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Design and Fabrication of a MitraClip Locator Prototype for Percutaneous Transcatheter Mitral Valve Repair System

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1 Background

Mitral Regurgitation (MR) is a malfunction of the mitral valve where the blood flows backward because of improper closure of the valve. The blood flows back through the mitral valve to the left atrium during the contraction of the left ventricle. This condition usually causes shortness of breath, fatigue, lightheadedness, and a rapid heartbeat. It is estimated that 2% of the global population have significant mitral valve disease. In US, more than 200,000 patients are diagnosed with this condition each year [1]. Current treatments include anticoagulation medication, and surgeries to replace or repair the dysfunctional mitral valve.

Open heart surgery has been the conventional approach to repair or replace the mitral valve. However, for a large percentage of patients (almost 30%), open heart surgery carries increased risk of mortality and morbidity due to their advanced age and dysfunction of the left ventricle [2]. Recently, less invasive, transcatheter approaches to mitral valve disease have been developed to decrease the surgical risk for these patients. [3]. One of the approaches that has recently shown promising outcomes is the placement of a MitraClip system (Abbott Vascular, Inc., Santa Clara, California) to stop or decrease the undesired leakage. MitraClip is a metal clip coated with fabric that is implanted on the mitral valve leaflets to allow the valve to close more completely. After clip placement, blood flows in an assisted fashion as the mitral valve opens and closes on the either sides of the clip.

The whole procedure for placement of the MitraClip in Transcatheter Mitral Valve Repair (TMVR) takes 2 to 3 hours under general anesthesia. A transesophageal echocardiogram is used to observe the blood flow and to trace the placement of the clip. A catheter is guided inside the femoral artery after percutaneous access is established. Then a guide wire is inserted to reach the mitral valve. At this time the MitraClip is threaded into the target position between the leaflets, and then, the guide is removed. Precise placement and orientation must be achieved at this point to best secure the clip with the minimum leakage possible. Since the implantation is being done inside a beating heart, this precise placement is the most challenging part of the surgery. Currently trial and error along with precise measurements are being utilized to find the best position.

This work introduces an innovative MitraClip locator device based on the most advanced materials and actuators to assist in the positioning of the MitraClip during implantation; this would potentially facilitate the most challenging and improtant step of the procedure. Currently, doctors are spending most of their surgical time (roughly 90 min) finding the correct orientation for the clip. The proposed self-actuated MitraClip locator device uses active Shape Memory Alloys (SMAs), Nitinol wires, in order to expedite surgical procedures with a higher precision. SMA wires have been used in medical devices safely and effectively [4,5]. Fig. 1 shows the schematic picture of our novel design that includes evenly distributed SMA wires inside a shaft to enable orientations in multiple directions. This design is proposed as a scaled model for preliminary testing. After thorough testing and evaluation on this model a real size prototype will be made for the real application.

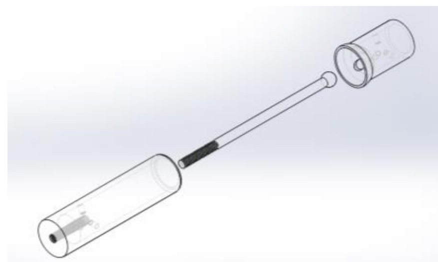

Fig. 1. Schematic design of the innovative MitraClip locating device.

This work presents a detailed design of our innovative device. This device has been fabricated and tested to show the proof of concept. The main purpose of this work is to show the feasibility of achieving movements in multiple directions using three shape memory alloy wires. As a long term plan, the authors aim to have this mechanism (while its accuracy and safety is assured) attached behind the MitraClip to facilitate controlled, accurate positioning.

2 Methods

The assembled model of the MitraClip locator is shown in Fig. 2. The design includes two concentric hollow shafts (D_{in}=19.90mm and D_{out}=17.90mm), connected by three completely stretch SMA wires. The SMA wires (purchased from Dynalloy Inc., Tustin, CA) with diameter of 0.20mm were hooked into the structure via the tiny legs that were implemented inside the shafts. To see the proper actuation capabilities of SMAs, they need to be completely stretched prior to the application of heat (some amount of pre-stress need to be set on the wires). For this purpose, a ball head long rod was made, guided inside the shafts to push the two shafts apart and stretch the attached SMA wires. This rod was screwed in at its threaded end to generate a desired amount of stress on SMA wires. The amount of pre-stress on the SMA wires was estimated by knowing the overall displacement. The top shaft was formed in a way to slide on this ball head rod to enable a 360º revolving joint.

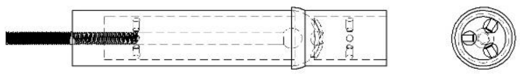

Fig. 2. Detailed 2D views of the assembled device.

Fig. 3 shows the 3D printed parts of the device. A 3D printer with resolution of 0.254mm was used to create the parts. The assembled structure with the middle part screw in is shown in Figs. 3(a). Fig. 3(d) shows the device with all three SMA actuators attached.

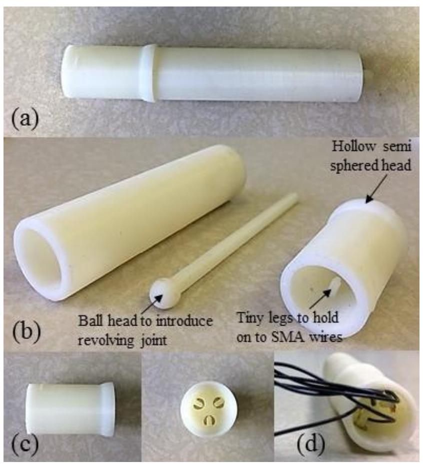

Fig. 3. 3D printed parts of the MitraClip locator device: (a) the assembled model, (b) individual parts, (c) side views of the top end, and (d) the model with the actuators attached.

3 Results

Fig. 4 shows the preliminary testing to illustrate how the prototype was actuated in one direction while one of the SMA wires was heated. Joule heating method was used to heat the actuators using a programmable power supply (BK Precision 1696, Yorba Linda, CA). To prevent damaging the actuators, the current was kept under 0.7A. After actuation, current was switched off and the other two wires were actuated to get the structure back into its original position. It was shown that our MitraClip locator device is capable of rotating its head to multiple directions and retrieve its original shape. The SMA wires, however, takes about 15 to 20 sec to cool down and recover their original length. The recovery was faster with the assisting forces applied by the wires on the opposite side. The authors are still working to find a way for cooling the heated actuators in the most efficient way.

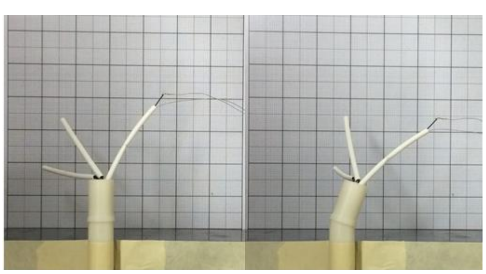

Fig. 4. Actuated prototype; left: the actuated prototype, and right: before actuation.

4 Interpretation

This study describes the initial proof of concept development for our novel MitraClip locator. Experimental investigations on this device are still ongoing to find the possible points of improvements. A finite element model of the device is currently under development to study all parameters that are involved, and to optimize the design to get the best possible performance. After thorough studies, this device will be made in real size and attached to the MitraClip for further evaluations.

A 3D model of the heart was printed (shown in Fig. 5) to investigate how our device would be able to orient and find the exact location of the MitraClip inside the mitral valve. The heart was printed using Polylactic acid (PLA) material. Also, a sectioned model was created to increase the visibility of our device while working inside the heart. The long-term goal of this study is to develop the heart with flexible materials and a perfect inlet/outlet to simulate a beating heart and artificial blood flow. The results of an experiment with this model will give a precise estimation of the time that would be saved during the procedure using this proposed device, in comparison with the current model.

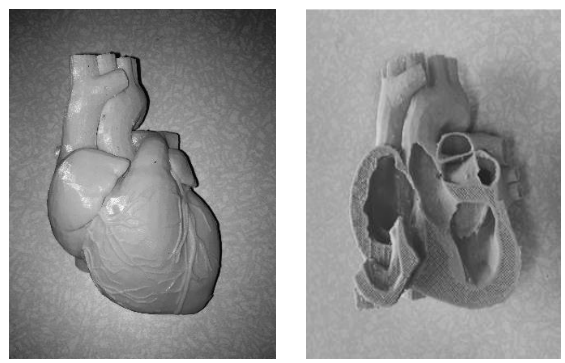

Fig. 5. 3D printed model of the heart; (a) the exterior view, and (b) the sectioned model for a better visibility of the left ventricle, the area that our proposed device would work in.

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