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Pop-up-inspired design of a septal anchor for a ventricular assist device

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1 Background

Heart failure (HF) is a serious condition in which the heart cannot pump sufficient blood to sustain the metabolic needs of the body. A common indication of failure is a low ejection fraction, or the volumetric proportion of blood ejected when the ventricle contracts. In end-stage HF, support from a ventricular assist device (VAD) can assume some or all of the heart's pumping work, improving the ejection fraction and restoring normal circulation. VAD therapy options for end-stage right heart failure (RHF) are limited, with only a few FDA-approved devices available for mechanical circulatory support [1]. These devices are based on continuous flow impellers; and despite anticoagulation therapy, use of currently available VADs is associated with thrombogenic risk since the blood must contact artificial non-biologic surfaces.

An implantable VAD for RHF based on soft robotic pulsatile assistance has previously been proposed [2]. This device is comprised of a contractile element that is anchored to the ventricular septum and the right ventricle (RV) free wall. The device is programmed to contract in synchrony with the native heart beat and assist in approximating the septum and free wall together in order to augment blood ejection (Fig. 1). Potential advantages of this approach include reduced risk of thrombosis, since there is no blood flow through the lumen of the device, and the possibility for minimally invasive deployment of the device under ultrasound guidance.

A key component in this VAD concept is the anchoring mechanism that couples the contractile actuator to the ventricular septum. In this work, we report design, fabrication and testing of a new septal anchor design. We exploit the emerging technology of pop-up MEMS [3] in order to fabricate a collapsible anchoring mechanism. Origami-inspired engineering and pop-up MEMS manufacturing techniques have previously been used for developing disposable and low-cost medical tools and devices [4]. The pop-up anchor can be deployed into the left ventricle (LV) via a standard delivery sheath. We validate the load bearing ability of the anchor and demonstrate deployment in an *ex vivo* simulation.

2 Methods

Design. To create a foldable mechanism that does not require manual assembly, pop-up MEMS design techniques were used. In this process, a layered laminate was created with rigid, adhesive, and flexible layers that results in a final mechanism with a high level of complexity (Fig.2). The anchor was required to be freely deployed through a 24Fr delivery sheath and so must be no greater than Ø6.5mm in its folded state. When deployed, it must be capable of withstanding up to 7N in order to meet the requirements of the VAD [2]. The unassembled anchor mechanism was designed using 3D CAD software (SolidWorks) and the custom 2D CAD software "popupCAD" [5], which has been developed to design multi-layer laminates for folding-based 3D mechanisms. The mechanism consisted of two sublaminates: the first (bottom) sublaminate forms the base of the anchor and the second (top) sublaminate utilizes a bistable parallelogram for pop-up unfolding during deployment.

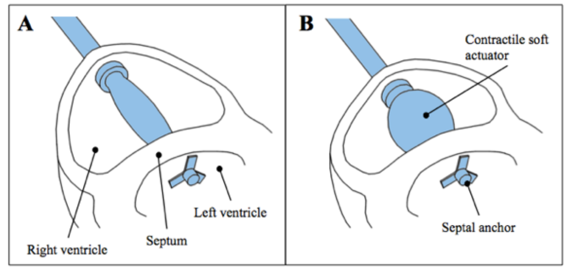

Figure 1. Schematic representation of the VAD and position of septal anchor during diastole (A) and systole (B).

Fabrication. For each rigid layer of the laminate, three sheets of single layer of carbon fiber composite were cured together at orthogonal angles, resulting with a thickness of 90 µm. 25 µm thick kapton and heat activated adhesive (Pyralux 1500, DuPont) were used for flexible layers which generate the flexures and adhesive layers which bond the layers of the laminate, respectively. Each layer was individually cut according to the design using a laser micromachining system (Oxford Lasers). After cutting each layer, the carbon fiber and kapton were treated using a plasma etcher and then cured together using heat activation. Once cured, the laminate was cut one last time, so that when released from surrounding material, the final geometry remained and the inner layers were free to pop open (Fig. 3). The final device weighs 70 mg, and the diameter is 6 mm when it completely folded, and 15 mm when it fully deployed. The device design can easily be modified to include additional layers. Fig. 3C shows an implementation of the prototype that incorporates an additional kapton layer to improve the contact with the tissue.

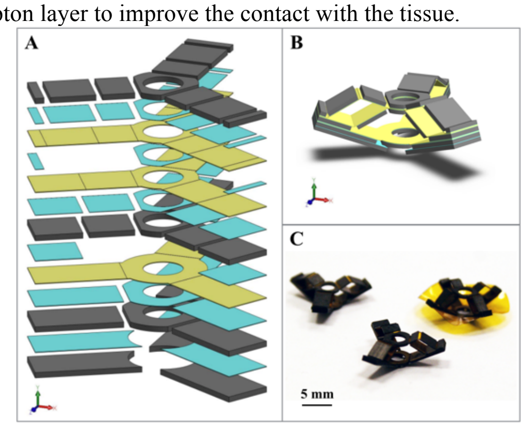

Figure 2. A. The pop-up anchor consists of 13 layers of rigid (carbon fiber), flexible (kapton), and adhesive (Pyralux 1500) materials, shown with gray, yellow, and blue, respectively. B. The anchor is designed using SolidWorks and popupCAD. C. Fabricated popup anchor prototype in the foreground, other prototypes, including one with an additional kapton layer in the background.

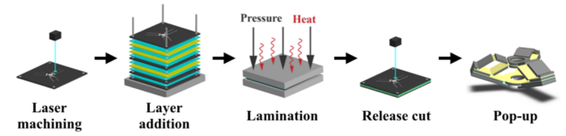

Figure 3. Prototyping the septal anchor involves laser machining, layer addition, lamination, and a release cut. The final device is ready for use immediately following the release cut.

3 Results

Load bearing. The anchor prototype was subjected to a load bearing test using a materials testing system (Instron Materials Tester 5544A, Instron) to determine its durability. A customized fixture was used to simulate the *in vivo* loading conditions on the anchor. First, the anchor was subjected to a cyclic load of 7 N for 60 minutes at 60 bpm (Fig. 4A). Then, the applied load was increased up to 30 N five times at a steady rate, where the anchor was still fully functional. Finally, an additional test was performed until failure, which occurred at approximately 35N (Fig. 4B and C). This compression test validated that the load bearing capability of the pop-up septal anchor was beyond the requirement of 7N of force applied on the walls of the heart in [2].

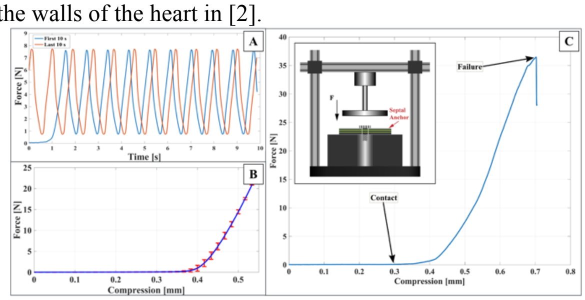

Figure 4. A. The pop-up septal anchor was subjected to a cyclic force at 7 N for 60 minutes at 60 bpm. The first and last 10s of the test is presented in blue and red, respectively. B. The pop-up septal anchor can function under forces as high as 30N. C. Failure occurs at approximately 35N. Inset shows the test setup schematically.

Ex vivo simulation. We demonstrated the feasibility of anchor deployment in an *ex vivo* study using an isolated porcine heart. Both ventricles were pressurized to levels that can be expected during RHF. The access through the RV free wall and ventricular septum was gained using the Seldinger technique. After a purse-string suture was placed on the RV free wall, a needle was introduced into the RV and passed toward the LV through the septum. A guidewire was then passed through, the needle was removed, and a series of dilators of increasing diameter were sequentially placed over the guidewire to create an access within the septum. Finally, a 24Fr delivery sheath was placed and the anchor was deployed into the LV. The threated section of the anchor protruded toward the RV through the transseptal access. On the RV side, a threaded disc was coupled to the threaded section of the anchor in order to create a "sandwich"-like fixation of the anchoring system to the septum. Fig. 5 shows the final insertion stages. An endoscopic camera was used to document the deployment process.

4 Conclusions

We successfully demonstrated the use of pop-up MEMS technology to create a functional septal anchor mechanism for an implantable VAD. The pop-up mechanism is made from non-ferrous materials which will enable magnetic resonance imaging (MRI) compatibility in future embodiments of the

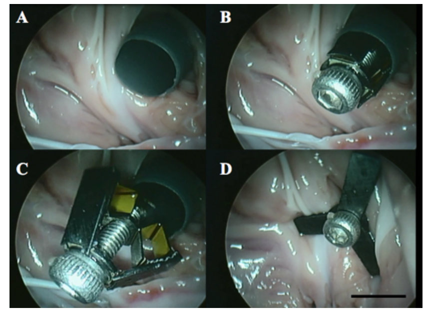

Figure 5. ***Ex vivo*** **deployment of the pop-up septal anchor in to the LV (A-D). (Scale bar: 5mm.)**

VAD. Although the materials used in the current design are not biocompatible, they have both ferrous and non-ferrous biocompatible substitutes. Another concern about the septal anchor is the sharp corners and edges. Due to the flexibility in the design and manufacturing processes, additional layers such as a surgical mesh can be added to prevent contact of sharp edges with the tissue. Furthermore, the device can be fully coated with biocompatible flexible materials, such as parylene without interrupting the device function. Future work will include further design refinement to incorporate the anchor fully with the VAD and to attain biocompatibility for *in vivo* testing without damaging tissues. *In vivo* MRI studies will allow accurate, non-invasive assessment of the RV function during operation. Additional and more rigorous testing of the anchor will be performed to assess its ability to withstand cyclical loading when implanted in a heart. This is the first proposed medical device implant application using pop-up fabrication methods. The flexibility of the design process allows the use of different materials at a range of physical scales. This fabrication technology may enable more sophisticated medical implant designs in the future.

Acknowledgements

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