An Intraventricular Soft Robotic Pulsatile Assist Device For Right Ventricular Heart Failure

Evelyn Park[1], Nikhil Mehandru[1], Tonatiuh Lievano Beltran[1], Erik Kraus[1], Dónal Holland[1,2,3], Panagiotis Polygerinos[1,2], Nikolay V. Vasilyev[4], Conor J. Walsh[1,2]

[1] School of Engineering and Applied Sciences, Harvard University, Cambridge, MA
[2] Wyss Institute for Biologically Inspired Engineering, Cambridge, MA
[3] Trinity College, Dublin, Ireland
[4] Department of Cardiac Surgery, Children's Hospital, Boston, MA

***Abstract*— Due to its more complex geometry and motion, right ventricular heart failure (RVHF) is less understood than left ventricular heart failure and has fewer treatment options. There are currently no mechanical circulatory support devices designed specifically for the right ventricle. This work presents the design of a ventricular assist device (VAD) which leverages the specific geometry and lower pressure of the right ventricle (RV) in order to avoid the major pitfalls of current VADs. The device consists of a contracting linear actuator spanning the RV, bringing its walls together and assisting in the ejection of blood from the ventricle.**

Keywords—ventricular assist device, right ventricular heart failure, soft robotics, cardiac surgery

I. Introduction

Heart failure occurs when either or both ventricles of the heart cannot pump sufficient blood to meet the metabolic needs of the body. While symptoms vary widely depending on which ventricle is failing and the underlying cause, the standard indicator of failure is low ejection fraction, which is the volumetric proportion of blood ejected when the ventricle contracts. Effective therapies for heart failure target the etiology, but treatment of symptoms is also necessary to sustain patient health and quality of life. Though early-stage heart failure can be treated with drugs, more advanced cases require support from a ventricular assist device [1]. Such devices assume some or all of the heart's pumping work, unloading the heart and restoring normal circulation, until the patient recovers or a transplant becomes available. Currently, only 1 implantable and 2 paracorporeal devices are FDA-approved for mechanical circulatory support of the right ventricle [2], and all are originally LVADs set to produce lower pressures. Implantation requires cannulation via sternotomy, which is a very invasive procedure. In addition, all current VADs require blood to flow through the device, which presents a thrombogenic risk. Newer VADs mitigate this by using magnetic suspension for contactless bearings, but this is power-intensive and reduces portability.

II. Methods

From clinician input, it was determined that the device must be compact enough to span the right ventricle and be deliverable via a mini-thoracotomy. In addition, to reduce the need for a strong anticoagulation regimen, which has undesirable side-effects, we sought to minimize the surface area of contact between the device and the blood. Because the target population is adolescents, many with congenital heart defects, the device also needed to be compatible with anatomical variation. Finally, we determined that the device should be able to generate the physiological 30 mmHg of systolic pressure in the right ventricle, which translates to an estimated 7 N of force applied on the walls.

The final device concept employs the use of a soft robotic linear actuator anchored in the free wall of the right ventricle and the septum (Fig. 1). The actuator contracts and brings the walls of the right ventricle together, contributing to the ejection of blood from the ventricle into the pulmonary artery.

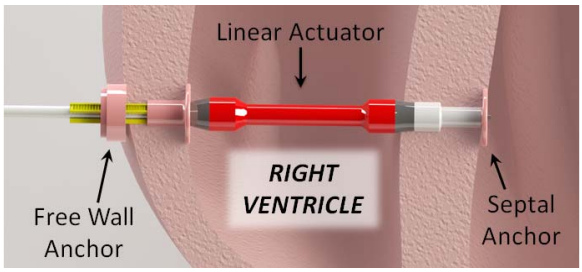

Fig. 1. Model of the device within the heart

The actuator is a pneumatic artificial muscle consisting of an inflatable inner bladder constrained by a braided mesh, which contracts in length when pressurized. To avoid the risk of air embolisms, the final device will use hydraulics instead of pneumatics. The actuator is only 5 mm in diameter when unpressurized, facilitating minimally invasive delivery. It is also very soft, with the inner bladder molded out of a 30 Shore OO hardness silicone rubber. This allows for operation at low pressures below 15 psi, and safer direct tissue contact.

Two anchors hold the device in place, one on the septal wall and one on the right ventricular free wall (RVFW). The septal anchor is delivered via catheter through the septum and unfolds in the left ventricle, and was thus designed to prioritize deliverability. The final design is a 1 mm thin circular disc of Elastosil M4601 (Wacker), a 28 Shore A hardness silicone rubber, and provides sufficient resistance to device pullout while still fitting inside a 10 mm-diameter delivery tube. The free wall anchor design prioritizes adjustability and tight sealing to prevent blood leakage. A thin Elastosil disk is deployed against the inner surface of the RVFW to provide a

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seal against leaks, and an external cap is slid on by the surgeon, clamping the RVFW in between. To allow for adjustability while still being secure, the anchor utilizes a triple-ratchet design (Fig. 2). The anchor is compatible with free wall thicknesses ranging from 5-10 mm.

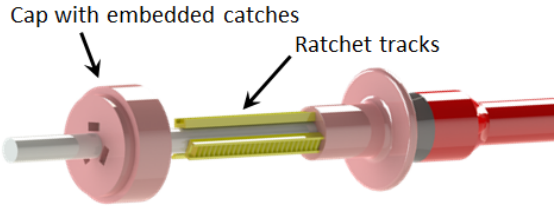

Fig. 2. Model of adjustable ratcheting free wall anchor

The final device prototype was constructed with a novel multi-step fabrication procedure utilizing shape deposition manufacturing techniques. Through multiple embedding and overmolding steps, the individual components are integrated into the device, which is finally encapsulated in a contiguous layer of elastomer to secure all parts in place.

III. Results

A simulated heart ventricle was built to evaluate the device, consisting of two sidewalls molded from Ecoflex 00-30 (Smooth-On), a silicone rubber with material stiffness similar to live heart tissue [3]. The septal and free walls are 10mm and 5mm thick, respectively, matching clinical values, and mounted in rigid frames set an adjustable distance apart. The device was mounted in the test setup, connected to a regulated 15 psi air supply, and actuated by alternating pressurization for active contraction with venting for passive relaxation. Frequencies of 60 and 90 cycles per minute were tested to demonstrate function at various heart rates. Videos of device operation were analyzed in ImageJ (NIH) to track device motion (Fig. 3).

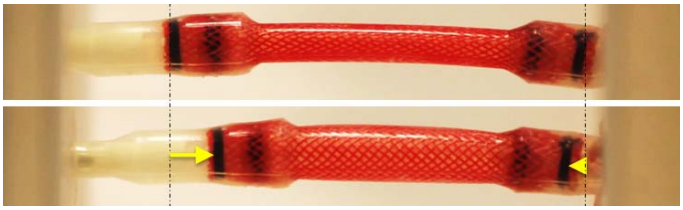

Fig. 3. Image tracking of device in test setup.

The device contracted up to 8 mm, pulling the walls together and reducing chamber width by 12%. The free wall motion was responsible for most of the displacement (Fig. 4), and in patients with RVHF this is expected to be even more pronounced as they have a dilated RV and a thinner RV free wall. This is the desired device behavior as large septal wall motion could impact the left ventricle.

As our testing did not decouple force and displacement, the force applied was calculated using the force-displacement curves of the two elastomer walls. From tensile testing (Instron) we found k_{septal}=0.0992 N/mm and k_{free}=0.08 N/mm, and combining this with the maximum measured displacements of d_{free}=5.73 mm and d_{septal}=1.91 mm, we calculated that the actuator was applying 0.65 N of force.

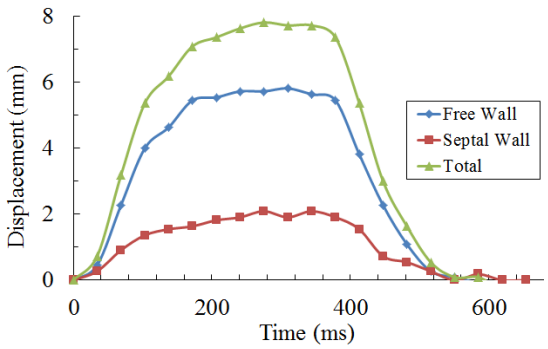

Fig. 4. Contraction of the device over one cycle

Due to the low stiffness of the walls and lack of fluid pressure providing resistance, the device reached its peak lengthwise contraction. As pneumatic artificial muscles have an inverse relationship between the degree of contraction and the maximum force, with the highest forces occurring at the beginning of the stroke, the small force value is expected. Isometric testing of standalone actuators achieved forces of up to 7 N, which is sufficient for the needs of the device.

IV. Conclusion

Compared to current VADs, our device can be delivered less invasively, is softer and less damaging to tissue, and has lower thrombosis risk due to reduced blood contact. With further refinement, it may become a compelling treatment option for patients with right ventricular heart failure. Further testing needs to be done with a more advanced and realistic setup that enables measurement of fluid displacement and chamber pressures. Future work will include making the device more compact, improving the contraction percentage, upgrading device control from simple timing to ECG syncing, incorporating adjustability for patient growth, optimizing anchoring disk design to reduce the risk of tissue necrosis from chronic force application, and making the free wall ratcheting mechanism reversible so that the device can be quickly removed in an emergency. Modifications for biocompatibility will also be made.

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