

Surgeon Q&A: Are Coumadin Requirements Being Lowered for On-X Mechanical Valve Replacements?

By [Adam Pick](#) on March 6, 2014

As we have learned together, there is no “perfect” valve replacement for patients who cannot have their own valves repaired. That said, as patients, we must weigh the pros and cons of each valve type – pig, cow, horse and mechanical – to determine which device is best for us given factors including age and lifestyle.

The mechanical valve replacement is an interesting choice for patients. It’s been around for over 40 years. It’s the most durable valve comprised primarily of a special form of carbon— pyrolytic carbon— that can last more than 100 years with the pressures inside the heart. And, there is some research, which suggests that patients who receive mechanical valves have lower complications over a 25-year period.



However, there are two disadvantages for mechanical valve recipients. First, some patients complain that mechanical valves “click” loudly inside the body – which can be annoying. Second, all patients who receive a mechanical valve must take anticoagulants (blood thinners) to prevent the risk of blood clots forming on the valve – for the rest of their lives.

For some patients, the thought of permanently being on blood thinners is just too much handle. As a result, some patients choose a tissue valve and risk the possibility of a future re-operation when their pig, cow or horse valve fails. But mechanical valves sometimes need to be removed from rare incidences of infection or clots.

New Study Lowers Blood Thinner Usage For On-X Mechanical Valve Patients

Interestingly... On January 14, 2014, we learned that a special type of mechanical valve, known as the On-X Plus 1.5™ Aortic Heart Valve, received an expanded CE mark in Europe which reduced the requirement of blood-thinners for patients. This important announcement was made after interim results from the PROACT trial were made public.

To better understand the implications of this study, I contacted [Dr. Marc Gerdisch](#). As many of you know, Dr. Gerdisch is a heart valve surgeon in Indianapolis, Indiana who has successfully treated many patients in our community — including Pamela Hudson, Angie Gregory and John Siamas – at Franciscan St. Francis Health Heart Valve Center.

Dr. Gerdisch Says...

Here are the highlights from my discussion with Dr. Gerdisch:

Adam: Dr. Gerdisch, thanks so much for taking the time to help educate our community about this exciting development regarding the On-X mechanical valve.



Dr. Marc Gerdisch – Heart Surgeon

Dr. Gerdisch: Adam, thank you for bringing this news to members of your community.

Adam: To start, can you tell us about your experience with the On-X mechanical valve in your practice? Which type of patients typically receive the valve? Why do those patients request the valve? How has the On-X valve performed in your patients?

Dr. Gerdisch: Whenever possible, if a heart valve can be spared or repaired, we do so, but if replacement is necessary, we offer patients the most advanced technology with decision making supported by the scientific literature. At Franciscan St. Francis Health Heart Valve Center in Indianapolis, we have been using the On-X mechanical valves since I came here in 2006 and have

implanted more than 225, which represents about 20% of our valve replacements. They are the only mechanical valves I have implanted for over a decade. The On-X valves are designed with breakthrough technology that causes less blood cell damage than traditional mechanical valves and are the only valves with a pure carbon coating. At the blood cell level, it is a smoother surface. In 2013, our team was first in the nation to implant the On-X Aortic Prosthetic Valve with Anatomic Sewing Ring, which is the first to address the important concern of distorting the adjacent structures within the heart, by matching its contour.

The average age for the patients receiving the On-X valve is 53 years. Any patient under 65 years old will typically consider the On-X valve, to avoid the potential for tissue valve deterioration. There is important evidence that younger patients requiring valve replacement benefit from receiving a mechanical valve. The decision of a tissue vs. On-X valve is based on the patient's likelihood of longevity, risks for anticoagulation (blood thinner) and personal preferences.

Patients have come to us seeking the On-X valve. We have been one of the leading enrollers in the PROACT Trial, the study that demonstrated lower complication rates for patients managed with lower dose anticoagulation when the On-X aortic valve was implanted. It led to European clearance for patients to be treated with the lower dose warfarin target range. Data for a similar evaluation for the mitral On-X valve is presently being accumulated. When patients research prosthetic valves, they will encounter information on the On-X valve and consequently ask for it by name.

Dr. Jack Bokros Ph.D. designed the On-X valve and is the originator of the modern bi-leaflet mechanical valve. He was involved in the development and design of all of the predecessor bi-leaflet mechanical valves, including St. Jude, Carbomedics and ATS. I have the privilege of knowing Dr. Bokros and being familiar with the progression of his scientific achievements. In addition to creating a pure carbon coating for the On-X valve, he also built it to mimic the dimensions of a native valve and to allow complete vertical displacement of the leaflets and therefore laminar (non-turbulent) blood flow. In addition, each leaflet has two points of contact at closure and the valve is typically quieter than others.

Adam: Can you expand on the PROACT study which led to CE labeling for the Aortic 1.5 Aortic Heart Valve to be managed with lower anticoagulation in Europe?

Dr. Gerdisch: The PROACT trial has three test groups and three corresponding control groups. A limb of the study designated as "high risk aortic" included patients with conditions putting them at risk for trouble with blood clots. These patients were randomized to being managed with either lower dose warfarin (INR 1.5-2) or standard anticoagulation (INR 2-3). The expanded labeling in Europe comes from this limb of the study. It found no difference in the stroke rate between lower and standard anticoagulation but showed a 60% reduction in the bleeding rate for patients on the lower anticoagulation regimen. This is a great finding for future aortic valve patients and all of those who currently have the On-X valve.

Adam: Why is this important for patients?

Dr. Gerdisch: Patients need to be fully informed of the scientific data available regarding prosthetic valve choice. There has been some progress in the performance of tissue valves, but nothing that

demonstrates significant improvement in longevity. The idea that young people can receive a tissue valve with the same long-term risk as a mechanical valve lacks foundation. We now perform [trans-catheter valves \(TAVR\)](#) for high-risk patients, and it is possible to implant a TAVR in a previously implanted tissue valve, but we have no evidence that it will provide a low risk, durable result. Clearance of the On-X valve for lower anticoagulation in Europe is based on a statistically significant data demonstrating better outcomes for patients with less aggressive anticoagulation. It brings us closer to providing patients with an even safer and more appealing option. Of course, I will implant whatever valve a patient might choose. I make a point of reviewing all of the current options with my patients and ensuring all of their questions are answered. We then proceed with a plan we have developed together.

Adam: Why is this important for surgeons, like yourself?

Dr. Gerdisch: The On-X valve has performed remarkably well in my practice. As part of our multidisciplinary heart valve center, a cardiologist specializing in valve disease and echocardiography performs a detailed study of the valve in the operating room at the conclusion of the operation and regularly in follow up. This group of specialists gives me continuous feedback on the superb hemodynamics and lack of complications achieved with the On-X valve. Their satisfaction reflects the superior outcomes experienced by our patients. Perhaps most important is the regular updates I receive from patients fully engaged in their active lives.

Adam: Is it likely that this reduced blood thinner requirement will take effect in the United States? If so, when?

Dr. Gerdisch: I know that the company has submitted the results to the US Food and Drug Administration for review. They are hoping for approval soon for this indication.

Adam: Is it possible that, in the future, patients may not need any blood thinners with mechanical valves?

Dr. Gerdisch: This is indeed a big question. When we talk about “blood thinners” are we including all agents used to prevent blood from clotting? There are many drugs referred to as “blood thinners”, that cause the clotting time to be increased by interrupting the clotting cycle at one point or another and therefore provide some protection for implanted devices, including coronary stents. Currently we are restricted to warfarin as the “blood thinner of choice” for implanted valves, but with improved technology, we may someday be able to use other drugs.

The majority of people taking blood thinners have arrhythmias or other conditions that require protection from clotting. In fact, about 30% of people with implanted tissue valves need warfarin on a long-term basis due to these other conditions. We have focused on moving as many of our patients as possible to self-testing for their warfarin. There is superb data revealing a dramatic reduction in complications related to warfarin for patients who self-test. In other words, they have a small machine at home that allows them to check their INR. As a result their levels are easier to manage and more tightly regulated.

I hope this helped you learn more about this exciting development specific the On-X mechanical valve replacement device. On behalf of our patient and caregiver community, I would like to extend a special thanks to Dr. Marc Gerdisch for sharing his clinic experience and research with all of us.

- [To learn more about Dr. Gerdisch, click here.](#)

Keep on tickin!

Adam