Improvements to the On-X Mechanical Heart Valve

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INTRODUCTION:

The On-X mechanical heart valve[1] is one of the most studied mechanical mitral valves and is designed to last a lifetime. It works to replicate an aortic valve with the same flow as a healthy human and ensures that blood flows in the correct direction, allowing oxygen to pass throughout the entire body.

How it Works:

Mechanical heart valves work to replicate normal human valves. Valves work in the heart to bring oxygen-poor blood into the right atrium where it is later sent to the lungs to receive oxygen; valves also work to pump blood out of the left ventricle to bring nutrients and oxygen to other parts of the body. A mechanical heart valve works to support and replace malfunctioning valves that might not pump blood effectively or in the correct direction by opening and closing at

specific times[10]. These valves can be created with different materials and functions to support everyone's varying needs.

Specifically, we looked at the On-X mechanical heart valve; this valve is built using On-X Carbon[6] (Pure Pyrolytic Carbon) which provides a smooth surface for blood to travel through without the formation of blood clots. It also uses 90° Leaflets[10], making it so that blood is able to flow straight through the heart and is less likely to be damaged. This acts similarly to a normal, regular working heart valve.

Ailments Addressed:

The On-X Mechanical heart valve works primarily for people with aortic valve stenosis and people with aortic valve regurgitation. Aortic valve stenosis is caused when the heart's aorta becomes thick and narrow due to age related calcium buildup[11]. This makes the heart not able to function normally and causes an irregular shape, reducing blood flow from the heart to the rest of the body. Also, aortic valve stenosis can occur in both tricuspid valves and bicuspid valves, both of which the On-X valves can resolve. Similarly, in aortic valve regurgitation, the aortic valve doesn't function normally[12]. The valve doesn't close completely, allowing for blood to flow backwards from the aorta into the left ventricle. This can be caused from calcium deposits which build up and cause the valve to lose elasticity (more common in people over 70). Both of these ailments can be resolved through a On-X Mechanical heart valve replacement. This valve would fully replace the malfunctioning leaflets, closing gaps and creating a tight and one-way seal for optimal blood flow.

Similar Devices:

A similar device to the mechanical heart valve is the ventricular assist device[19]. This device helps circulate blood throughout the body when the heart is too weak. Both devices help oxygenate blood and safely deliver it as a healthy body would.

BENEFITS:

On-X is the only heart valve with leaflets that turn 90 degrees, ensuring blood flows straight through the heart, making it less likely to be damaged. This simulates a healthy heart. At a low INR[6] (a blood test designed to discover how long it takes blood to form a blood clot), the On-X mechanical heart valve showed an 87% reduction in major bleeding in a five year study without an increase in thromboembolism (when a blood vessel is blocked from a blood clot moving from a different part of the body). Moreover, On-X is designed to be a valve for your whole life, which means that patients are able to safely and efficiently manage doses.

DRAWBACKS:

Like most mechanical heart valves, the On-X valve requires a patient to take anticoagulant medication such as Warfarin to prevent clotting by thinning the blood. Blood thinning[2] can make patients more susceptible to bruising, bleeding, and other complications. In addition, Warfarin is known to cause fetal malformation, posing a large risk to women who are planning to have children[3].

IMPROVEMENTS:

Using materials that are resistant to coagulation, patients would not have to take anti-coagulants that thin their blood. These materials would need to be biocompatible so the

body does not reject them. To help with blood clotting and risks that come with thinners, researchers have considered using human donors[4]. This would allow the human heart to keep its natural properties and eliminate the need for thinners, but it has low availability. There is still a possibility that the body may reject the transplant because it comes from an unfamiliar source.

Because of these reasons, synthetic heart valves are a popular choice for their durability and availability[5]. However, the materials often used in mechanical heart valves, (carbon and metals) On-X included, are prone to blood clotting. This is why patients are administered blood thinning medication. To improve on the design, our group is proposing coating the leaflets of the valve in an anticoagulant material[7] made by grafting or ionically attaching it to its surface.

In the last decade since the first implantation of the On-X heart valve in 1996, similar research has been continuing the development of fully anticoagulant heart valves. The TRIFLO, designed originally by Didier Lapeyre in 1999 and first implanted in 2022 proved revolutionary for its tri-leaflet central flow design that mimics a natural human valve to eliminate stagnant flow zones, which drastically reduces blood clots and potentially has the ability to eliminate the need for anticoagulation therapy.

Materials considered[7]:

Ultrananocrystalline Diamond Coating[8]	Polyurethane
Non-polymeric	Polymeric
Anticoagulative	Anticoagulative
Biocompatible	Biocompatible

Does not interfere with the geometry of the valve	Highly modifiable
Difficult to produce	Not enough research, room for improvements

TESTING:

To ensure our device functions the way it is supposed to and is a reliable piece of equipment for actual human use, we will test it in four different categories: function, efficacy, durability, and cytotoxicity.

Function[13]: To test the function of our device, we will be using a device called a Pulse Duplicator. This device is designed to simulate the function of a heart by generating a pulsatile flow through tested prosthetics that would be placed in the model heart. Using this device, we could test and see whether or not our mechanical heart valve performs up to standard by measuring the regurgitant fraction, identifying how much fluid leaks backward when the valve is closed.

Efficacy[14]: To test the efficacy of our model, we could use an echocardiogram, a test that measures high frequency sound waves to take pictures of a patient's heart. This shows us how the heart moves, details thickness, size, and movement of a heart's walls, and shows the strength of the heart's pumps and ensures the valves are functioning correctly. Using this method, we could observe differences between our heart valve and the On-X heart valve to see if improvements have been made.

Durability[15]: One possibility to test our devices durability is using the Accelerated Wear Testing technology designed by Vivitro labs.[16] Vivitro labs uses the AWT with dual control technology to ensure that the device being tested is sufficient for medical application. The AWT

rapidly cycles heart valves through millions of open-close cycles to simulate long term wear and reveal durability issues and wear much faster than real time.

Cytotoxicity[17, 18]: To test the cytotoxicity, or the capacity of a chemical agent to damage or destroy living cells, we will use a method called the Extract Test. This method is commonly split into 3 parts. First, the process, where the heart valve is placed into a liquid culture medium/saline solution to extract chemicals/residuals from the valve. Second, the testing, where the liquid solution is then placed on cultured fibroblast cells and incubated. In the analysis, we observe what happened to the fibroblast cells. If the cells were to stop proliferation or completely die out, it would indicate that toxic and harmful substances had leached into the solution, deeming the mechanical heart valve unsafe.

CONCLUSION:

An anticoagulant coating would possibly eliminate the need for blood thinning medications such as Warfain. As a result, patients would be less susceptible to bruising, bleeding, and additional complications. Possible anticoagulant and biocompatible coatings include ultrananocrystalline diamond (non-polymeric) and polyurethane (polymeric). These materials would undergo a series of experiments to test for function, efficacy, durability, and cytotoxicity. If successful, these improvements could revolutionize mechanical heart valves.

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