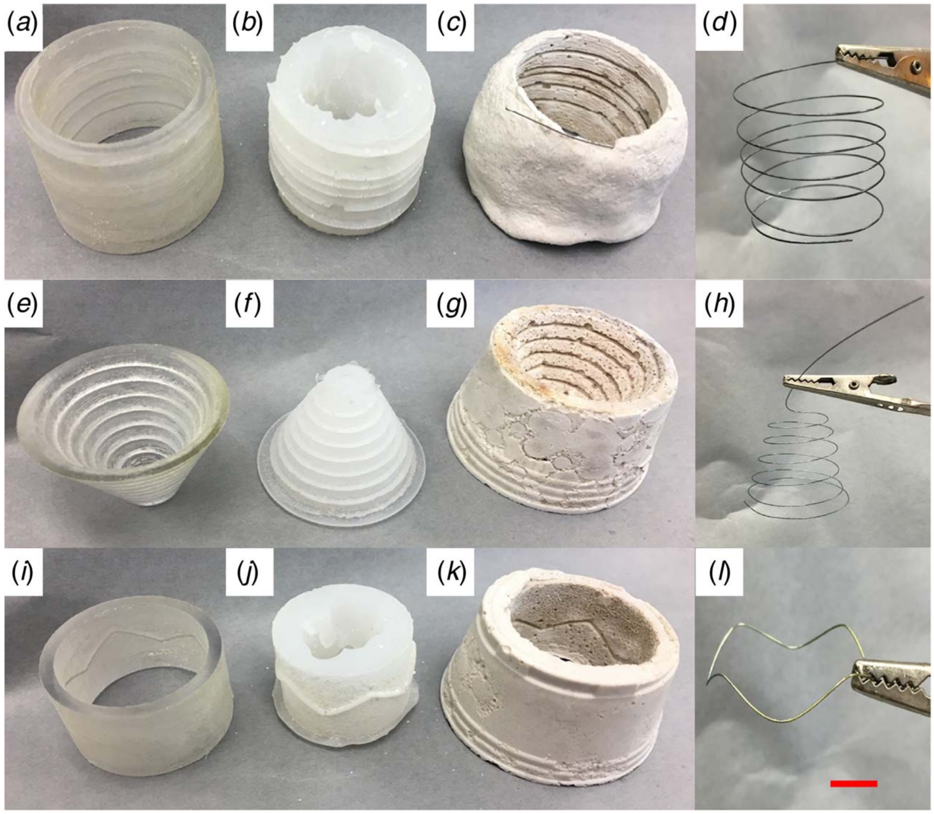

Fig. 3 Heat set processing for a helix with varying pitch, conical spiral, and Z-stent: (*a*), (*e*), (*i*) 3D printed mold, (*b*), (*f*), (*j*) silicone mold, (*c*), (*g*), (*k*) ceramic mold, and (*d*), (*h*), (*l*) final heat set nitinol wire. Scale bar: 10 mm.

30 s. A silicone (DragonSkin 20, Smooth-On, Inc., Macungie, PA, USA) intermediate mold was formed from the 3D printed part. Much care was taken for minimal formation of bubbles during the silicone pour onto the 3D template, and the mold was cured in a 60 °C oven for an hour (Fig. 3(*b*)).

2.3.3 Ceramic Replica Assembly. After the silicone was cured and demolded, the castable ceramic was mixed and pressed to assemble around the silicone parts. The castable ceramic replica, Rescor 750 (Cotronics Corp., Brooklyn, NY, USA), was mixed by hand at a 28% w/v ratio with 100 g of base and 28 g of activator. Once mixed to a thick paste consistency, it was applied around the silicone templates. The assembly of the ceramic and silicone was then baked in a 60 °C oven for an hour. After that, the assembly was placed into a 145 °C oven overnight. Once the ceramic fully cured, the silicone was removed from the assembly, leaving the hardened ceramic replica (Figs. 2(*c*) and 3(*c*)). All the ceramic replicas were sintered to ensure that the ceramic powder coalesced completely.

2.3.4 Heat Set Nitinol. The kiln (Evenheat Kiln, Inc. Kingpin 88, Caseville, MI, USA) was pre-heated to 550 °C. For 2D models, the nitinol was placed into the mold and sandwiched between the ceramic and a glass slide to prevent it from migrating during heat setting. For 3D objects, the nitinol wire was arranged into the ceramic mold (e.g., Fig. 3(*c*)). The nitinol assembly was heat set in the kiln for 7 min. Then, the assembly was removed and left to cool down at room temperature.

3 Results

To showcase the utility of this rapid heat setting nitinol method, we demonstrated various 2D and 3D structures based on rapid heat setting of nitinol wires and tubes. The process flow for heat setting 2D structures of nitinol wire is illustrated in Fig. 2, showing the subsequent stages of 3D printing and replica molding. Initially, trenches are engraved in an acrylic plate via laser cutting (Fig. 2(*a*)). This template is used to cast intermediate PDMS molds (Fig. 2(*b*)), which are inverted into ceramic molds at room temperature (Fig. 2(*e*)). Finally, the nitinol wire is confined in the trenches of the ceramic molds using clamps and a glass slide prior to placement in a furnace for heat setting. The 2D shape (Fig. 2(*e*)) can also be further modified to realize a 3D design. It is notable that the 2D curves are quite arbitrary. Therefore, the procedure provides a cost-effective means (2D laser cutting) for prototyping of nitinol devices. Furthermore, one can adjust the width of the trenches to accommodate wires with various diameters. This processing can be achieved using a low power CO_2 laser that is suitable for polymeric materials. This substantially reduces the cost of engineering compared with other methods for machining of metal mandrels or nitinol (e.g., CNC machining of fixtures or ultrafast laser cutting of nitinol).

For 3D shapes, a slightly modified workflow was used to achieve shape control by producing different objects such as a cylinder with varying pitch (Fig. 3(*a*)) and a conical spiral (Fig. 3(*e*)). Even more importantly, we were able to shape nitinol into a Z-stent pattern as a rudimentary prototyped stent design (Fig. 3(*i*)). The example of the final shapes of the three designs (helix, cones, and Z-stent shape) can be seen in Figs. 3(*d*), 3(*h*), and 3(*l*).

One of the major applications of nitinol is transcatheter-delivered devices; here we demonstrate a heart valve stent, suitable for this application. For this purpose, we began with a laser cut (Laserage™) nitinol tube, and then used mandrels of increasing diameter to expand it in multiple steps. Utilizing the workflow in Fig. 1, we created a 3D printed mold (Fig. 4(*a*)), and eventually a ceramic replica to use as a heat setting fixture. The ceramic mold was used to hold the nitinol in compression during heat setting—allowing the tines to be shaped, based on the 3D design (Fig. 4(*d*)). Alternatively, other tine geometries could be experimentally evaluated by iterating this design and prototyping process.

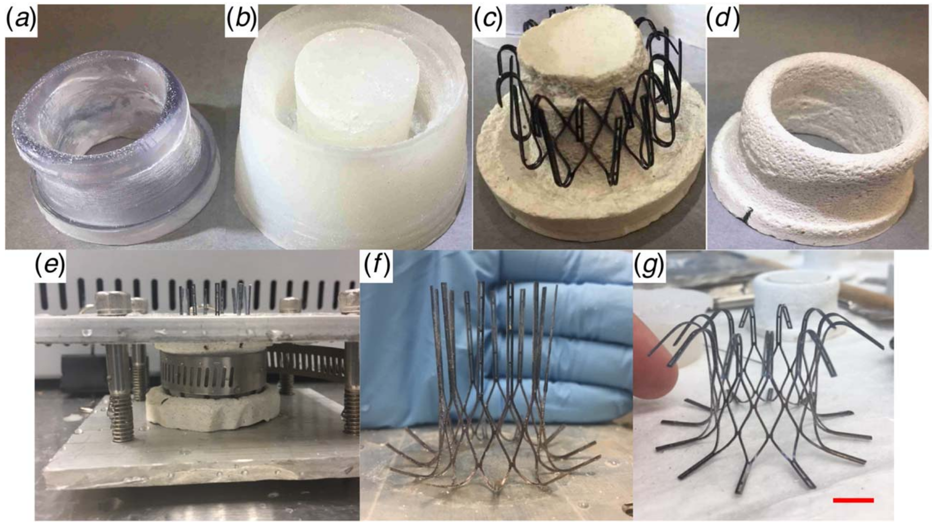

Fig. 4 Shaping and expanding a previously laser cut tube of nitinol for a mitral valve stent, formed by using ceramic fixtures and clamp: (*a*) 3D printed mold, (*b*) silicone mold, (*c*) ceramic mold, (*d*) shaped tines of nitinol stent, (*e*) compression setup to hold nitinol tines on the bottom of the stent in place with ceramic mold during heat setting, (*f*) result of heat set shaped nitinol tines on the bottom of the stent, and (*g*) result of heat set shaped nitinol tines on top and bottom of the stent

The efficacy of anchoring was assessed by placing the nitinol wire designs into cadaveric porcine hearts to understand the way these designs interact with real cardiac structures (Fig. 5). We utilize the 2D shape produced in Fig. 2, folded it into a stainless-steel tube, and heat set it again to create a 3D shape that could be used in biomedical applications such as a catheterized anchor or support for a device deployed across the atrial septum (Fig. 5(*a*) inset). In Fig. 5(*a*), the 2D processed nitinol (shaped into a 3D leaflet) was placed on the septal wall of a porcine heart. In Fig. 5(*b*), the Z-stent from Fig. 3(*k*), sutured with Dacron®, was placed in a porcine aorta. In Fig. 5(*c*), we see an example of a tube of nitinol (that was laser cut previously), used as a mitral valve replacement.

Figure 5 displays the applicability of this technique. In Fig. 5(*a*), the septal occluder prototype was designed and tested within a span of 24 h as was the Z-stent design in Fig. 5(*b*). With the exception of developing very large parts, the entire workflow, including 3D printing/laser cutting, replica molding, and heat setting could be completed within 24 h.

While the scope of this study was to develop an early prototyping method for testing acute performance of nitinol devices, we also performed an additional tensile test to provide a more comprehensive outlook of the performance of shaped nitinol. As shown in Fig. 6(*a*), the stiffness was measured ($n = 7$), and Young's modulus was determined using a circular cross section for the moment of inertia. The Young's modulus of the pre-heated nitinol and post-heat set nitinol was 66.2 ± 2.84 GPa and 64.7 ± 1.02 GPa, respectively. The study was done on a nitinol wire, with length 16 ± 0.06 mm and diameter 350 ± 1 μm, as a simply supported beam with a point force in the middle. The Young's modulus was also within the known austenite range of nitinol [31,32]. From a student's *t*-test at 95% confidence interval, the difference between the pre-heat and post-heat set nitinol was statistically insignificant ($p \geq 0.05$).

Furthermore, we conducted a three-point bend test to determine any fundamental mechanical characterization change to the nitinol after the heat setting occurred. The load-deflection curves in Figs. 6(*c*) and 6(*d*) show that indeed the materials exhibit shape memory effects. The loading forces for the pre-heat set and post-heat set nitinol wires at the maximum deflection point of 6.0 mm were 357 ± 6.16 cN and 296 ± 1.90 cN, respectively.

4 Discussion

The techniques described here allow for rapid prototyping of a wide variety of complex 2D and 3D nitinol shapes. We have demonstrated different types of device geometries that can be engineered with simply a 3D printer (or laser cutter), several low-cost moldable plastics and ceramics, and a small furnace. This processing method allows the user to quickly design a 3D shape, 3D print the mold, use a ceramic heat set assembly, and fabricate a nitinol structure within 24 h, which allows for iteration and testing device designs in situ within a conventional laboratory setting.

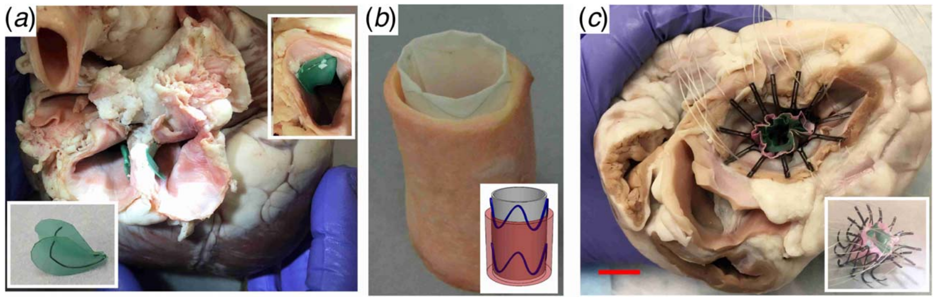

Fig. 5 Examples of nitinol shapes deployed in the porcine heart and aorta: (*a*) a fabricated clip anchored on septum between left and right atriums, (*b*) a Z-stent prototype in aorta, and (*c*) a mitral valve prototype

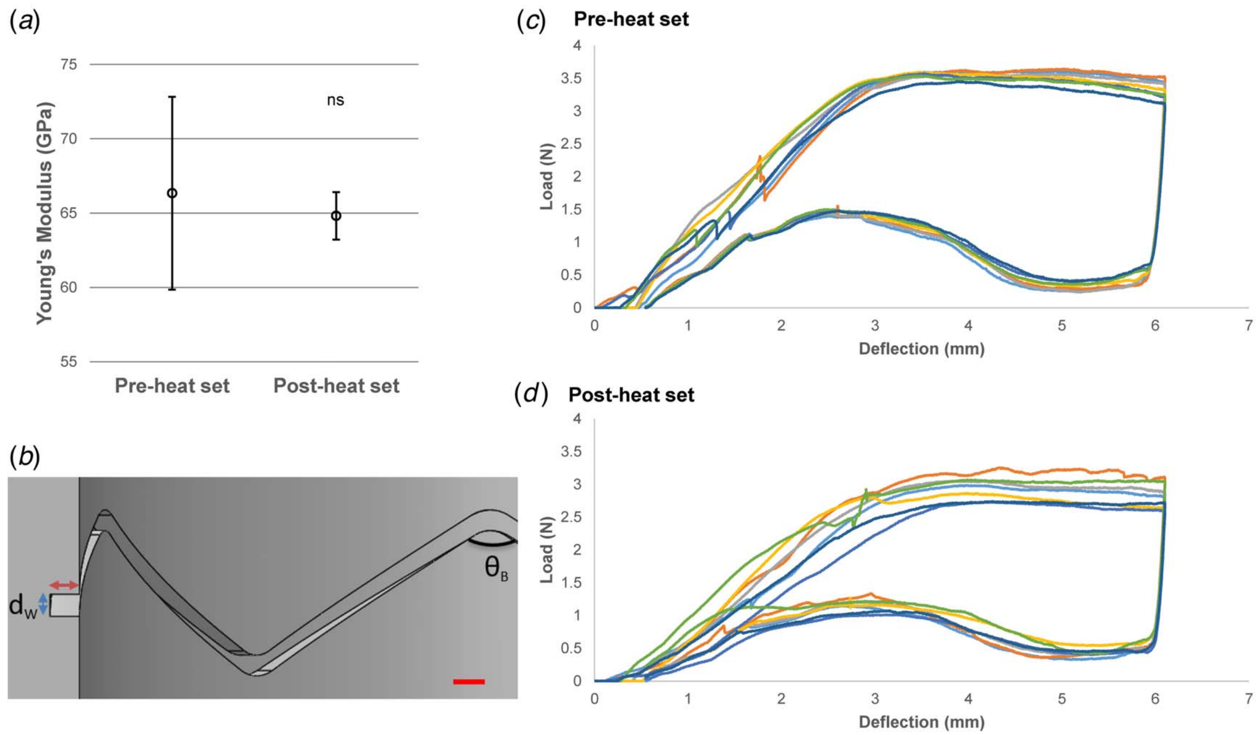

Fig. 6 **(*a*) The Young's modulus of a nitinol wire before and after the heat set procedure; error bars represent 99% confidence interval, (*b*) design of Z-stent in SOLIDWORKS showing variables that have design limitations, (c) three-point bend test for mechanical characterization of nitinol wire before heat set procedure: nitinol wire load-deflection curves ($n = 7$), and (*d*) post-heat set nitinol wire load-deflection curves ($n = 7$)**

Heat setting nitinol is commonly achieved with the aid of fixtures or pins and plates fabricated or assembled by conventional manufacturing technologies. However, they are still limited by the same limitations of conventional manufacturing technologies such as the labor cost for assembling fixtures and the cost for subtracted metals. The technique presented in this work allows for fabrication of almost any fixture geometry; it requires minimal equipment costs due to a lower cost of 3D printing plastics, and provides a balance between the surface quality, small feature sizes, cost-effectiveness, and a fast turnaround of the prototypes. It is also noteworthy that many conventional fabrication techniques require access to facilities or tools with high capital cost or high skill to operate. The method we have proposed is a technique that can be performed anywhere someone has access to a 3D printer, basic tools for molding, and an oven.

The proposed rapid prototyping method greatly reduces lead time for prototyping; assuming all steps are performed sequentially without delays, as quickly as ~16 h, limited primarily by the curing of the ceramic (~8 h). It is also cost-effective because the bulk of the costs is associated with the 3D printed part aside from the initial upfront costs for an incubator, oven, and 3D printer. It is notable that the cost of the 3D printed part can be as low as $20/kg [33] depending on the quality of the printer, plastic, and printing specifications. The cost of the 3D printed parts for each nitinol shape shown is around $8 while the cost of all other components is <$10.

Furthermore, this rapid prototyping technique also provides access to extensive design space to explore arbitrary nitinol geometries. There are a wide variety of applications for this technique, particularly in the medical device field for products like stents, thrombotic filters, orthopedics, and orthodontics. Specifically, this technique allows to rapidly test a variety of designs for research and development of medical devices interacting with real tissue, which is anatomically complex. While concerns about the effects of heat treatment on the mechanical properties of nitinol are valid, a three-point bend test shows the nitinol wire maintains its superelastic and shape memory properties as compared to previous literature [34]. While the load force at the maximum deflection point is slightly affected, but not dramatically, between the pre-heat and post-heat set nitinol wires, it is sufficient enough to evaluate the nature of the device performance such as anchoring and deliverability [35].

Our proposed method allows for iterative testing which enables the ability to determine the design extent and limiting specifications capable with this method. For example, with the simple Z-stent design shown in Fig. 3(*k*), the CAD shape design needs to consider the aspect ratio and bend radius of the nitinol wire. With aspect ratio, the 3D printed part needs to have channels deep and wide enough for the nitinol wire to be placed in the ceramic replica. Moreover, the aspect ratio of the ceramic grooves should be limited ($AR < 2.5$) because the intermediate silicone mold is soft enough to break if the aspect ratio is too high. Regarding bend radius, nitinol wire with larger diameter (diameter, $d_w > 0.014$") has larger resistance to bending. This resistance does not allow it to bend easily into a Z-stent pattern with a bend angle $\theta_B < 110$ deg (see Fig. 6(*b*)). Using the 0.014" nitinol wire, we are able to overcome the wire resistance to bending and create a Z-stent pattern.

The fabricated clip (illustrated in Fig. 5(*a*)) demonstrates that we are able to explore different designs for a septal occluder. This geometry can be used to anchor devices that reside in the left or right atrium and can easily be deployed via a Transseptal puncture. Additionally, the fabricated Z-stent prototype (Fig. 5(*b*)) can be used as a support for a variety of vascular grafts and other medical devices. By integrating it with Dacron fabric (suturing, Fig. 5(*b*)), functional prototypes can be rapidly iterated. Finally, when this process is coupled with laser cut nitinol tubes, complex stent designs for applications such as valve replacement can be explored (Fig. 5(*c*)). Due to the complex D-shaped mitral annulus, optimizing anchoring presents a dramatic challenge that is difficult to resolve [36].

This approach presents a promising method to explore designs that address the anatomic complexity and variation seen between individuals. While the approaches described here allow for complete and arbitrary design freedom, we refer readers to previous works describing best practices for the effects of strain, temperature, and time on the overall properties of the resulting nitinol [10,12,20,29,37].

5 Conclusion

Here, we demonstrated a simple, cost-effective method for rapid prototyping of nitinol designs. This method allows researchers to iterate device designs which can also serve the function of verifying numerical modeling and in-silico testing. This approach allows researchers to evaluate devices in tissue and cadaver environment that are difficult or impossible to accurately simulate due to the highly complex and non-linear properties of tissue. It also provides a cost-effective experimental method that can be used to compliment traditional numerical models. Numerical and finite element simulations allow researchers insight into fatigue mechanics, which is difficult to assess experimentally [25,26]. These methods allow for evaluation of the acute performance of implants, such as their ability to anchor or conform to tissue without the presence of leaks. However, these methods do not address the issue of long-term fatigue performance. Here, as described by Robertson et al., conventional methods should be considered [38]. Thus, these methods along with more traditional approaches represent critical steps for developing device strategies.

While the full extent and limitations of design specifications have yet to be explored, the results show a reality where in situ testing can be done in an efficient, affordable, and approachable manner. By using complementary ceramic molds, a user can create intricate self-produced stent designs for vascular and cardiac use. Uses of this technique have the potential to significantly reduce costs and save time while appreciably enhancing the ability to manipulate nitinol into complex structures. The possibility of conducting high-throughput iterative tests for different nitinol designs, especially toward the medical device field, highlight the true usefulness of this rapid prototyping method.

Conflict of Interest

There are no conflicts of interest. This article does not include research in which human participants were involved. Informed consent not applicable. This article does not include any research in which animal participants were involved.

Data Availability Statement

The datasets generated and supporting the findings of this article are obtainable from the corresponding author upon reasonable request.

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