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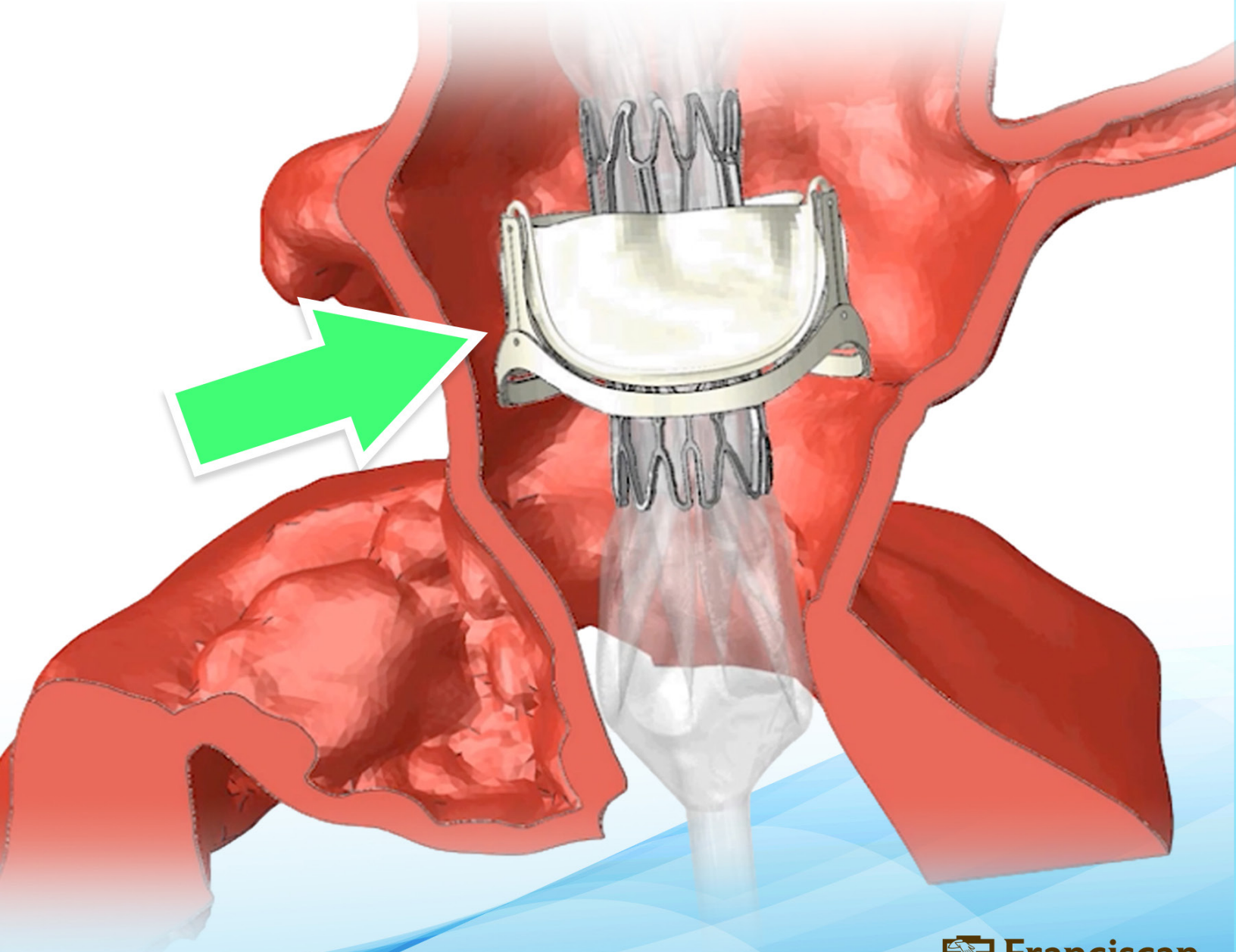
ADVANCING AORTIC VALVE SURGERY:

3D IMAGING AND ARTIFICIAL INTELLIGENCE



Franciscan HEALTH

Featured Speakers

Dr. Marc Gerdisch

Chief, Cardiac Surgery
Franciscan Health, Indianapolis, Indiana
(317) 682-0089
Learn More.

Adam Pick

Patient, Author & Website Founder
HeartValveSurgery.com
(888) 725-4311
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Please note: A complimentary video playback of this eBook is now available on YouTube at this link.

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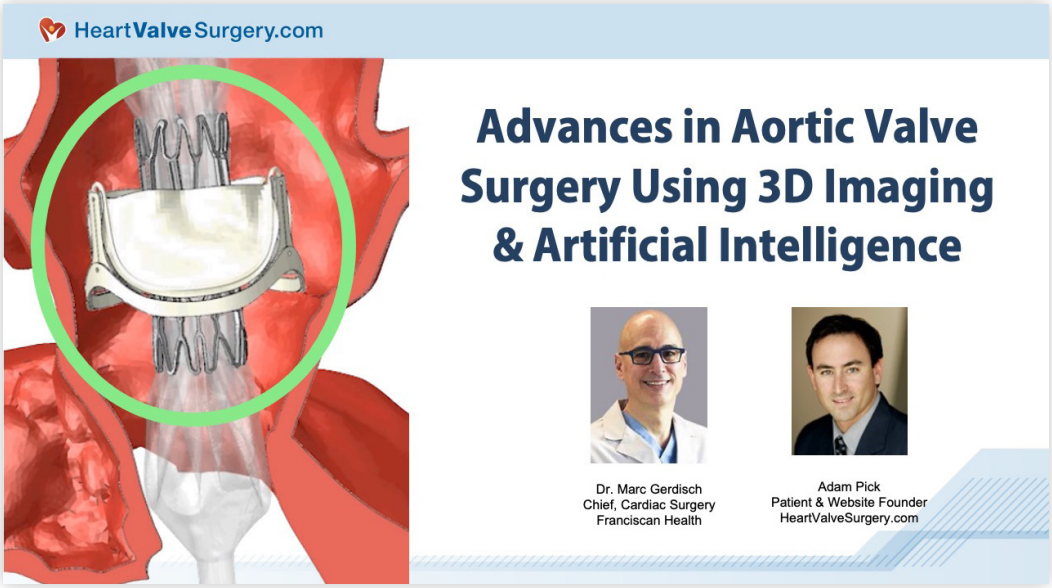
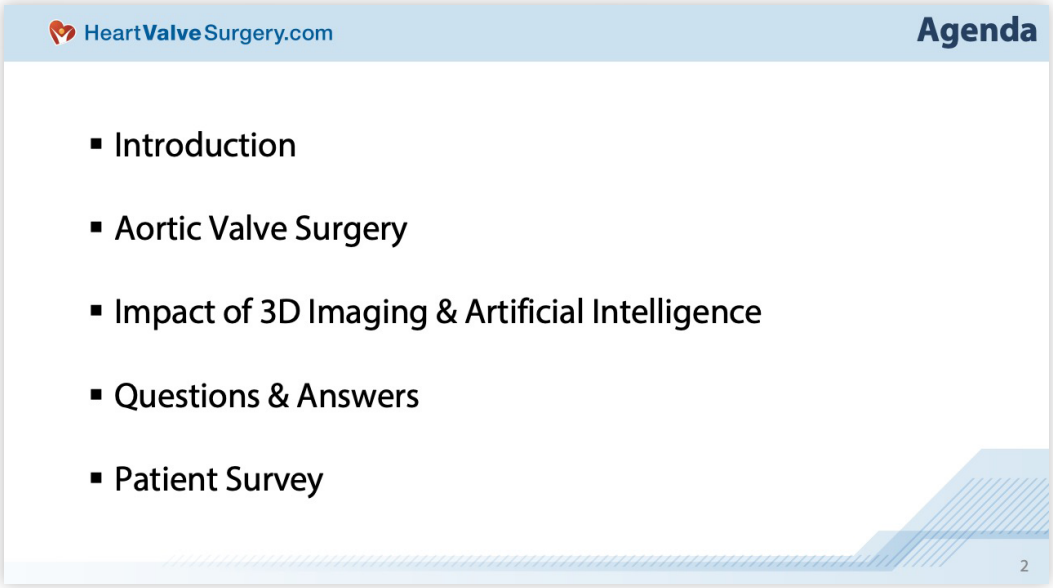
Introduction



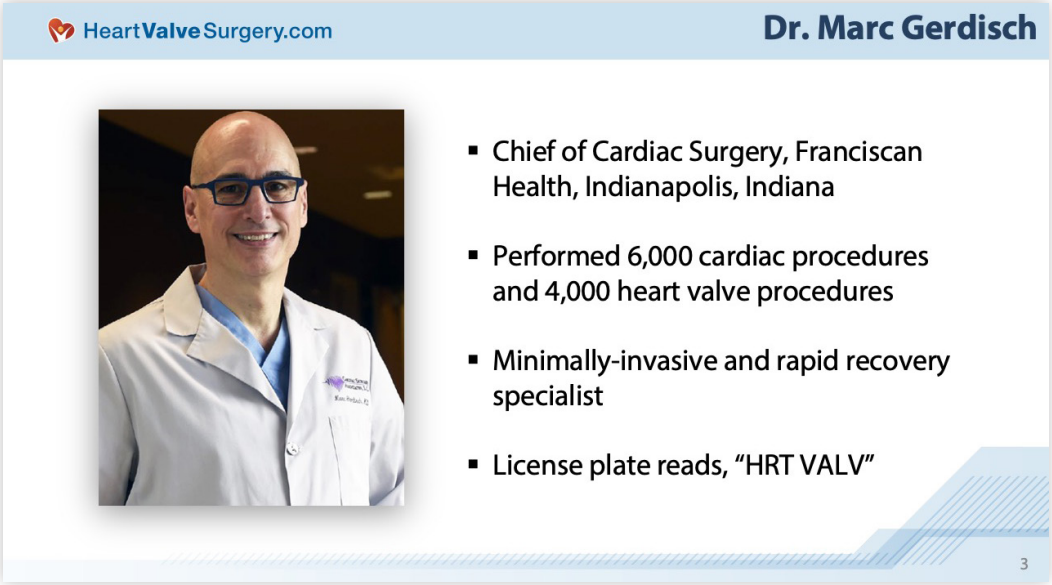
Adam Pick: Hi, everybody. My name is Adam Pick, and I'd like to welcome you to the webinar titled, *Advances in Aortic Valve Surgery Using 3D Imaging and Artificial Intelligence*. If I've yet to meet you, I'm the patient who started HeartValveSurgery.com all the way back in 2006, over 15 years ago. The mission of our website is really simple. We want to educate and empower patients and people just like you all about heart valve disease management and treatment. This webinar which has had registrations from over 480 people in countries all over the world was designed to support that mission.

During the webinar, you're going to be in what's called "listen only" mode, but I'd encourage you to go ahead and submit your questions that are in the control panel on your screen. I'll explain why as we move over to the agenda. Today, I'm going to go ahead and introduce our featured speaker.



Adam Pick: We're going to talk about aortic valve surgery. We're going to have an opportunity to see the impact of 3D imaging and artificial intelligence on the future. I would even say the current day of aortic valve surgery. I believe this is going to be a first-time showing of some new technology that patients haven't seen before. I believe many doctors haven't seen before either, so I'm really excited about this.

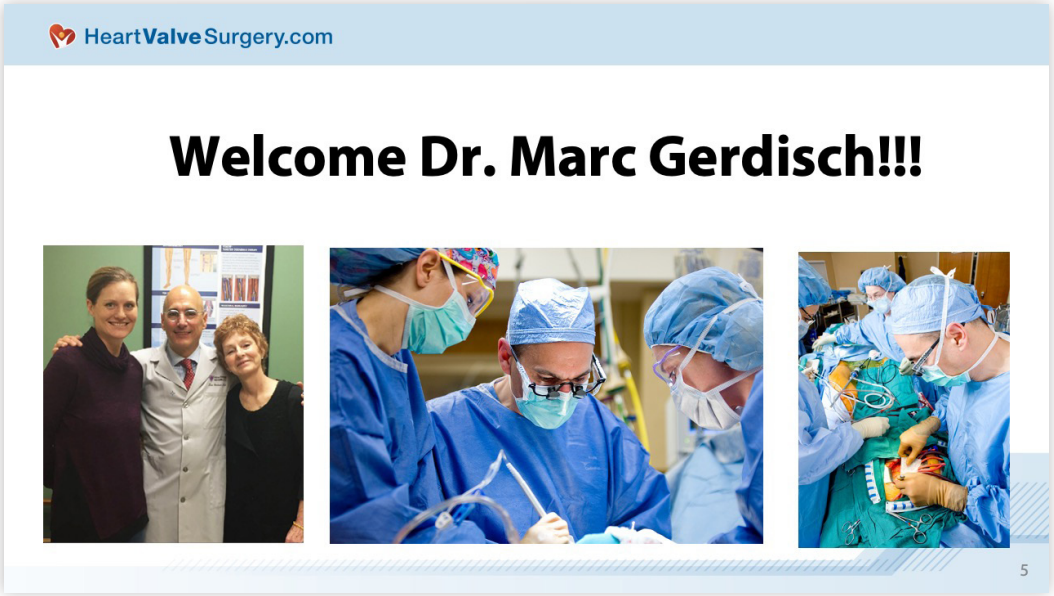
About Dr. Marc Gerdisch



Adam Pick: Now, when it comes to the featured speaker of today, I'm honored and I'm humbled to introduce Dr. Marc Gerdisch, who is the chief of cardiac surgery at Franciscan Health in Indianapolis, Indiana. During his extraordinary 25+-year career, Dr. Gerdisch has performed over 6,000 cardiac procedures and more than 4,000 – that's right, 4,000 have involved some form of heart valve repair or replacement. He is a researcher. He is an innovator. He is one of the leaders when it comes to the development of minimally invasive techniques for valve surgery, and he's designed a very special rapid recovery protocol. He's so committed to the treatment of heart valve disease – yes, his license plate reads HRT VALV, heart valve, and that's not a joke. I've seen it.

Dr. Gerdisch's Patient Success Stories

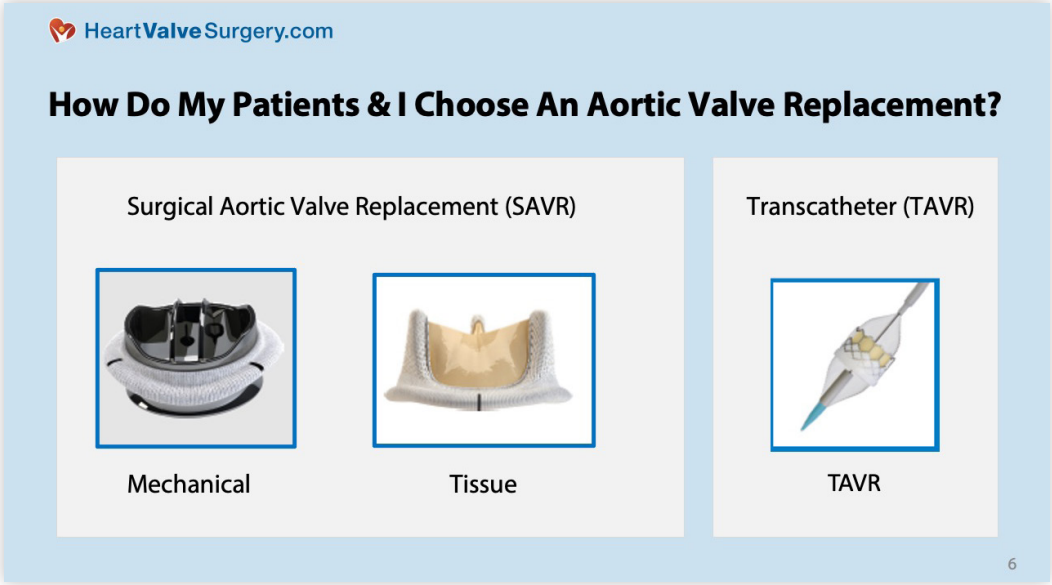
Adam Pick: This is the other thing I love. It's not just about what the patients say. It's how they appear, right, and the smiling faces of his patients, whether it's Todd Runnenbohm, Tom Derloshon, Matt Shutte, Timothy Kennedy, Linda Kincaid, Nina Bamford, John Pershinger, and in February, Janelle Hurst. She had a successful mitral valve repair with Dr. Gerdisch, and just two weeks ago Dan Rhoden, who's on the line today, had a successful aortic valve surgery with Dr. Gerdisch.



Adam Pick: With all of that being said, I'm sure he's maybe blushing a little bit because he's so humble, I'd like to introduce you all to Dr. Marc Gerdisch.

Aortic Valve Replacement Options

Dr. Marc Gerdisch: Hi. Good afternoon and evening, everyone. Thanks for getting on with us. This is actually going to be pretty fun. It's stuff that is really fun for me, and I think you'll enjoy it. I love all these pictures because I don't really ever get to see them, and actually on that left side there, that's a mother-daughter pair that had the same operation, and the gal – the mom, she came in with her best friend on the same day and had their surgery together, so it's really fun.

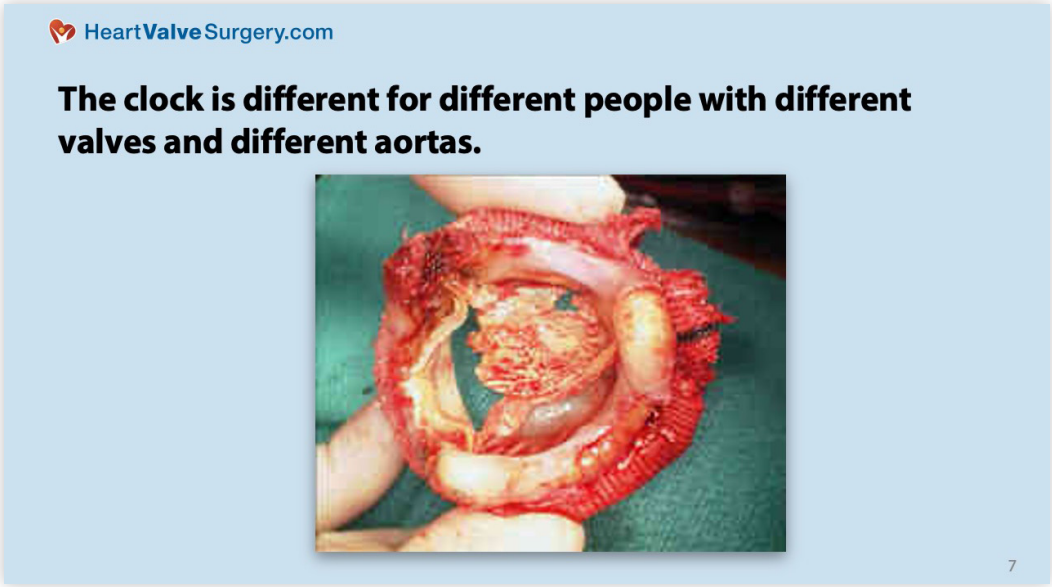


Dr. Marc Gerdisch: Let's see. Great. We're going to have – this will be an evolving conversation. I want to get to all the sexy and fun stuff pretty quickly, but I'm going to talk about a little bit of the landscape that goes into the human side of figuring out – when I say human, not on the psychosocial and emotional components but the physiologic aspects of putting a device in a human being in that environment, in that milieu. How do we figure it out? How do the patient and I make the call? How do we decide when and what are we doing?

You all know. You've all seen surgical valves, transcatheter valves. On the left there is an On-X valve. Some of you who know me know that we did some pretty spectacular studies with that device, and we have one ongoing now where we are instead of using Warfarin or Coumadin we're using Eliquis or Apixaban, and we're well into that study, which a randomized control study for the FDA, and that's exciting. The next valve is a standard tissue valve. It's probably the most implanted prosthetic valve on the planet, which is the Edwards Magna, and it has a kin, which is a newer version, which is designed to take the next one, the TAVR. We put a TAVR inside of a tissue valve.

You've all heard about that, which is pretty cool and a little bit glamorous, but we have to think about it in terms of – because sometimes people say can't I just have a TAVR later? You certainly can, but it's not like a haircut. You're coming in to have a major procedure again, so we want to forecast what that major procedure will be like. Can we make it seamless and not difficult experience for the patient?

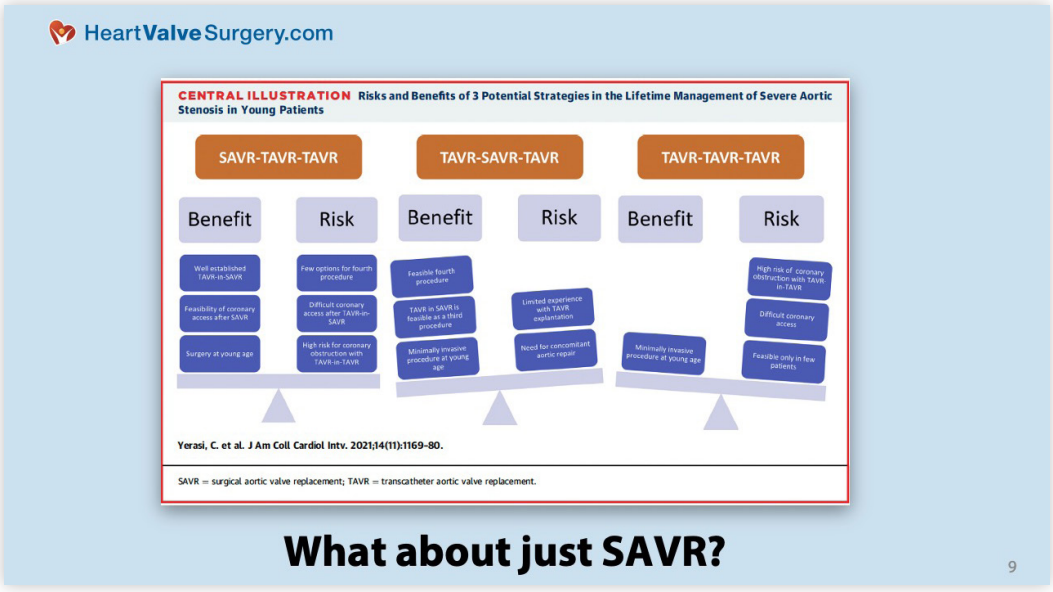
The "Ticking Clock" for Bioprosthetic Valves



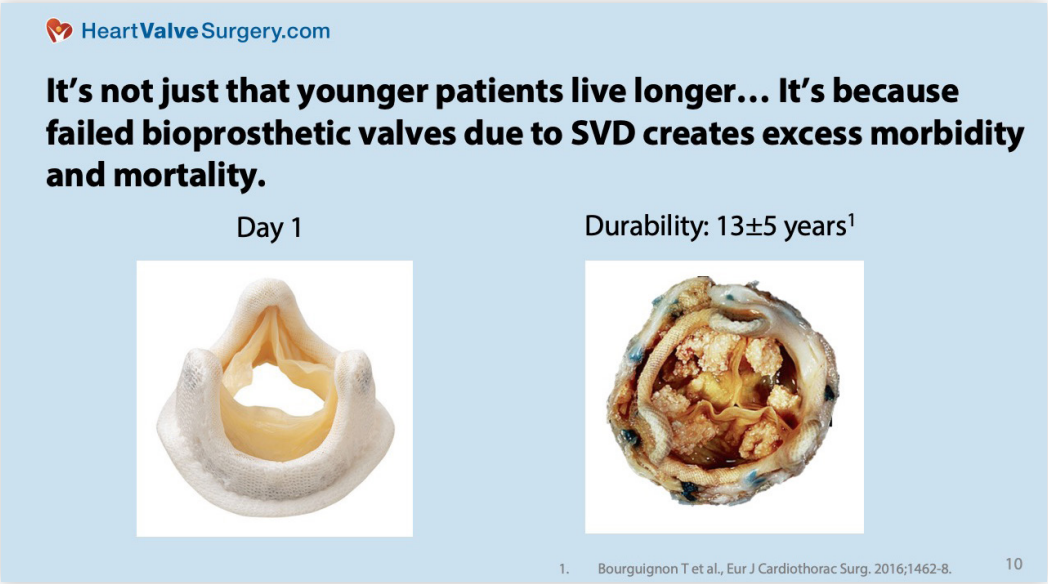
Dr. Marc Gerdisch: With that, people have heard you talk about this before. The clock's different in every human being. You cannot tell someone who long a tissue valve is going to last. The environment's are all different. Now we can make some predictions – and here are the things that we can predict. The bigger the valve we put in, the longer it lasts because as the valve stiffens and the hole gets smaller, it's a relative thing. So, it's the size of the valve versus the size of the patient, and there are some other things we can talk about with respect to that environment and physiology that I'm going to get to in a minute that help people put valves in the context of their body and think in terms of what their goals are.

SAVR Versus TAVR Considerations

Dr. Marc Gerdisch: This is a neat paper, although I do have a bone to pick with it. It's still fun to read because it talks about what we just talked about, so what do you do? Do you do SAVR-TAVR-TAVR, TAVR-SAVR-TAVR, TAVR-TAVR-TAVR? How do you figure that out, the risk benefit relationship, the seesaw? I think this is the perfect diagram for it because it's a seesaw where you're balancing things.



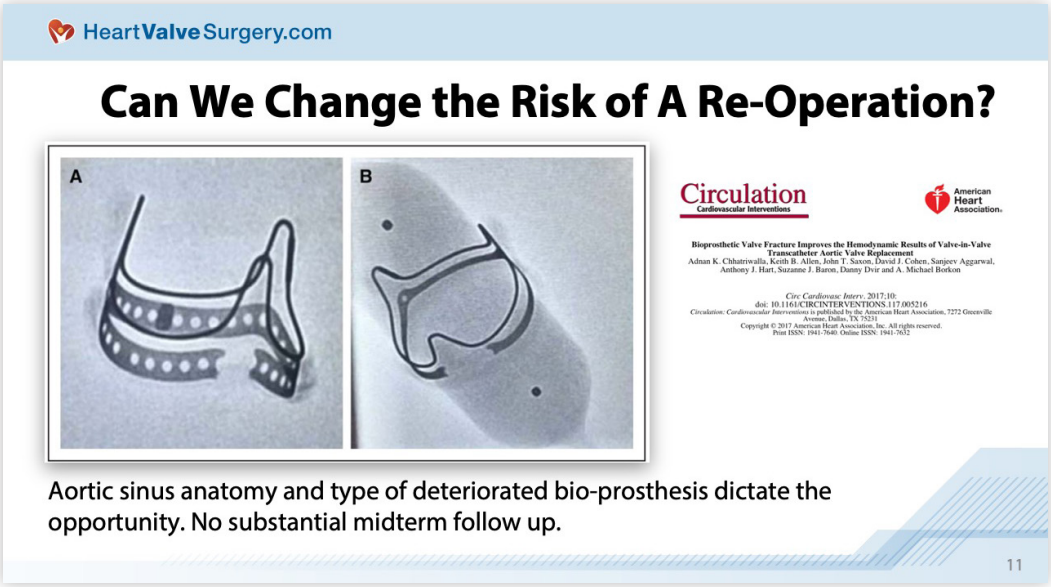
Those elements weigh differently for different human beings, and it's not – there's nothing robotic about it because you'll see that in the context of a person's physiology and their specific anatomy, which we're really going to get into, the behavior of the valve, the performance of the valve, the hemodynamics, everything is different. Then, I put down at the bottom what about just SAVR because mechanical valves can't be left out of conversations, especially the On-X valve where we're switching to a non-Warfarin therapy. There are people who are going to have one procedure for their whole life. It's worth thinking about.



It's not just that younger patients live longer, right?

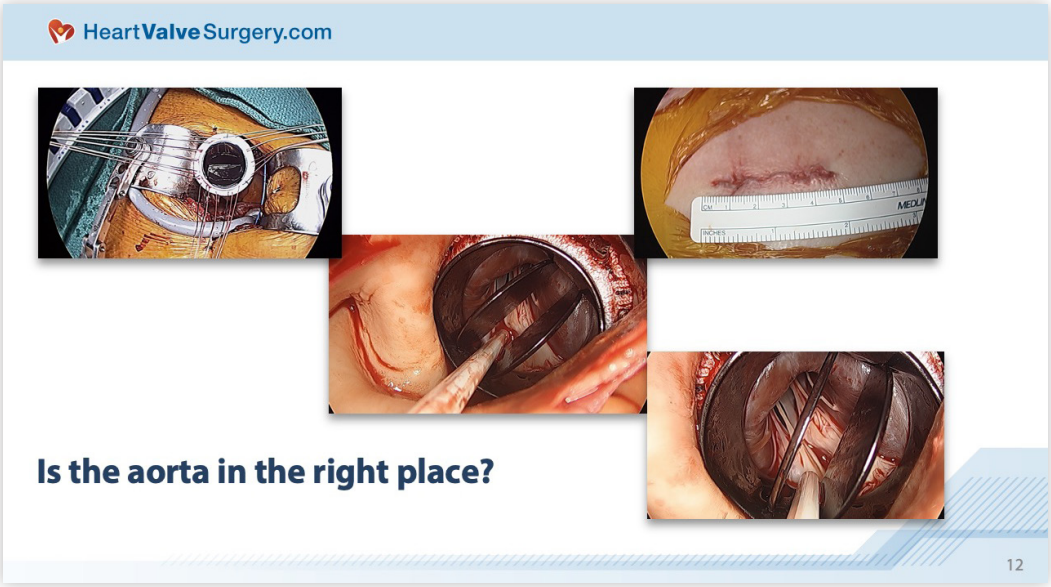
You get this long time. The clock is ticking. Their valves are going to wear out. It's also true that those bioprosthetic valves, if we don't reconvene at the right time, if we haven't made the right predictions, and if we don't have the right options that that's going to create some morbidity and issues for patients over the years.

Valve-in-Valve Re-Operations



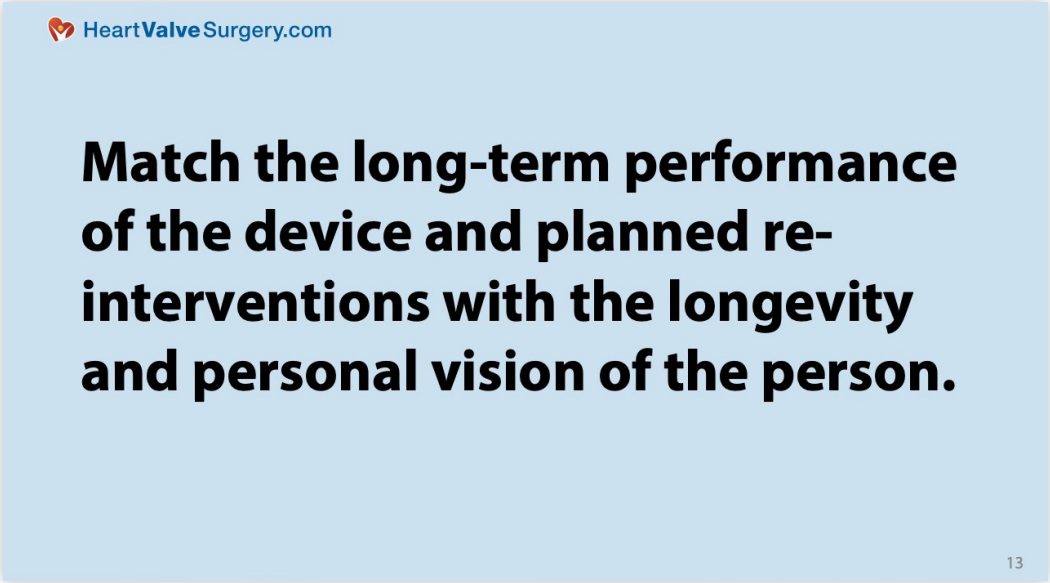
Dr. Marc Gerdisch: Now, this is a procedure that I love to do. I think it's probably – of all the things we had with valve-in-valve, this changed, I felt, the trajectory of it. We can only – we're only supposed to do it for high-risk patients, but we can take a transcatheter valve, put it inside the old valve, and then crack the old valve. But. if we're going to do that, we better know the anatomy. We have to have room for it. It's not in an empty space like this is. It's inside your aorta, inside your heart, so we have to be able to make predictions.

Aorta Anatomy



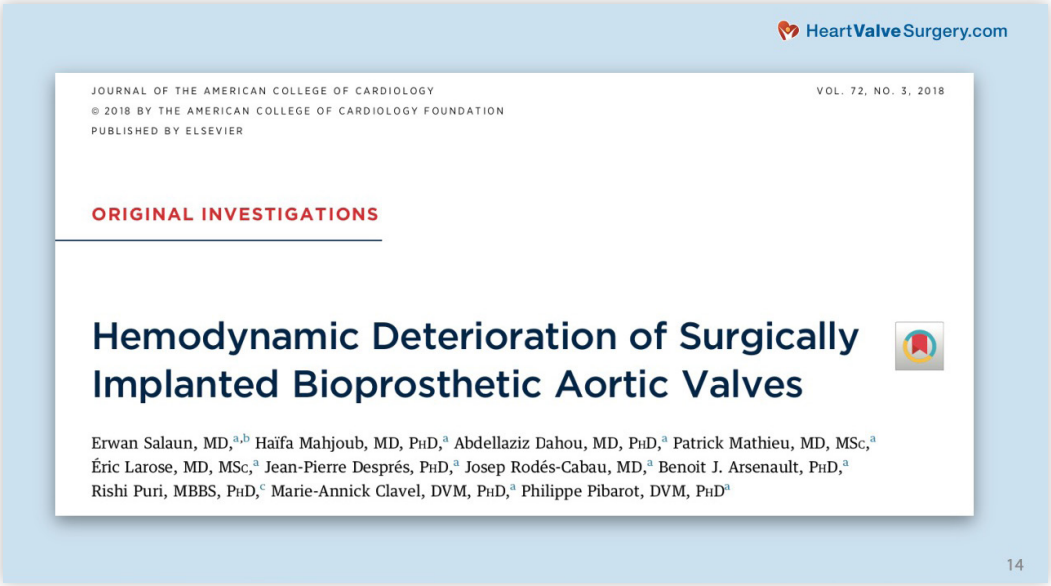
Dr. Marc Gerdisch: The other thing is we have to know where the aorta is. This is a minimally invasive aortic valve replacement through an incision that's four or five centimeters long, which is great. But, we've got to know that when we go in through that spot that that's exactly where the aorta is, and we have to know the dimensions of the aorta, and we have to know where the coronary arteries are. We have to be certain about what we're doing.

Understanding the Patient's Goals



Dr. Marc Gerdisch: We want to match the long-term performance of the device and planned re-interventions with longevity and personal vision of the patient. What does the patient want? What do they see in their future and what they want to deal with?

Durability of Bioprosthetic Valves



Dr. Marc Gerdisch: As I mentioned before, the milieu, the physiology of the human being affects the durability of the valve, and these two slides are really almost placeholders to remind me to talk about it because

I don't expect you to understand the drawings, the graphs, but what this delivers is information that tells us that folks that have an increased level of inflammation in their body, if they have what we call cardiometabolic syndrome, which is extremely common now in our current society – the hallmarks are central adiposity, diabetes, hypertension. Those things will diminish the durability of a valve. They'll change how long it lasts, so we have to have an honest view of it.

CENTRAL ILLUSTRATION **Predictors and Impact on Outcomes of Valve Hemodynamic Deterioration and Leaflet Calcification in Patients With an Aortic Bioprosthesis**

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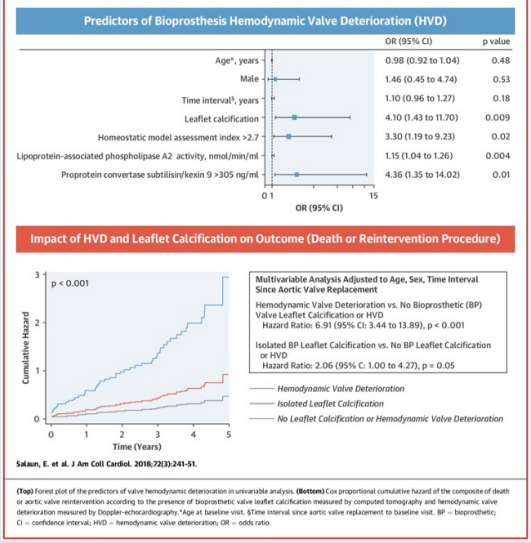

SaLaun, E. et al. J Am Coll Cardiol. 2018;72(3):241-51.

(Top) Forest plot of the predictors of valve hemodynamic deterioration in univariable analysis. **(Bottom)** Cox proportional cumulative hazard of the composite of death or aortic valve reintervention according to the presence of bioprosthetic valve leaflet calcification measured by computed tomography and hemodynamic valve deterioration measured by Doppler-echocardiography.*Age at baseline visit. †Time interval since aortic valve replacement to baseline visit. BP = bioprosthetic; CI = confidence interval; HVD = hemodynamic valve deterioration; OR = odds ratio.

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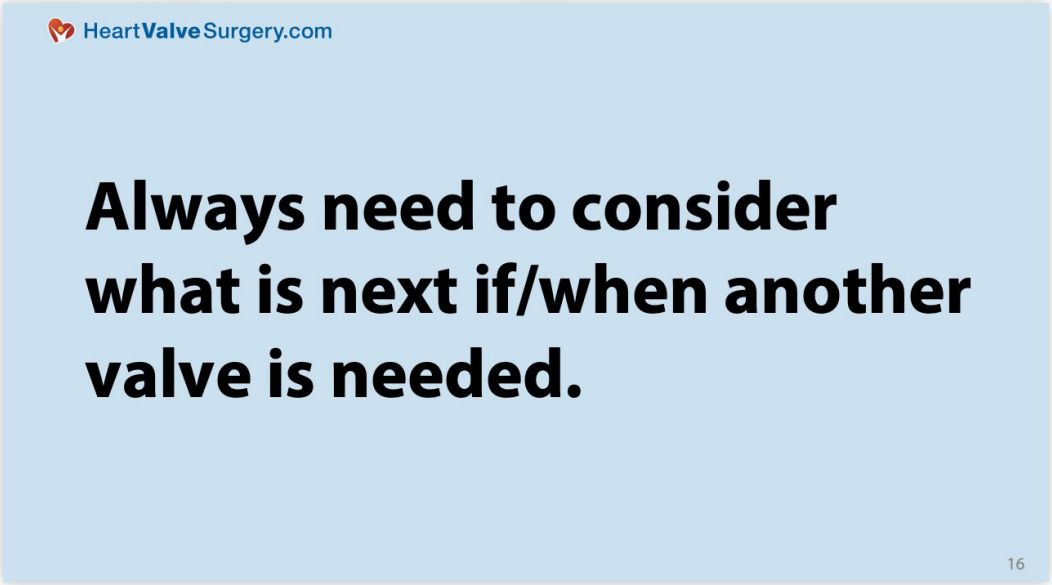
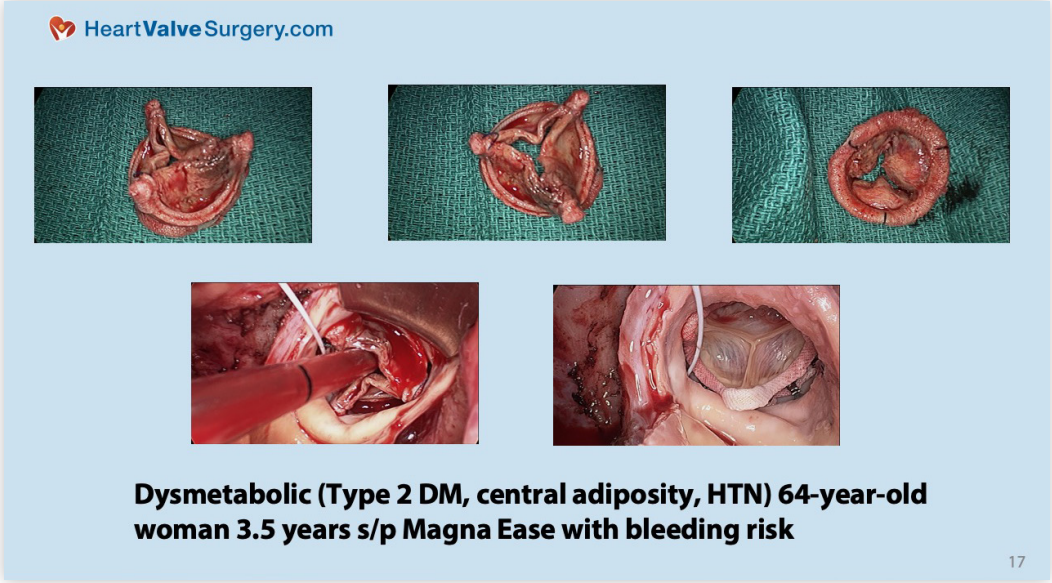
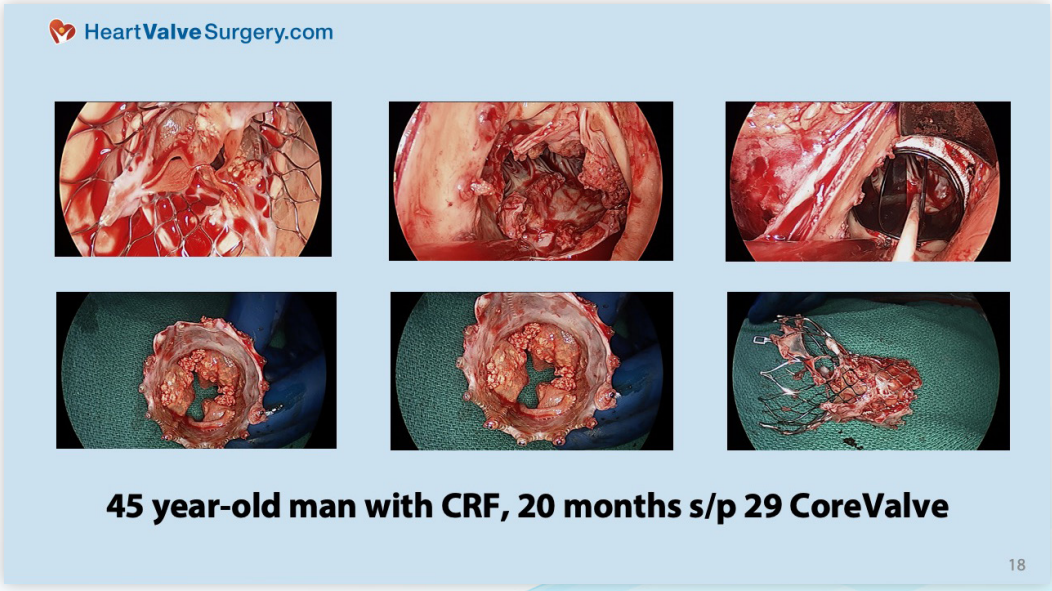


We have to have perspective with respect to that and then offer the patients that will impact them in the most positive way, so we always need to consider what is next if and when another valve is needed, right?

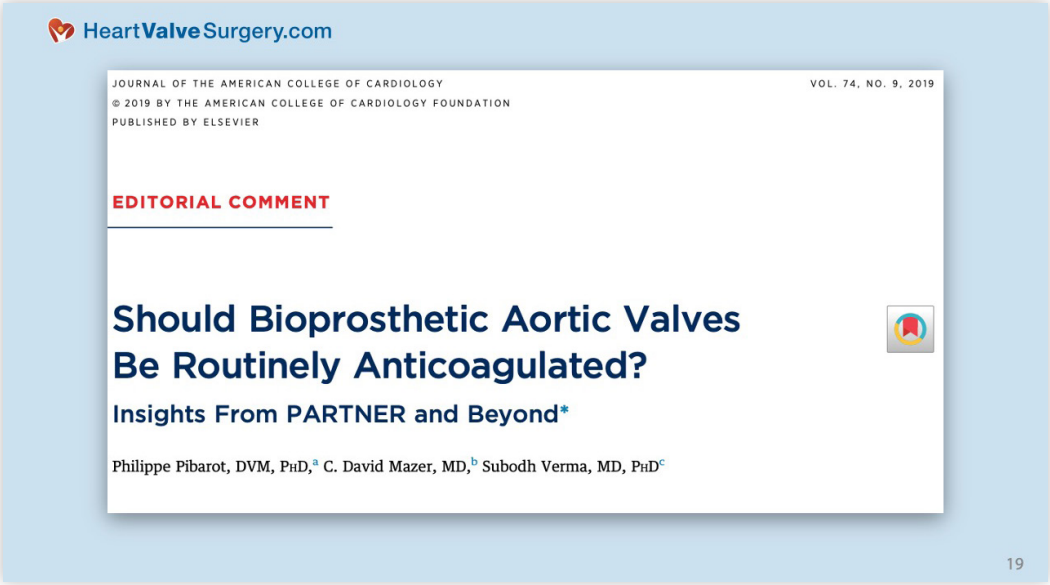
Examples: I just talked about dysmetabolic syndrome, 64-year-old gentleman, diabetes, hypertension. He's 64 years old. This was a woman, actually. Only 3.5 years into the valve, so this is early, right, but the patient also had a high bleeding risk, so I had to use another tissue valve. This time I switched to a



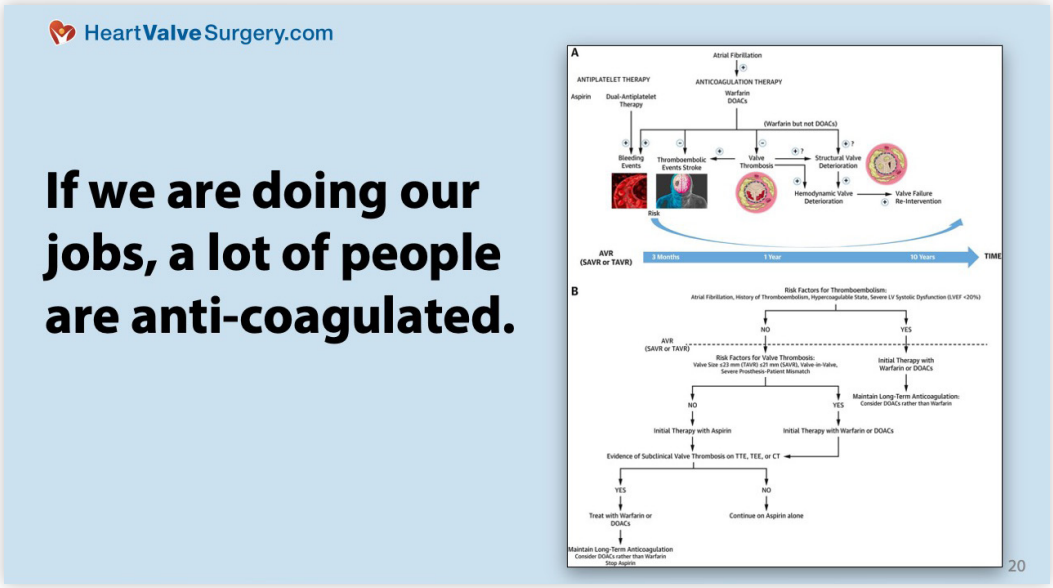
different type of tissue in hopes that we might get a little more mileage out of it, and I made sure I put a big valve in. The point being that the clock is different for every human being.



Blood Thinner Use for Bioprosthetic Valves



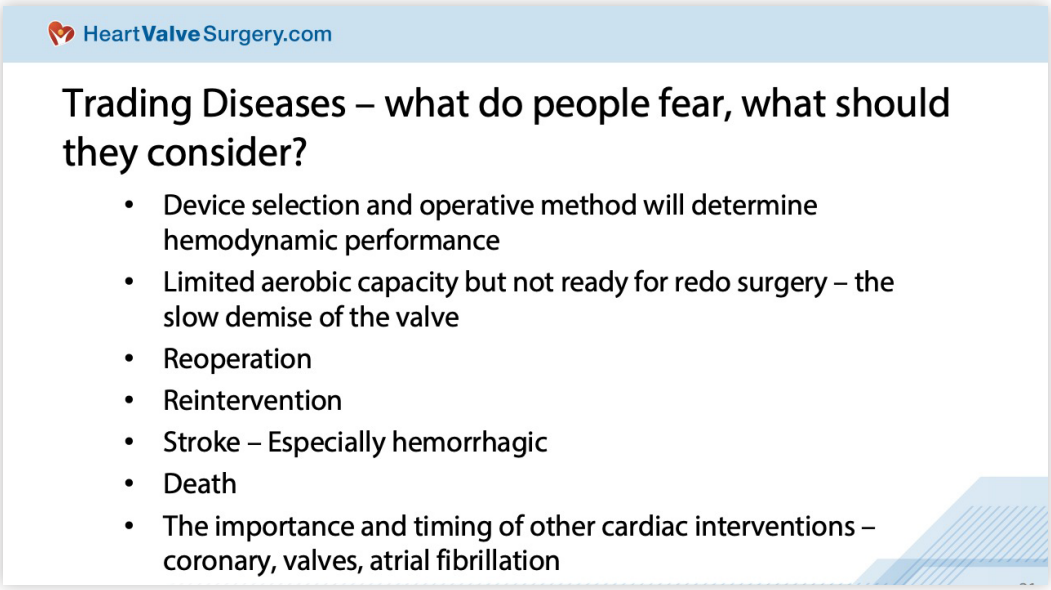
Dr. Marc Gerdisch: Here's a really tough question, right? This is not something people want to see. Patients don't want to talk about being on blood thinners or getting a tissue valve, but the reality of it is – this is Dr. Pibarot, who is just brilliant. His whole lab is fabulous in telling us the truth about things. If we're doing our jobs – we just had a patient we were talking to earlier who's on blood thinners.



If we're doing our jobs, we offer and treat people with blood thinner in the appropriate scenarios, so if a patient has a thromboembolic event, stroke, a thromboembolism, if their valve is deteriorating, if it's severely deteriorated, it's become stenotic, we should probably have them on anticoagulation. If we do a valve in valve – we haven't figured this out yet. Is everybody supposed to be anticoagulated, or some supposed to be anticoagulated? We're going to talk about that a little bit later, and you'll see why.

It's not a free pass. Tissue valve isn't a free pass. **If we look at nationally, one third of people who have tissue valves are on blood thinners, real anticoagulation like Eliquis or Warfarin.** Remember, you've got a disease. We're trading it for a different one. What are people afraid of, and what do they need to think about? Device selection. We talked about that. Operative method, also, right? We need to think about is it minimally invasive. Do we need to do a root enlargement? Do we have to replace the whole root? We have to treat the aorta?

Trading Diseases



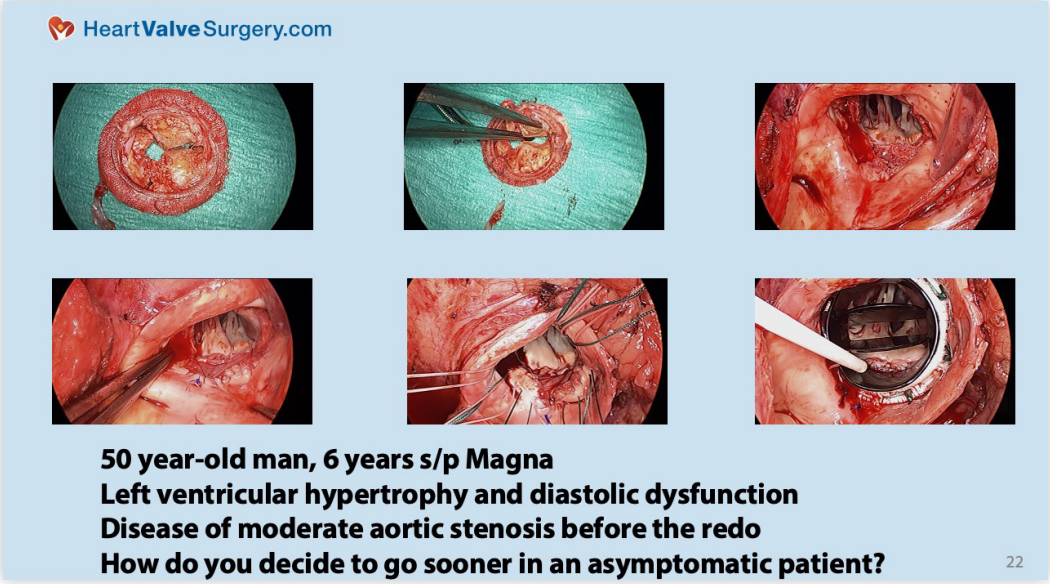
Dr. Marc Gerdisch: What are we doing at that moment in time to ensure the best long-term trajectory, and we have to think a little bit about the fact that some of those valves when they're starting to get diseased but they're not ready to be replaced or redone yet, they're still not performing fully, so you're going to have a valve that doesn't work perfectly. Reoperation, reintervention, stroke, death, the importance of timing of other issues, right, coronary bypass, coronary interventions might be stents or treatment of atrial fibrillation, managing those disorders that come with – come commonly with valve disease.

Adam Pick: I've got one question because I think this is a point that a lot of patients, including me, don't always understand, this idea of trading diseases. I've got aortic stenosis. I've got symptoms. I need a valve to help out, but what you're alluding to here – and correct me obviously if I'm wrong. What you're saying here is by getting that bioprosthetic valve, now you have a different type of disease. Is that what you're suggesting?

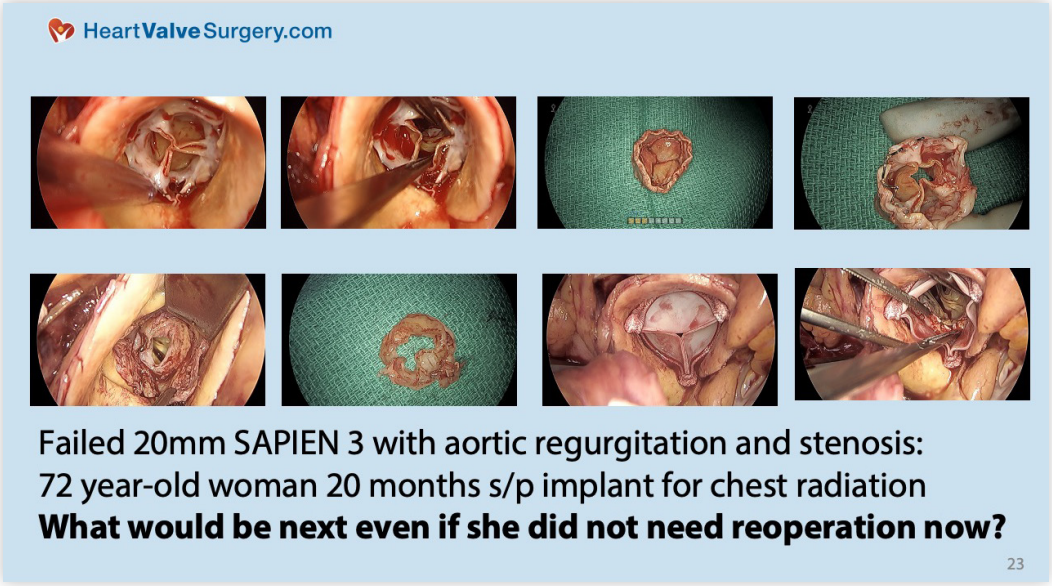
Dr. Marc Gerdisch: Yeah, we all have our physiologic burdens, right? We all have things about us that are changing, that pose some kind of threat. It's the nature of being a human being. People with valve disease, it's the valve, so the valve gets – the native valve gets to a point that we know that if we don't do something, the patient's going to live shorter, and we know from the data that replacing the valve makes them live longer, so we try to time it right, but that's their new disease. They had a bad disease. Now they have a less bad disease. Now the tissue valve is going to run its course, right?

It's going to change over time, so that's the progression of that disease to the next level. If you're 80 when you get the valve, it's probably going to last you the rest of your life. If you're 65 and you've got 20, 30 years in you, guess what, the valve's not going to last forever, so that valve is going to get to the point where it's not working great. You've got to decide if it's time to go, do you just deal with it for a while, but mechanical valve's not perfect either, right? Mechanical valves you've got blood thinner. There's risk related to that. There's maintenance of the blood thinner. The nice thing about a mechanical valve is that once they're working, they work the same forever, but they still – there's still the hassle. That's your other disease, right? Your new disease, I've got a mechanical valve, and I have to be on blood thinners for it.

Heart Valve Replacement Reoperations



Dr. Marc Gerdisch: So, here's a 50-year-old guy. This is just what we were talking about. He got his valve six years before, so he was 44, and sometimes a tissue valve in a 44-year-old will go a decade, sometimes they'll go 12 years, and sometimes it doesn't. When his valve started to deteriorate, his heart started to pay the price. It started to get thick and wasn't working as well. We call that the disease moderate or moderate to severe aortic stenosis before the redo, so how do you decide to go sooner in an asymptomatic patient. Fit person, they're doing okay. We don't have the answer to that, by the way, so I'm not saying I have an answer. I'm just saying it exists, so it's important that people are – as the valve starts to show changes, that's when surveillance has to become tightened up a little bit and look for more subtle changes so that you can have an ongoing conversation with the patient. He was still young, so we gave him a mechanical valve.

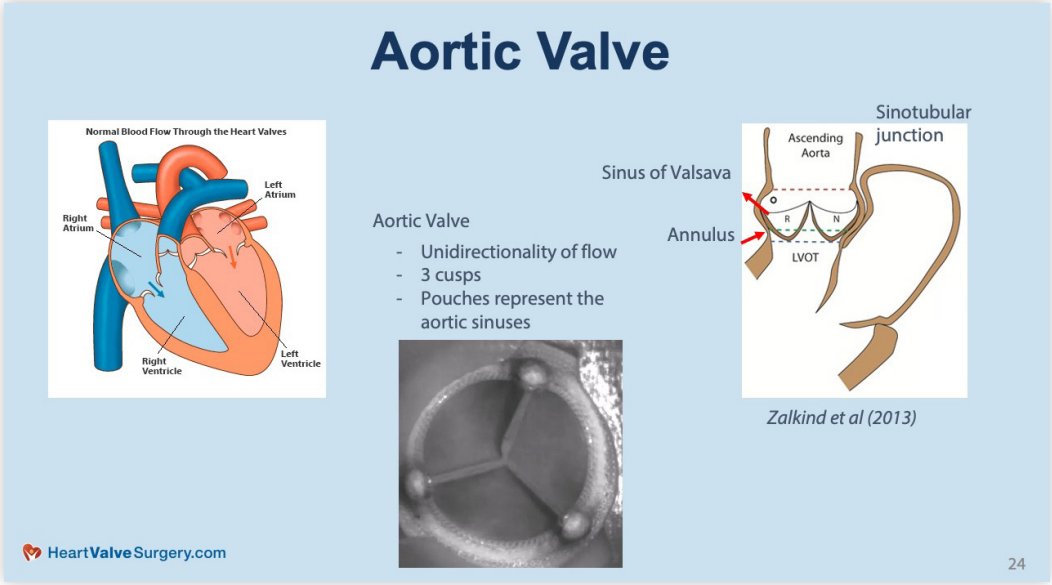


There we go. This is a really interesting story. 72-year-old woman, 20 months out from a SAPIEN transcatheter valve. They had done it because she had chest radiation, and they were worried about going in after her chest radiation, but it didn't last very long, and there's two reasons for that. If you look at the picture up on the left, the first thing you see is that small valve – that's the smallest version of the valve that they make, so it's already a little bit of an eight ball, but it's pinwheeled. See those leaflets aren't fully expanded. When it went up, it didn't expand all the way. I'm going to show you some technology toward the end of this that would've predicted that.

The other thing is you'll see when we look through the valve, the leaflets don't open super well and once you have it out – right here, if you can see my pointer, that's a ring of what we call pannus or tissue ingrowth that was underneath the valve, so this was the little hole that she was pumping her blood through. We cut it all out and put a big old bioprosthetic valve in there for her. This is an interesting story because more than the fact that it failed – okay, it failed. More than the fact that it failed, she was 72 when she got a 20mm SAPIEN 3.

What was the next valve going to be? Even if she'd gotten eight years out of that valve, now she's 80 and then she has to have surgery. So, what's the next move for the patient?

Aortic Valve Anatomy Review



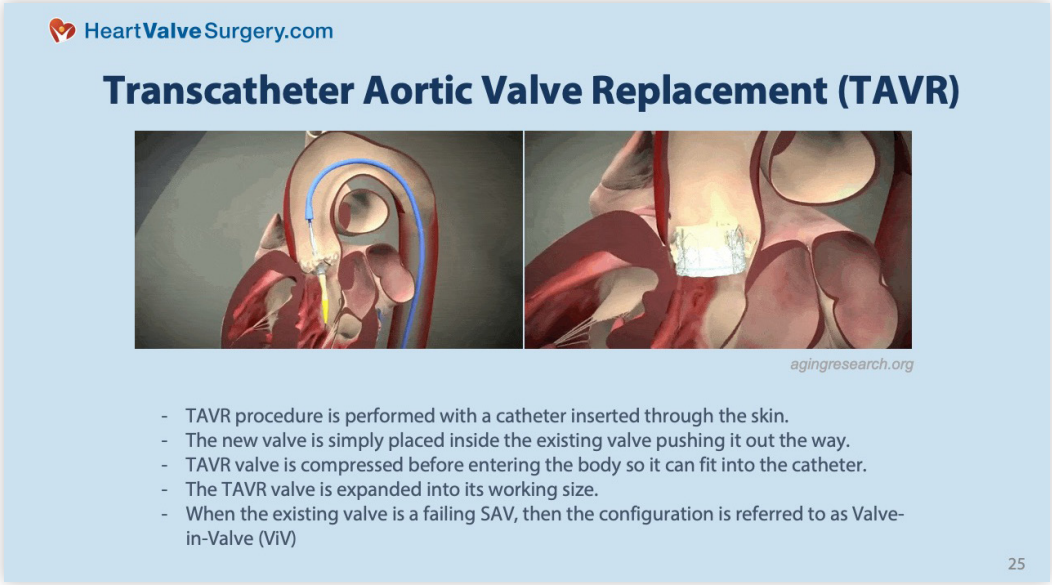
Dr. Marc Gerdisch: This is a little diagram just to remind people what we're talking about. You can see over here on the left the left ventricle pumping, pushing the blood through the aortic valve. Blood comes through – comes through the lungs. I have a little model, a little classic model, that my patients will tell you I show everybody, and I actually show where the blood goes because people sometimes they don't – they can't put it all together, right? Blood coming back from the lungs, oxygenated blood goes through the mitral valve, left ventricle pumps, pushes it through the aortic valve into the aorta out to the body, and we see it over here diagrammatically.

These are some of the components that I was talking about with respect to nuance.

It's not a pipe with a valve in it. It is an organ almost. The aortic root is its own organ. It has its own behavior. It is responsible for making sure that the blood flow in this aortic root is of a nature that keeps the leaflets clean, lets them close properly, and the blood has to go into the coronary arteries to feed the heart.

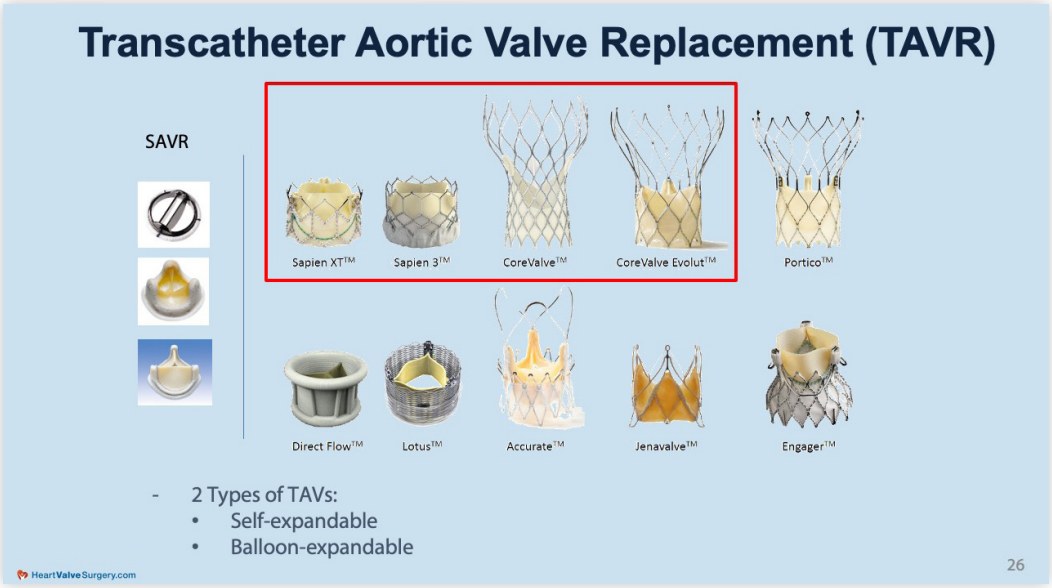
As soon as we disrupt that root, as soon as we do something to it, we change the characteristics of that flow, and so we have to be – we have to be aware of it, and we have to pay attention to all of that. I'm going to show you that.

The TAVR Revolution



Dr. Marc Gerdisch: Transcatheter valves, let's face it, an unbelievable asset. It's the greatest thing that's happened to aortic stenosis in 20 years, certainly has allowed us to treat people that were challenging to treat in the past, so that's wonderful.

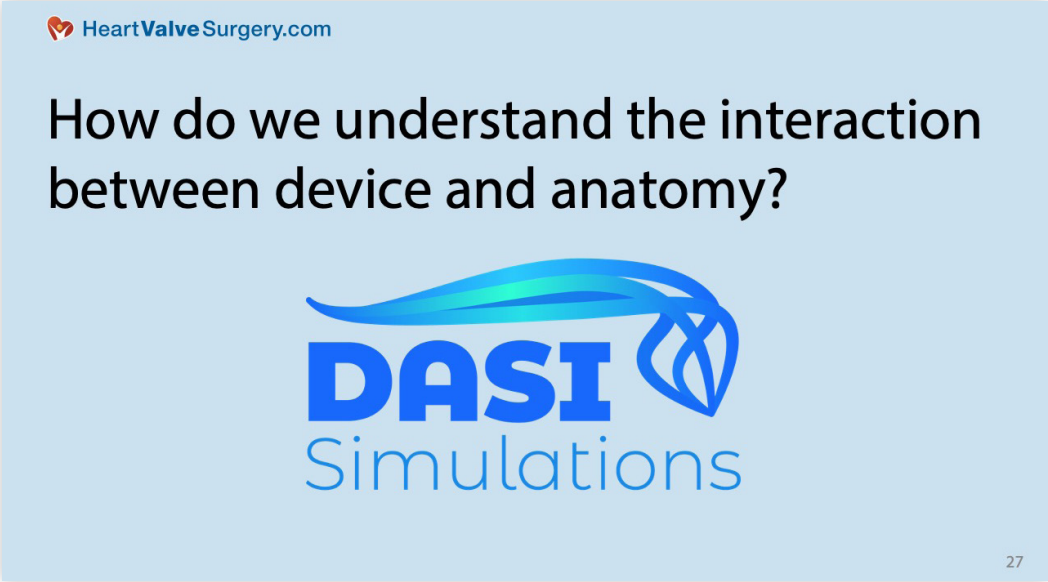
So now we see also we can use it in folks who are lower risk. We have the opportunity to do valve-in-valve when bioprosthetic valve is failing. We're going to talk a lot about that.



A lot of different transcatheter valve out there. The ones that folks will see the most of are the CoreValve and SAPIEN. These are clearly the front-runners, and SAPIEN's the most implanted transcatheter valve in the country.

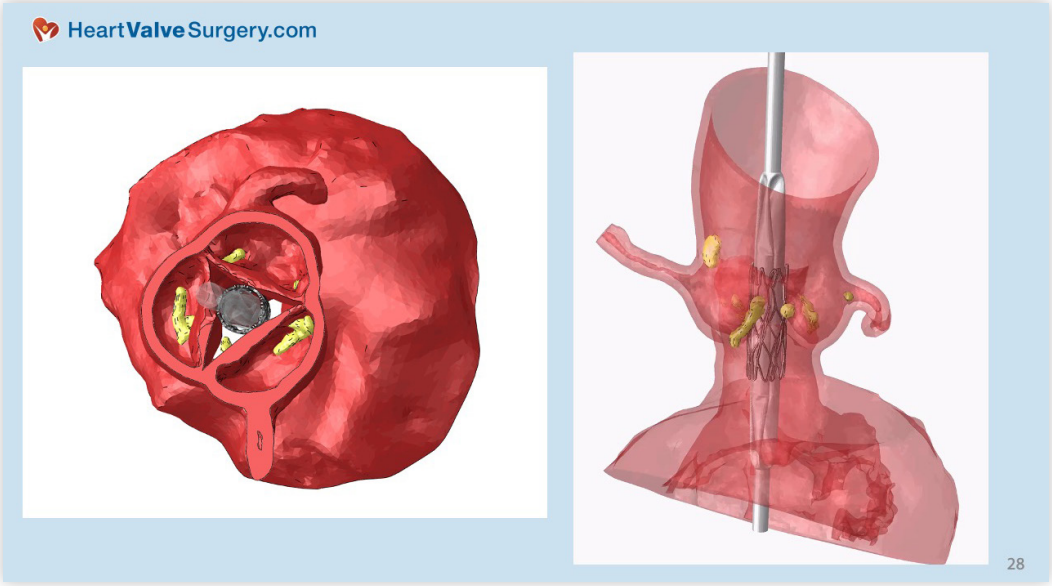
We also have some valves like the Jenavalve, and there's another one called the J-Valve that we can use for air-to-valvular insufficiencies, so leaking aortic valves. The two basic types, though, transcatheter valves are self-expanding, so that's the CoreValve. It opens up on its own once we release it; or the balloon expandable which is the SAPIEN. We're going to look at how those look in the aorta.

Technology Update: Dasi Simulations



Dr. Marc Gerdisch: How do we understand the interaction between the device and the anatomy? How do we figure that out? This is DASI. DASI is a company. It's also a man. We talk – you mentioned artificial intelligence. We're not actually using artificial intelligence; we're using human intelligence, and it's Dr. Dasi's. Dr. Dasi could probably do a much better job than I'm going to do talking about this, but he knows that my enthusiasm is unfettered. Hopefully I'll get the messages across.

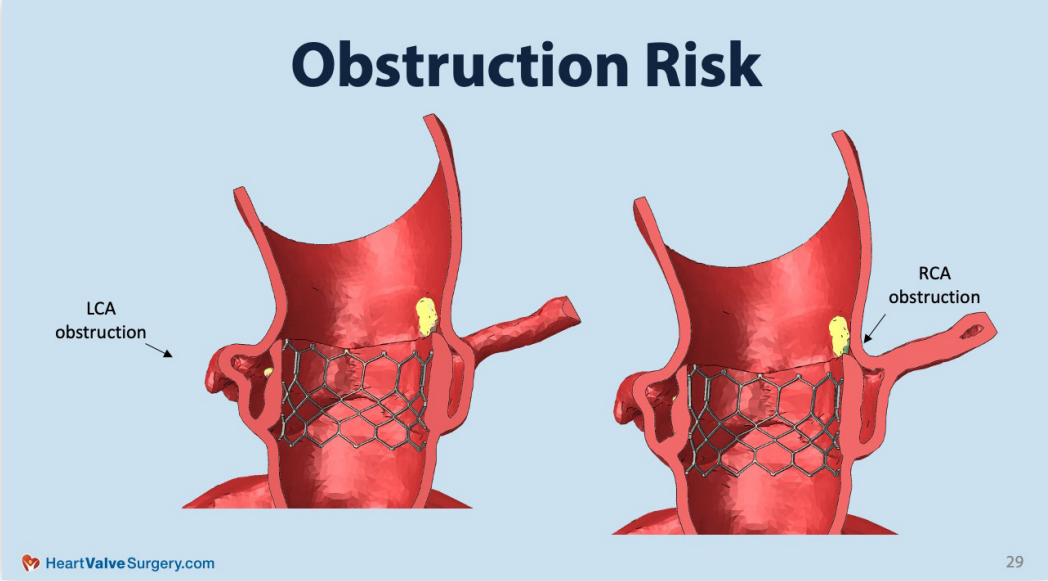
This has taken us to a different level of prediction, our ability to model the aortic root to make predictions about what the future will be for this. I'll say before I get into this, this is the tip of the iceberg. You are seeing the beginning. We will make our way down into the ventricle. We will be able to model aortic valve repair. We will figure everything out eventually with respect to flow. As a matter of fact, I'm going to hearken back to Da Vinci in a few minutes, and you're going to think wow, Dasi, Da Vinci; that's how it works.



Dr. Marc Gerdisch: We've got examples of the interaction, the interplay. This is the right time we've been able to really characterize – this is an actual aorta of somebody. We've been able to characterize what will be the behavior of the aorta, the leaflets, the sinuses.

Look at on the right side. Look at the annulus expanding, the sinus geometry changing, the calcium in the leaflets moving, the leaflets moving toward then eventually the coronary arteries and taking up space in the sinuses. It's cool that we can just push – like you see on the left side, we can push the leaflets out of the way, but now what have we done? We've pushed the leaflets out of the way. Now they're in that space where they're not usually stuck, so we're going to look at the impact of that.

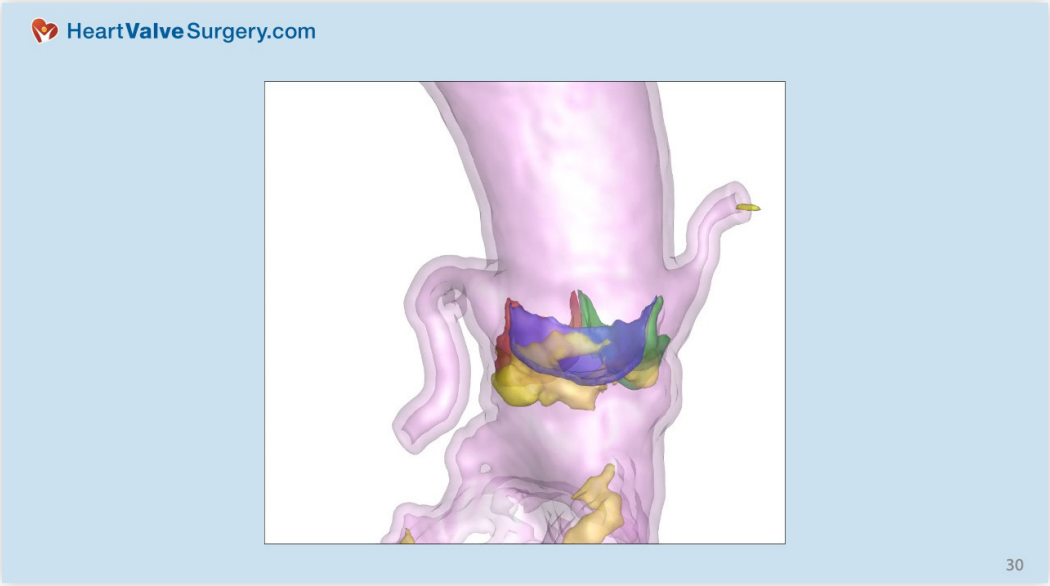
Key Patient Risk: Coronary Obstruction



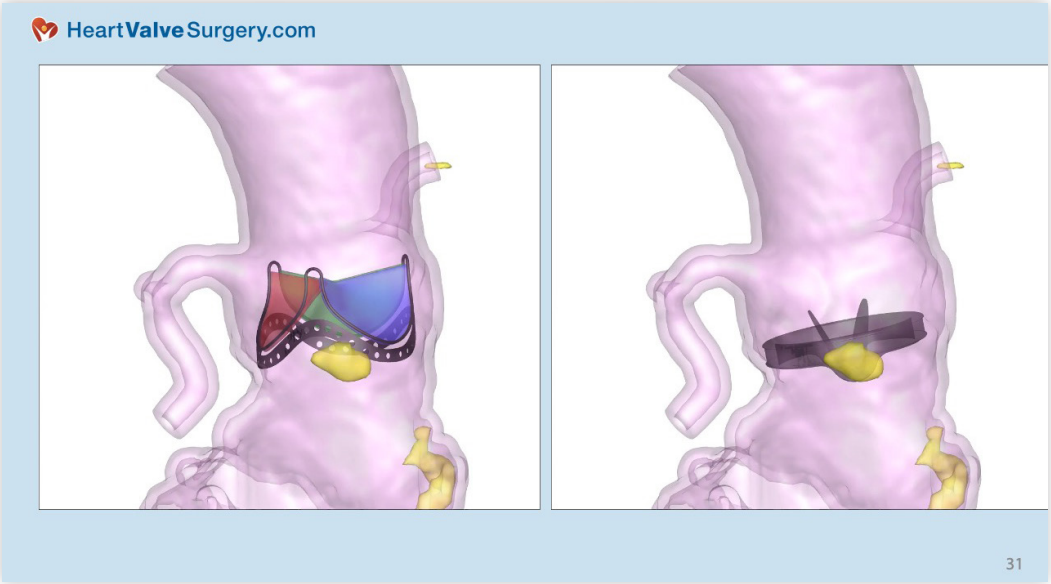
Dr. Marc Gerdisch: Here's one of those impacts. This is the most – this is probably the most important element of this with respect to saving lives. We're going to get into more esoteric, sophisticated, physiologic things, but when you think about putting this cylinder up inside of a person's aortic valve, now the aortic valve leaflets are standing up straight because the cylinder is pushing up straight. If it just so happens that the leaflets are long, or the sinuses are short, or the sinuses are small, those leaflets can get pushed back until they cover the coronaries. This is an example of that. This left coronary artery's obstructed; this right coronary artery's obstructed. The blood can't get to the coronary artery. The patient will die.

This is extremely rare. We are incredibly compulsive about ensuring that we've done every measurement possible, but there are some very close calls. This technology which I'm showing you can ameliorate it, can eliminate it.

Modeling Heart Valve Replacements Inside the Aorta

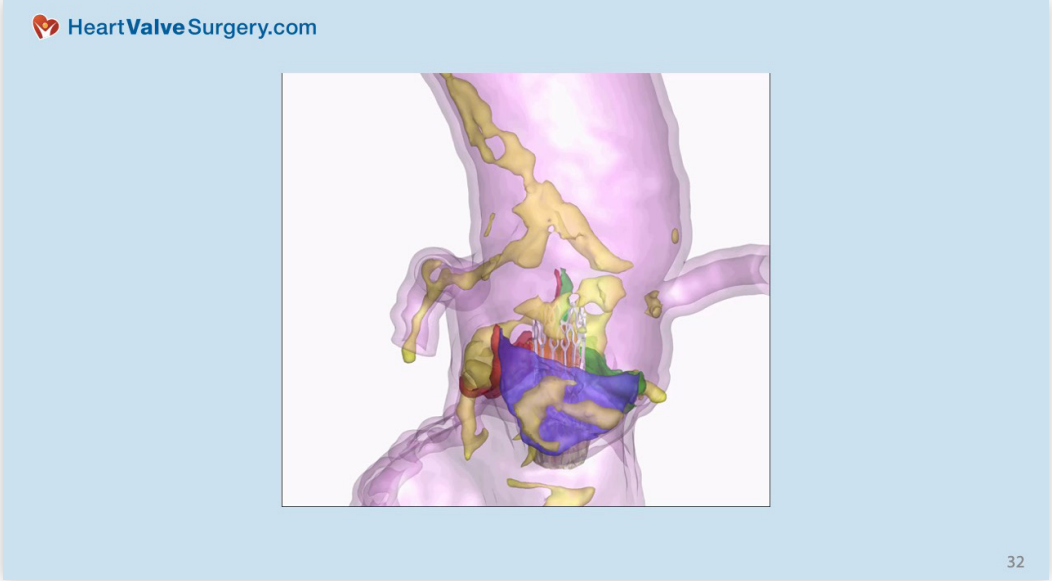


Dr. Marc Gerdisch: Here's a valve in an aorta. This is actually a valve in an aorta. Dr. Dasi's kind enough to color-code the leaflets so we don't get confused. We can see the coronary arteries coming off, that big curly one with the branch on it, the left main coronary artery; the other's the right main coronary artery. It's still attached to the heart there. You can see the calcium; the calcium's the yellow. Those leaflets have that calcium occupying that space. The calcium's responsible for limiting the movement of the leaflets, and we also see this big boulder underneath the valve. That new valve is going to seat underneath there. If we're going surgery, we cut all of that stuff out and put a new valve in. If we're doing a transcatheter valve, we push it out of the way, and that's fine, and it usually is not a big deal. You can see there's calcium down in the mitral valve, too. Look at that. See that calcium, that worm there? That's mitral annular calcification. We have to deal with that, too, when we do mitral valve surgery.

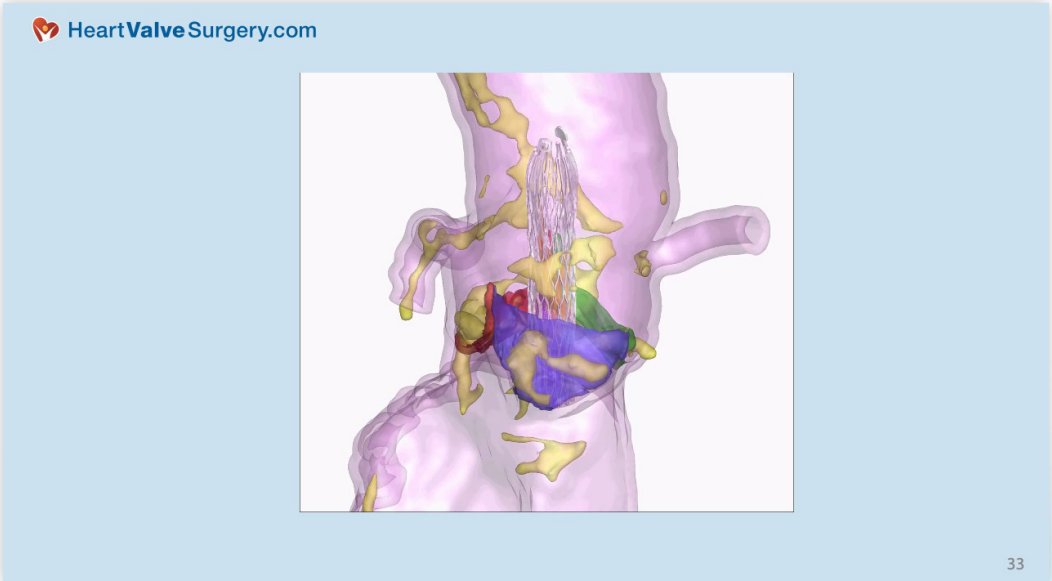


On the left is that aorta, same aorta, now with a bioprosthetic valve in place. You can see the leaflets have been taken out. There's a bit of calcium left that wasn't in the annulus; it's outside of it. That valve just gets seated in there after cutting out the leaflets and leaves a clean space in the sinuses. This is a mechanical valve, and now all mechanical valves are bi-leaflet like this.

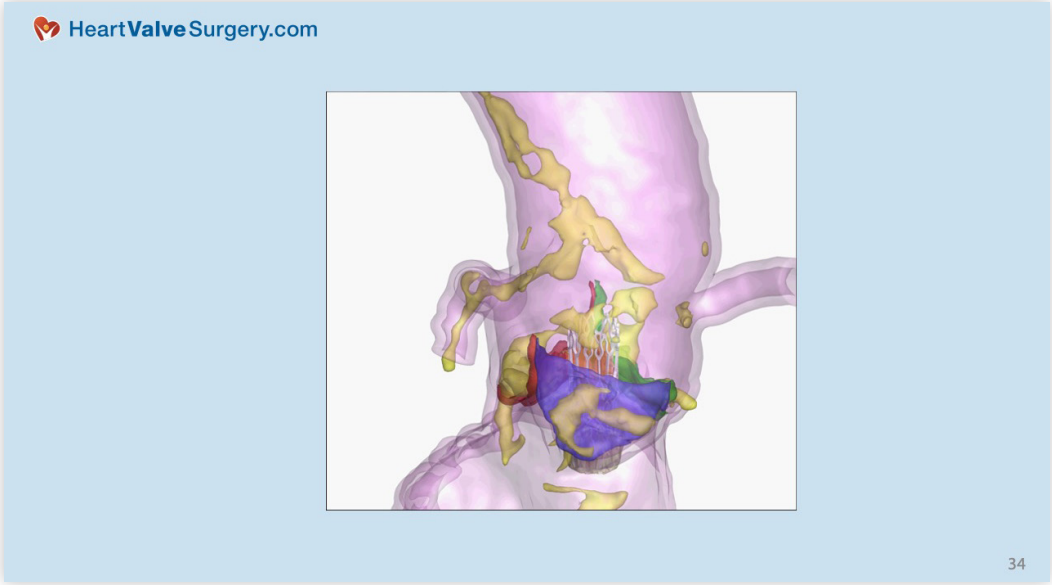
You can see they have a very low profile. Of all the devices we implant, they occupy the least space in the aortic root, so they allow for a little bit more natural flow in the aortic root. This gives you an idea of what it looks like in the human aorta. That's the same aorta.



This would be the positioning of a transcatheter valve. This would be the positioning of a different transcatheter valve. First one was a SAPIEN. I'm going to breeze through these because you're going to see the money shot here.



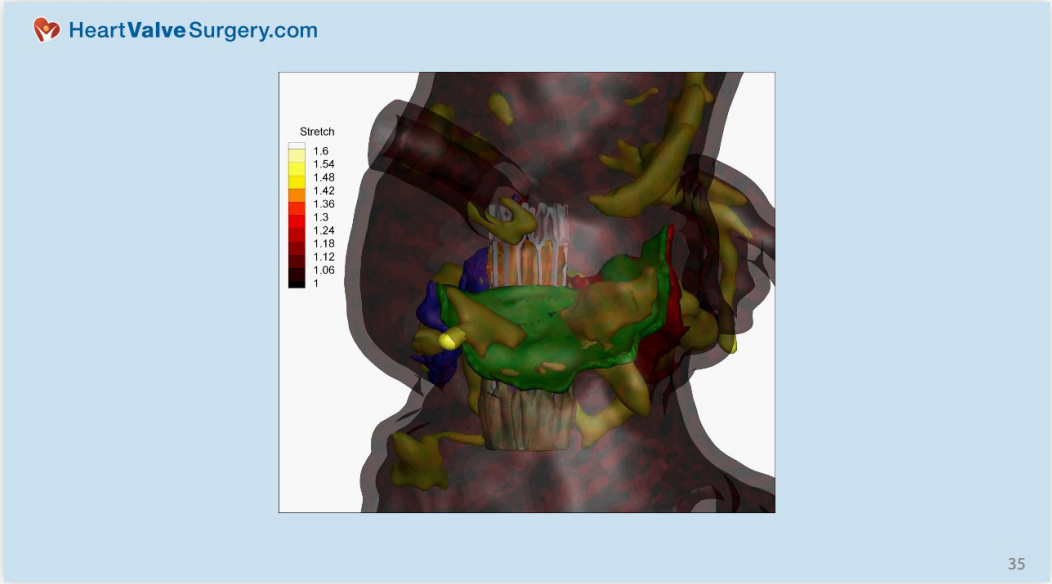
TAVR Expansion In The Aorta (SAPIEN and CoreValve)



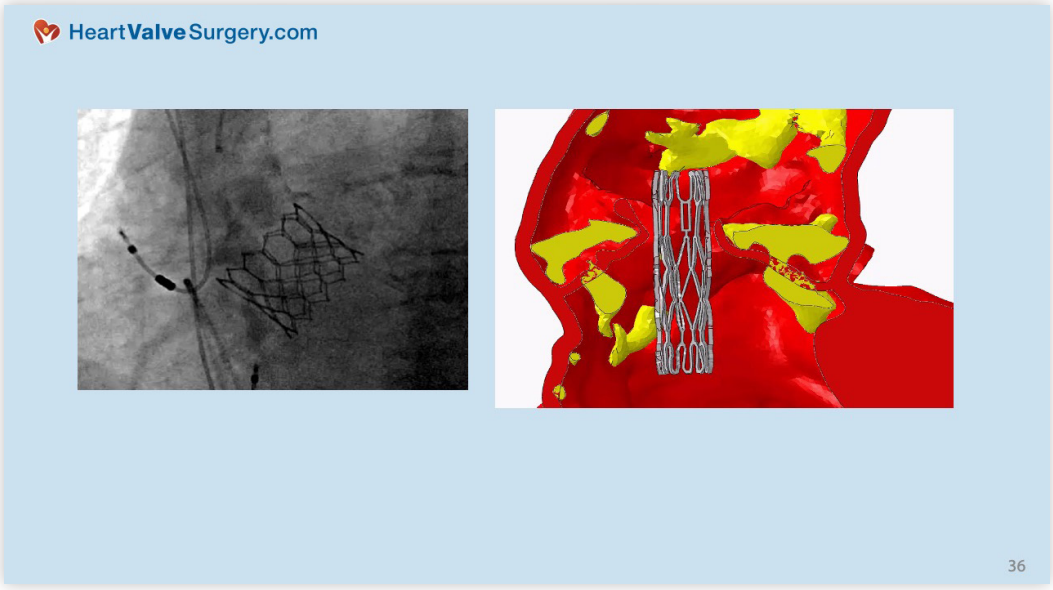
Dr. Marc Gerdisch: Now this – that is the SAPIEN valve positioned across the aortic valve modeled in an actual aorta. That is the CoreValve positioned across the aortic valve in the same aorta. You see that big chunk of calcium there.

You can see those valves open up and you see that – you actually see the SAPIEN valve pushing on that big chunk of calcium harder. That's a signal. That's a warning. We might have trouble there. The SAPIEN valve, the Edward valve, they go up by different processes. The SAPIEN valve, like I said, is the most common valve, the one most commonly implanted. We put that up with a balloon. The CoreValve, which is the Medtronic device, which is the taller one, that one expands on its own, so that's the SAPIEN again pushing on that calcium. That's the Medtronic and it takes on a configuration that allows it to wrap around that area where the calcification is.

Heatmap Modeling for Calcium Risk Mitigation



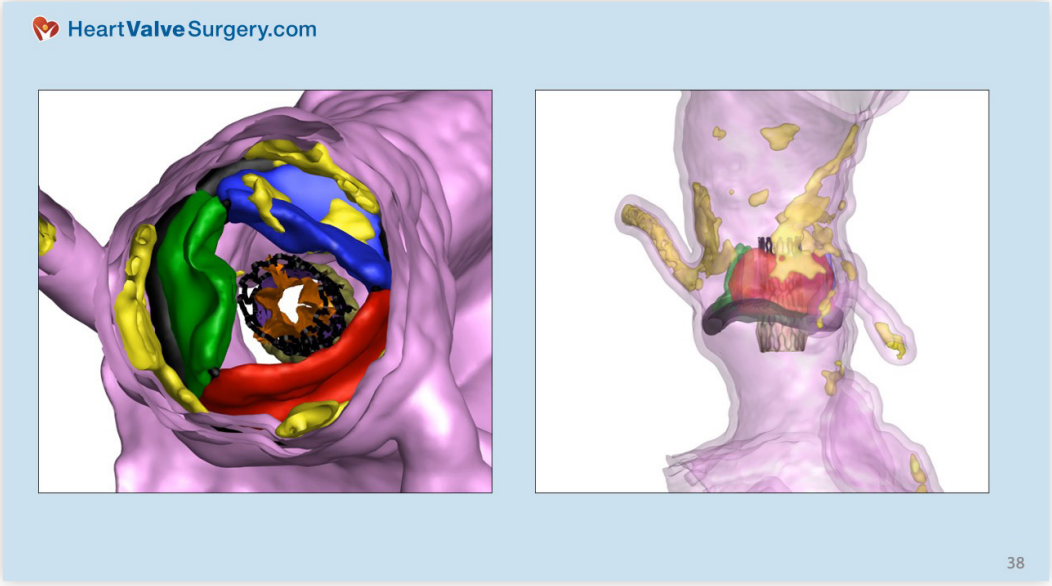
Dr. Marc Gerdisch: Here's the importance of that. This is basically a heat map, and that heat is that chunk of calcium going through the aorta. This is an actual video from an actual patient. It's not my patient; I just know this is an actual patient – where the choice that was made, and it was a logical choice based on what the standard CT scans showed – so on a standard scan, you might look at this and say oh, yeah, SAPIEN's going to work well. If you have a dynamic image like this that includes information on how solid calcium is, how soft or not soft the aorta is, calculations can be made from this technology and they keep making it better to determine the risk. This is an actual patient That chunk of calcium went through the aorta and the disaster then ensued.



This is the actual cath from that patient when it was done. What we see here is dye going in. The valve has been deployed. This valve is up. This contrast up here isn't supposed to be here. That dye is leaving the patient's aorta and going into the patient's chest. That is a disaster. The valve is leaking down here into the ventricle, but more importantly, it's leaking out here into the chest. Here's that same valve being deployed and pushing the calcium. Here's the calcium. See this plate of calcium? That goes right out through the aorta. That's the potential devastating consequence.

Modeling Valve-in-Valve Procedures: Opportunities & Risk

Dr. Marc Gerdisch: Here is a valve that's already been implanted. That's a bioprosthetic valve that's already been implanted and become diseased. It's stiffened. We can see the relationship of the leaflets to the aorta. We can see the coronary arteries where they come off. We can see the calcium in the aortic wall and the calcium in the coronary arteries. This is ultra-important because if we want to treat this with a valve-in-valve, we need to predict what's going to happen to that bioprosthetic valve that's already in there.



There's the valve going up. This is an actual patient. This isn't one of my patients until I operated – until I did surgery on the patient. This is what happened to the patient before I operated on the patient. That bioprosthetic valve that we saw back here – I'm going to go back to it, actually. This bioprosthetic valve, they went through the aorta with a SAPIEN valve and put it inside of this bioprosthetic valve. That's it being expanded. You see it expanding and pushing the leaflets of the bioprosthetic valve against the aortic wall. Problem is those leaflets are going to stay high, and in fact when they did the procedure, fortunately, they were talented enough and adept enough and fast enough to put stents in both of these coronary arteries as the bioprosthetic valve crushed up against the coronary arteries because it was choking off the flow to the heart muscle. The heart would be to have a massive heart attack. They were able to avoid that but the problem is they've got those stents in there now. The stents are smashed in there, and now you have this.

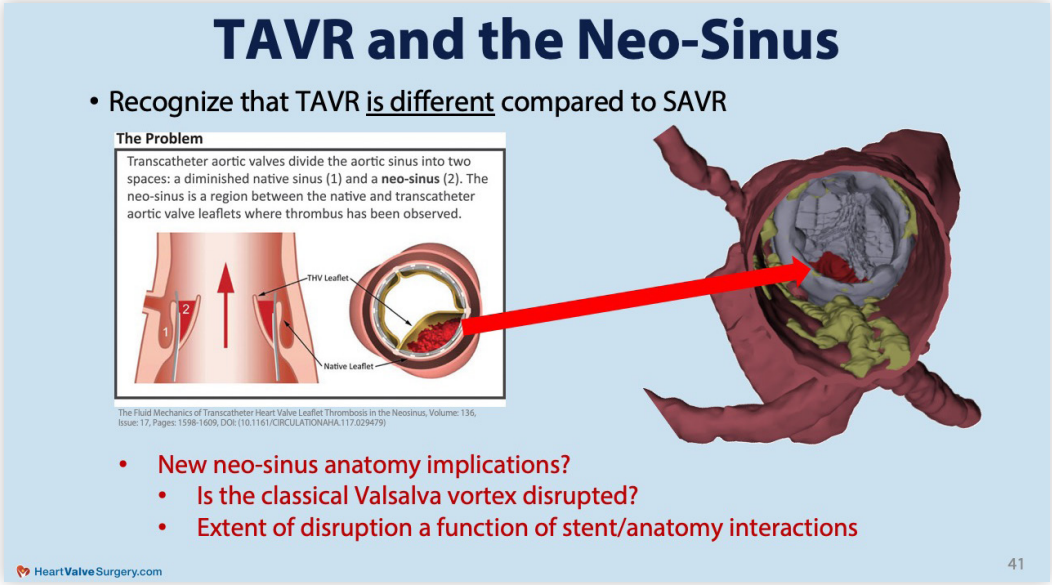
Now you've got a SAPIEN valve inside of there. This is the actual patient before I operated on him. That SAPIEN valve is not fully expanded, which is not good. We want it to be fully expanded. We want to even bust the old valve to make it nice and round. In the process of being expanded to the extent that it was, you can see that the leaflets are pushing up against the coronary ostia. They're blocking the blood flow in the coronary ostia, especially the right coronary artery. The blood has a way to make its way in there. There's a little track. The patient stayed alive but was short of breath and having chest pain because he wasn't getting enough blood flow to the heart muscle, and the valve wasn't working very well.

Now this is taken from the actual CT scan that was done before I operated on the patient, and it really nicely shows – when we're looking at a scan, a CT scan, a Dasi scan, of a transcatheter valve that's already been implanted, it looks this thicker kind of network. You can see how it flares at the bottom. That's because it's under-expanded. It has a little bit of a waist to it. Then you can see it comes up, all the way up to these coronary arteries where it's overlapping the coronary arteries There's just a little flow path to get in there. We just took all of that out and then put a new bioprosthetic valve in.

Now you say well, why did they do a valve-in-valve in the first place?

The risk can be calculated. It's also in the eye of the beholder. I never, ever criticize somebody for trying to take the safest path that they identified for the patient at the time. They were intimidated by the calcium in the aorta. They didn't feel comfortable doing a second operation on him, and they did what they thought was the right thing to do. I just did the second operation and took everything out, put a new valve in him, and he did fine, which of course is good.

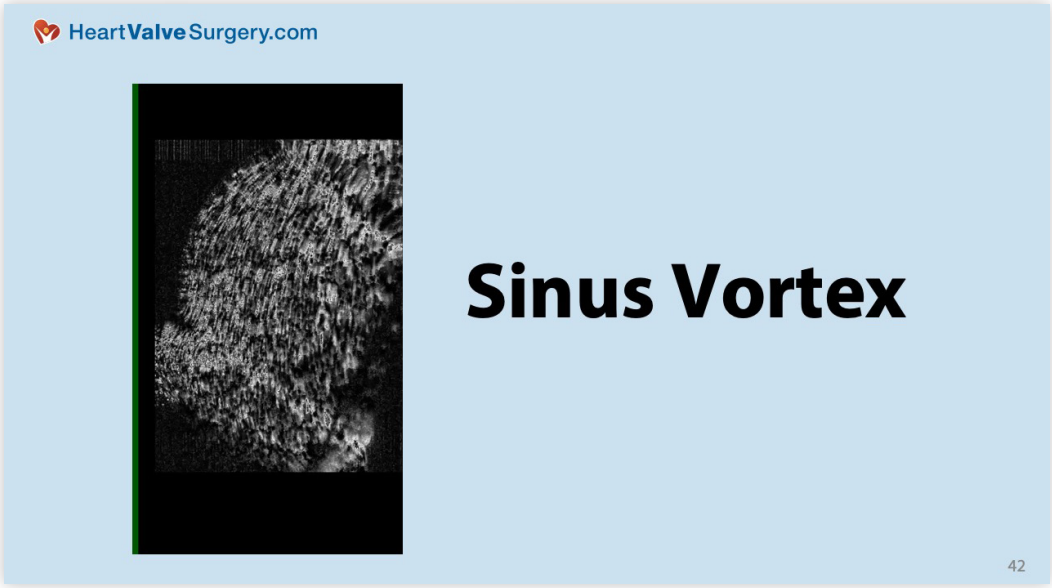
TAVR and the Neo-Sinus



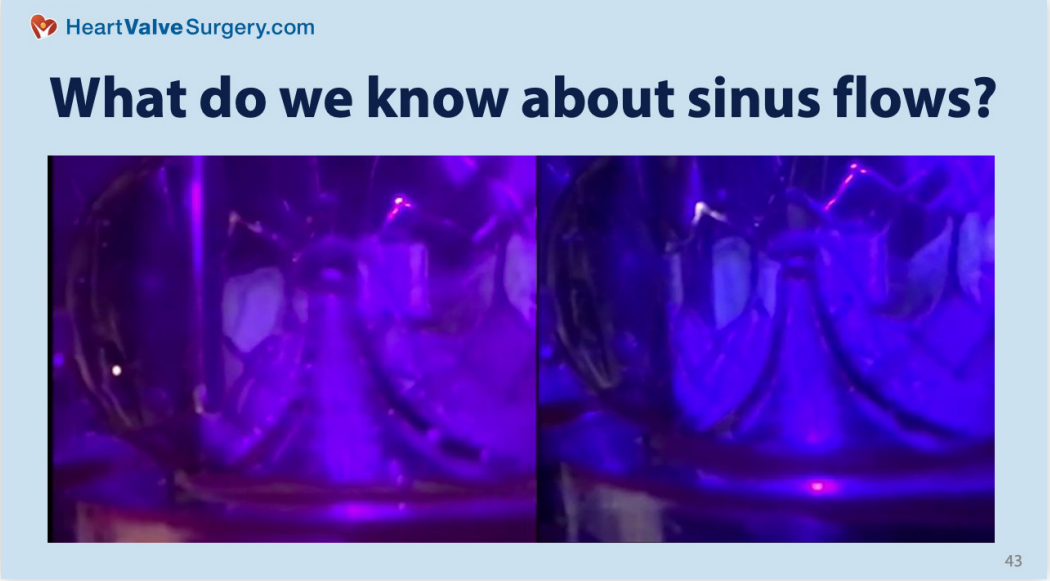
Dr. Marc Gerdisch: This is another really fascinating part. I am really intrigued with this because I've always been really interested in vortical flow, the flow in the coronary sinuses. As I mentioned before, actually, it was literally described by Da Vinci. Da Vinci described the flow pattern in the aortic root and was able to ascertain its role in maintaining the valve and maintaining the flow. It's pretty often, actually, that I find things people think they discovered and they were discovered before.

This is a really brilliant picture because it tells an important story. When we put the transcatheter valve in – you see the valve in on the right side. That's a transcatheter valve that's been implanted. We've pushed those leaflets out of the way. Now we don't have one sinus anymore; we have two. When the leaflets get pushed out of the way, there is a little gap. There's going to be a little gap between the prosthetic valve, the transcatheter valve, and the leaflet tissue that's standing up. It's in here, and that gap then is the place where the blood is that is between the patient's native leaflet and the leaflet of the transcatheter valve.

One of the things we've been trying to figure out is can we predict and how do we manage the presence of clot on the surface of bioprosthetic valves called Halt. It's thrombus that's a clot that forms on the surface. It can happen on a surgical bioprosthetic valve. It's less frequent, but we see why it – we think we see why it happens with transcatheter valve, at least to some extent. It's because we lose that vortical flow and we have these spaces where the blood can become static. Then you can get a clot that forms on the leaflet. You don't have this open space here anymore. We've pushed the native leaflet back, and we've split this space into two spaces. You see here when we deploy a transcatheter valve, some of the calcium will limit the expansion, will change the anatomy of the aortic root. We changed that anatomy; therefore, we changed the flow.

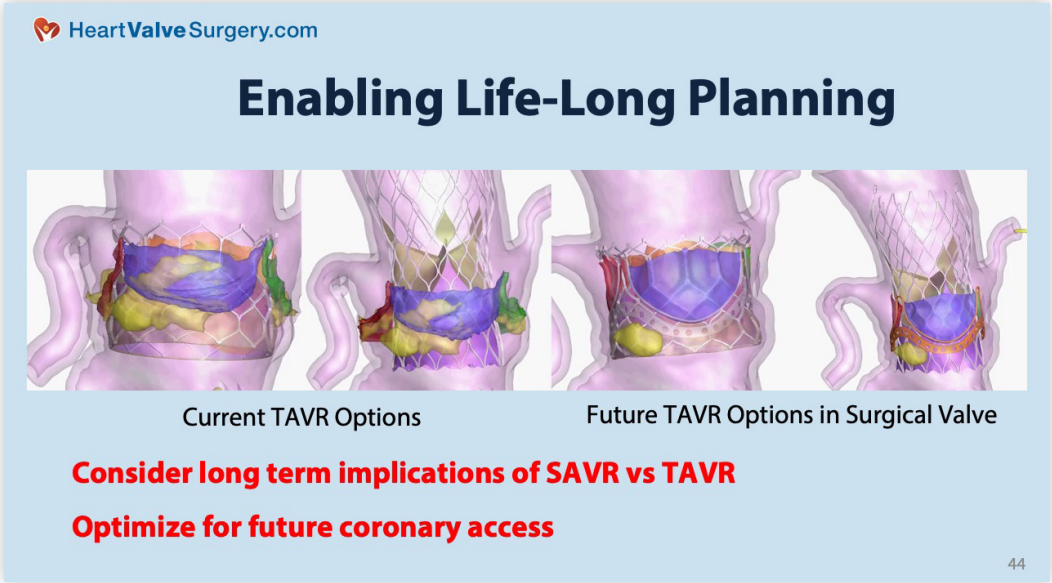


This is a really pretty diagram of that. See, this is the root. This is a sinus. This is the left coronary sinus with flow into the left coronary artery, and you see what's supposed to be happening. See that vortex? Watch it swirl; here it comes. Wait a minute, wait for it. There, see that flow like that? That's what we want. We want those vortices that are responsible for cleaning the leaflets, keeping the space in motion, keeping the blood in motion.



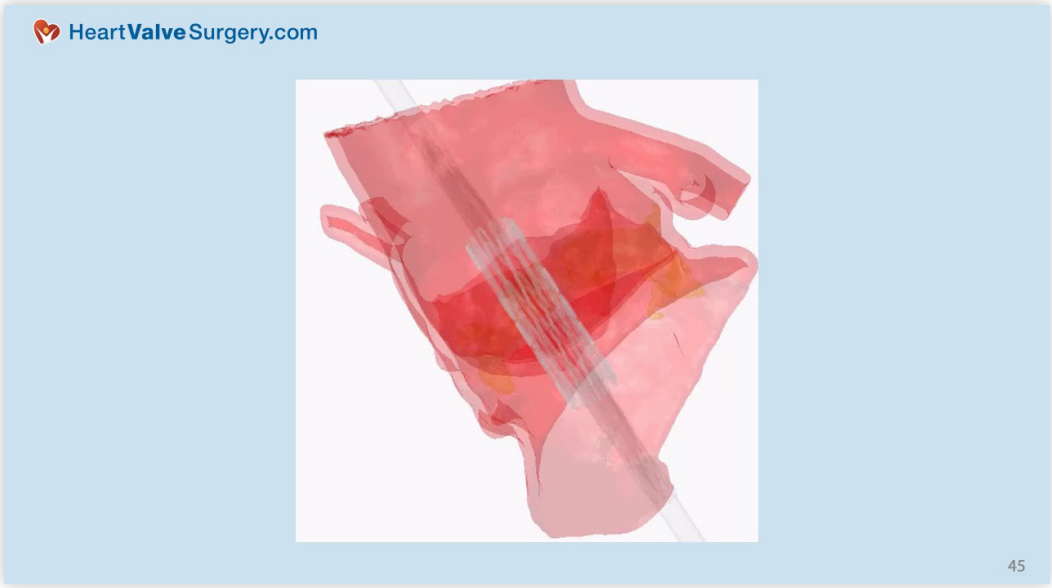
This is a really cool image using fluorescein contrast, and what they've done here – and this is in Dr. Dasi's lab – they've taken a bioprosthetic valve, made the leaflets clear so you can see the transcatheter valve inside of it, and then looked at the pattern of flow with the fluorescein in the sinus and the neo-sinus. On this side, the contrast gets injected into the neo-sinus. Wait a second. I think it'll come again. This is the neo-sinus. This is the actual native sinus over here. This is the neo-sinus right next to the device. That's to qualitatively, at least, look at the behavior of the blood and how it changes when we implant that device. We have to think about those things.

Lifelong Planning of Heart Valve Disease

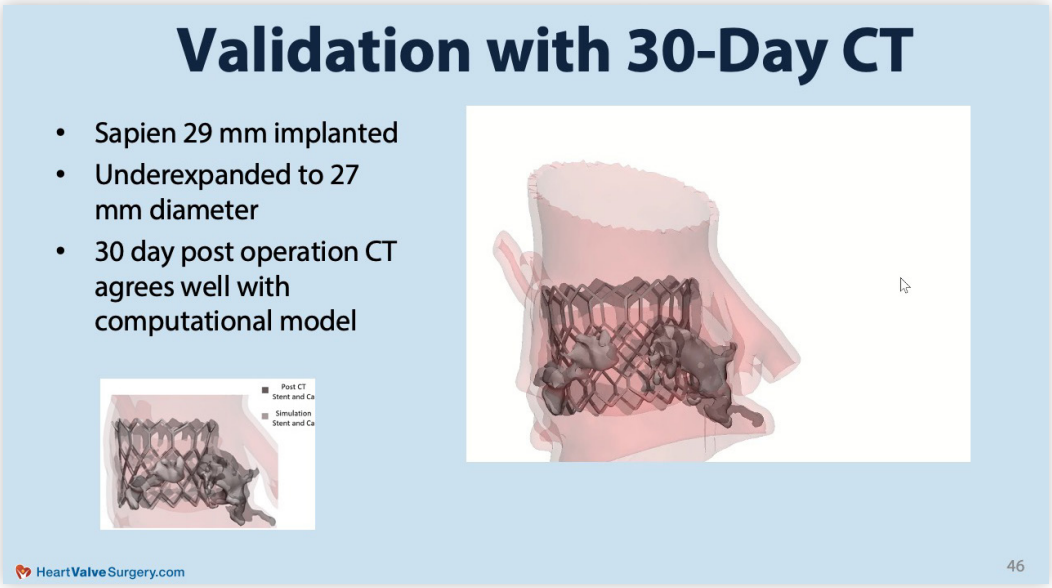


Dr. Marc Gerdisch: Again, how do we plan life long? Can we enable that through 3D imaging? Can we use the – an understanding of flow physiology combined with aortic root geometry and anatomy and anticipate what the flow dynamics will be and anticipate what we can do in the future? What can we do? Should we do TAVR? Should we put a bioprosthetic valve in and plan on a TAVR in there? Should we put a mechanical valve in so they don't have to – that might be their last valve because their anatomy calls for it and because their life choices are such? In the future, which transcatheter valve might we need to implant in that bioprosthetic valve? Could we predict that? Long-term implications.

That includes coronary access. I should go back one. This is important When we put a transcatheter valve in, we put any valve in but especially transcatheter valves, it changes the way we can access the coronary arteries later. Somebody needs a stent in their coronary artery, it can be impaired or made more difficult by the transcatheter valve. It's not a nightmare. It's just something we have to think about. It's a little bit more difficult with the Medtronic valve, although it's getting better because they made the cells, those openings, they made them bigger, but it's something we have to think about.



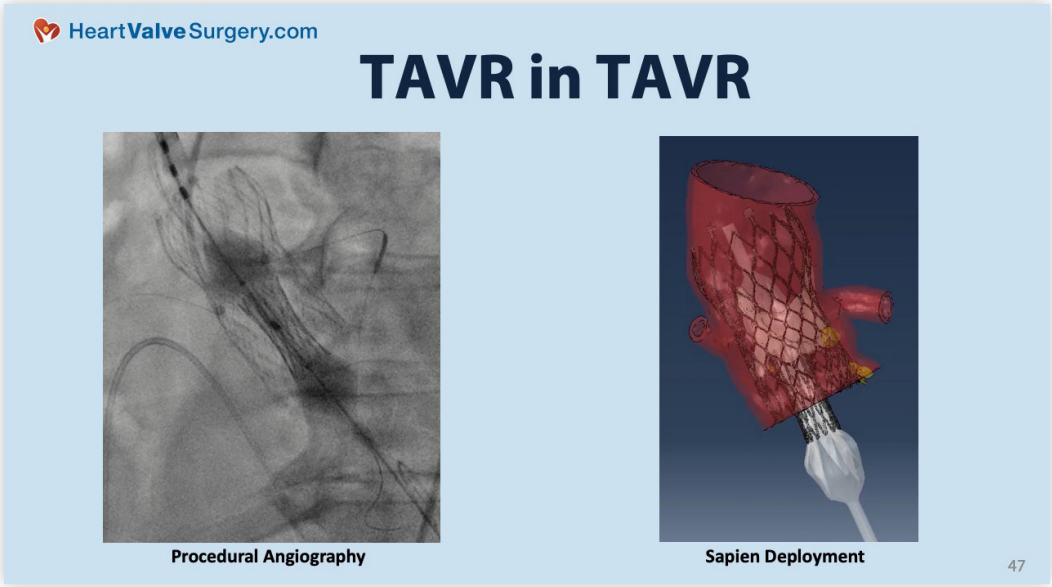
So now bicuspid valves, as many people know, are near and dear to my heart because I do a lot of aortic valve repair for the leaking ones, but they do get stenotic, too. They need to be replaced at time. This is a valve being put up in a bicuspid valve. Now, the anatomy is such that with bicuspid valves that if you could imagine – and I'll show you this a little bit better later.



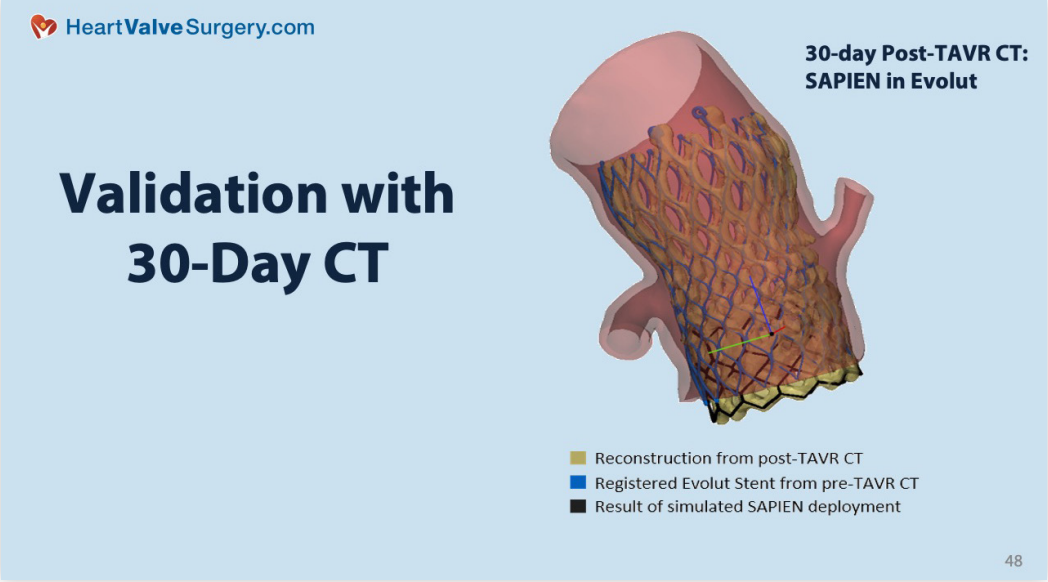
A bicuspid valve doesn't have the normal three commissures. It doesn't have three separate leaflets. It has usually two leaflets; one could be much bigger than the other, two fuse leaflets. We can get into the details of the anatomy if people want to. I'd be happy to do another talk on it, because it would take another talk.

The important thing is bicuspid valves are much harder to do transcatheter valves in because they open up differently. They can open up more like an ellipse. If you can imagine putting something circular in an ellipse, then you can have leaks on either side of that circle. This is a really cool image because this is modeling. This is taken the SAPIEN 29 implanted, under-expanded a bit. Thirty-day post-operative CT agrees with the computation model, meaning that if you look here, the thick lines, that's the actual valve after it's been put in. In other words, that's a CT scan of the valve after it's been put in. The thin lines are the model. They overlap exactly, so that means that the model that was done before that valve went in predicted exactly what it would look like later. That is confirmation that the technology worked.

TAVR-in-TAVR Modeling Using Medtronic CoreValve

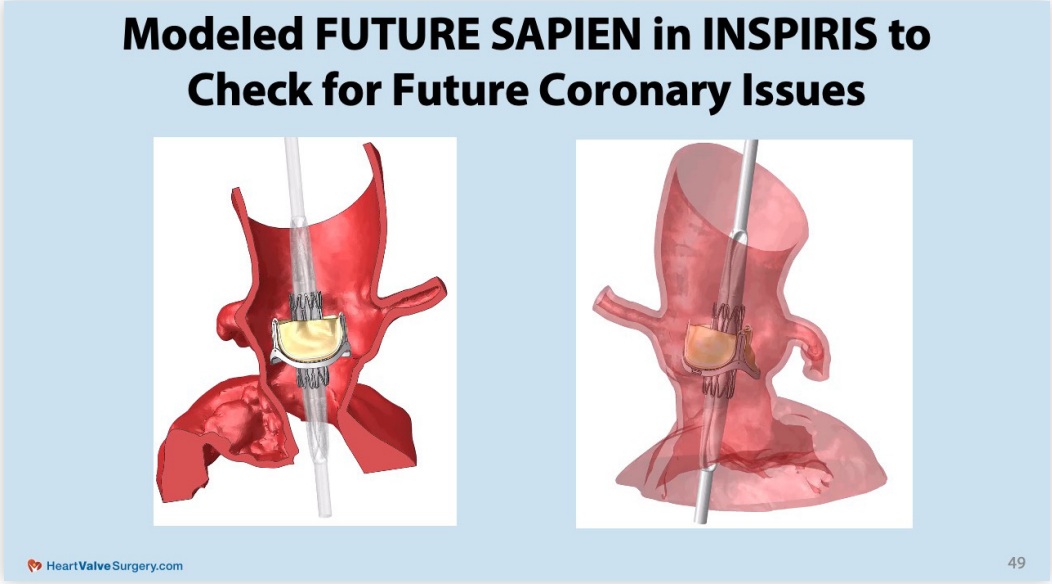


Dr. Marc Gerdisch: TAVR-in-TAVR, can we put another TAVR inside of a TAVR? I showed that lady that had the 20-millimeter SAPIEN. There's no way she gets another TAVR. There's no room. We can. We've done it. You can see here actually, so this is a SAPIEN valve going up inside of a CoreValve, so a Medtronic valve getting an Edwards valve put inside of it. You can see by deploying just a little bit low here, it keeps those leaflets of the Medtronic valve from getting in the way of the coronary arteries. We can be tactical in the deployment of the second transcatheter valve, if they need it, and in so doing, avoid complications. We all are good at the procedure. We can be better at the outcome if we have the information at our fingertips and in our mind walking in. That's what this is about.



Again, validation with a 30-day CT scan, it's the same thing. Again, this has all of the images in one. It's kind of confusing. Basically what it tells you is that the preoperative or the pre-TAVR in TAVR prediction was accurate, that it worked out fine.

TAVR-in-TAVR Modeling Using Edwards SAPIEN

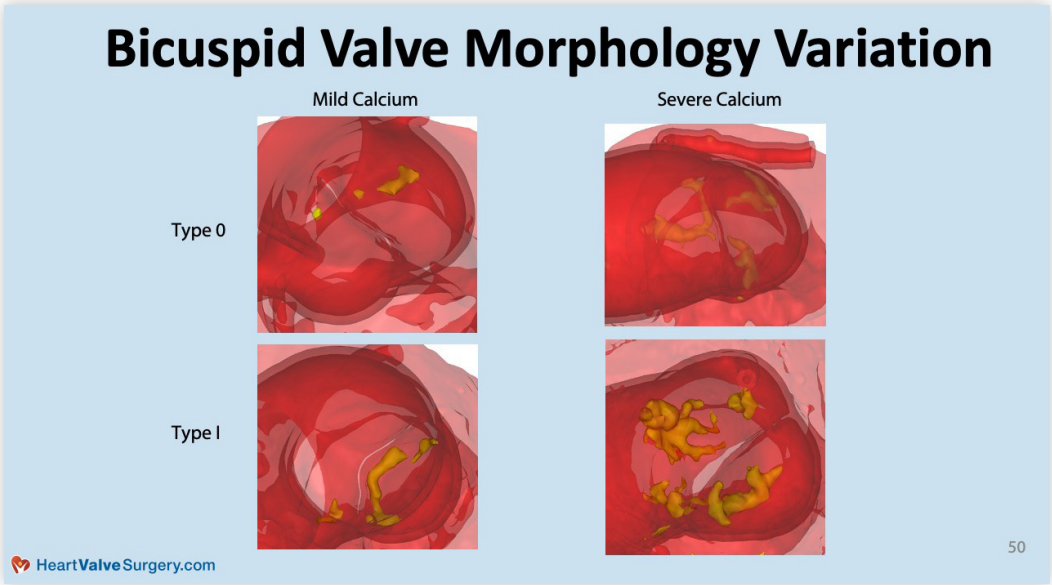


Dr. Marc Gerdisch: Again, we talked about this. Can we model the future of valve in valve? If someone is youngish or doesn't want to be on – can't be on anticoagulation or whatever and we know that we're going to have to do another valve, and maybe they're old enough where we think they're not going to need another surgical valve but we can do a transcatheter valve, or maybe we're going to do two transcatheter valves in them later, that can be modeled ahead of time.

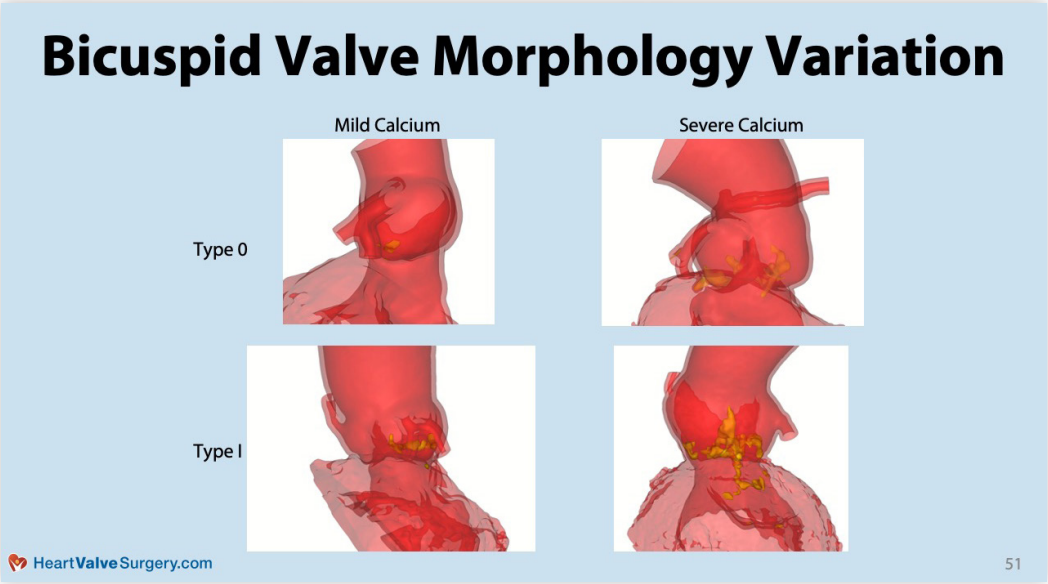
You've probably heard of the INSPIRIS valve. It's predesigned so that it will do what I talked about earlier, so you don't have to crack it. It will actually slide open and become larger. It has a linkage built into the frame that allows it to expand. This is modeling for that, so this is the transcatheter valve going up in that INSPIRIS.

The finished product is this nicely expanded valve with plenty of room. It's actually a little bit bigger than the surgical valve was, because they expanded past the surgical valve, but still plenty of room to get blood into the coronary arteries and good sinuses. One of the nice things about having a surgical valve in place already is that all the old leaflet tissue's been cut out.

Bicuspid Aortic Valves Morphology Variation

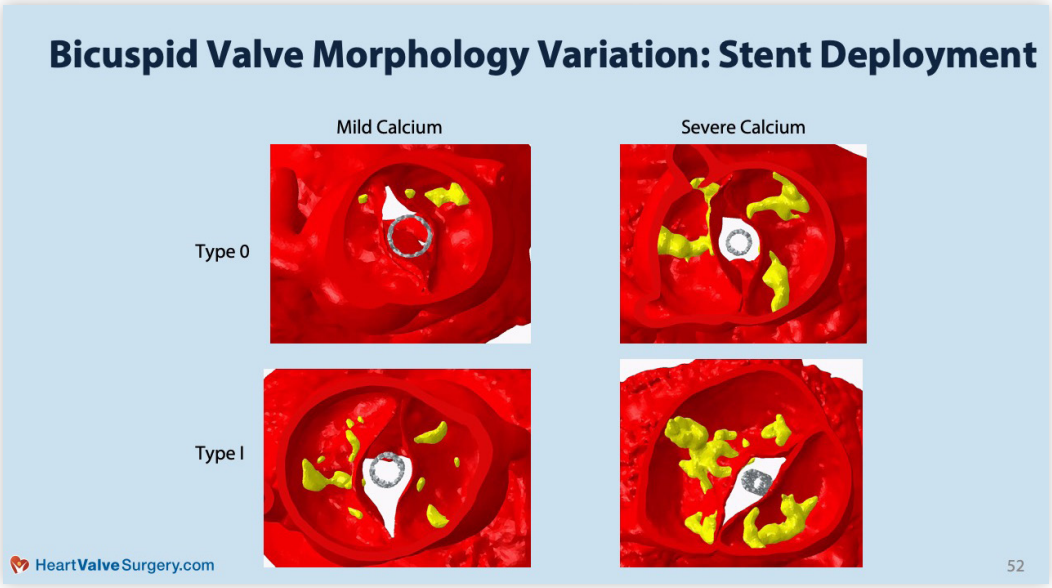


Dr. Marc Gerdisch: Bicuspid morphology, this is a little bit harder for you to understand just from these images, but type 0, type 1 – type 1 is the most common. It has a little bit more of an arcing opening. It has two leaflets that are fused together and one that is not. This is a type 0 where you have these kind of 2 even big leaflets.

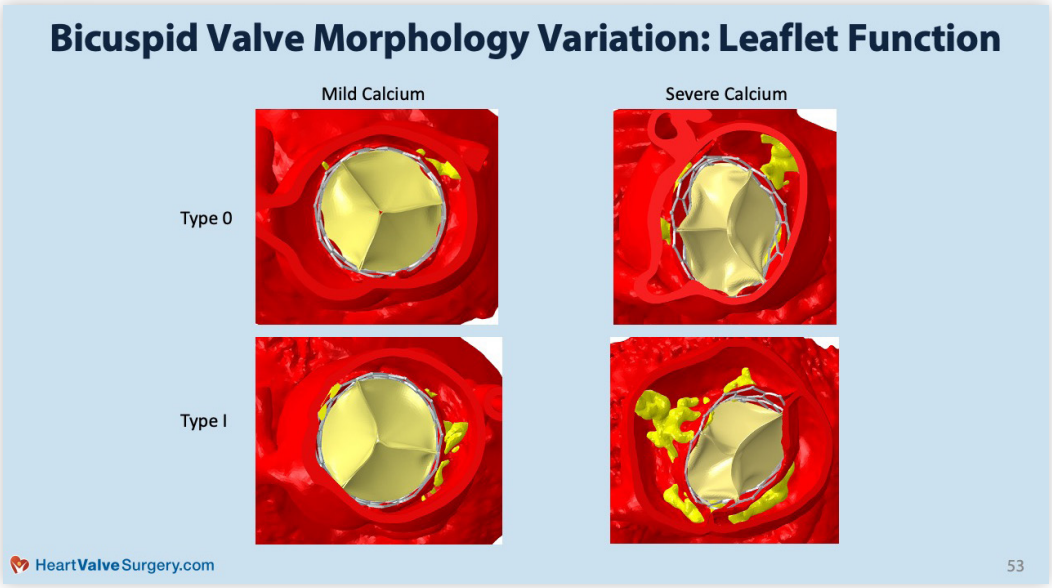


Here's the cool part. If you have a type 0, for example, which is just going to open as almost like a fish mouth, with equal sides – you can see the commissures on both sides, little tents on both sides. You can have mild calcification or you can have more severe calcification. That will change the outcome for us, if we want to do this as a transcatheter valve.

Now still, most bicuspid valves we will do surgically, because we can do a minimally invasive little incision. You can have your bicuspid valve taken out and put a surgical valve in and we don't have to worry about the leaks. We don't have a lot of data for transcatheter valves and bicuspid valves. We have very little data for it. We can be successful with it. The best way that we're going to be successful with it is to predict what it's going to look like after we put a valve up in it, so let's look at that.

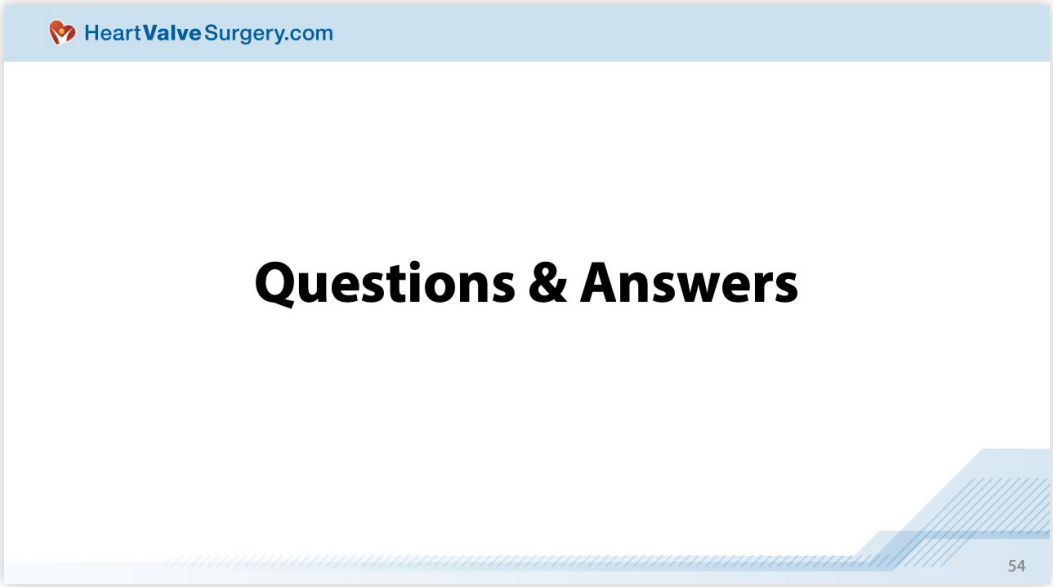


Mild calcium, big circle, and this is with the SAPIEN valve, balloon expandable, big circle. Severe calcium, we don't finish up with such a nice circle. Mild calcium, severe calcium, with the Edwards valve. Mild calcium, we get that expanded. We have good tissue approximation. We don't have the holes. Severe calcium, not so nice. It's not round. If that valve isn't round when we finish, it will not last as long. It is more likely to get clot on it. It is less likely to perform the way it's supposed to perform.



What do we get? We get these. This is the configuration we want, round, no leaks around it. This is the configuration we do not want, irregular. Leaflets are going to open up incorrectly, and there's space around that for blood to leak through down into the ventricle – unhappy.

Questions & Answers:



Adam Pick: I've got to tell you, I heard about DASI a bit ago, but this is really some next-level stuff. I've never seen anything as a patient where I could conceptualize and see things like the calcification of the valve, the impact of expanding the leaflets inside the – this is really beyond cutting edge. I'm curious to know, is this something that most doctors are using, most surgeons, interventional cardiologists are looking at, or is this – are we in the infancy here of the utility of this technology? It seems like you got upside for durability, modeling, long-term performance, lifelong plan of valve therapy. I'm really just beyond excited for what this means to the industry.

Dr. Marc Gerdisch: It is a little bit in its infancy in two ways. One is what I talked about earlier, which I think that it's a sky is the limit kind of process, especially with the kind of intellectual horsepower that they have working on it.

The other is that, as you can imagine, people's physicians who do things very well sometimes have trouble appreciating how they might do it better. It's not to say people are arrogant or anything. It's just that, boy, I tell you, the surgeons and cardiologists that do this stuff are so good and they're so successful, it's hard for them sometimes to think beyond the methodology that they have. People don't like to change when they're successful. Can you be a little more successful? Can you predict things better and can you fashion and model things for the future better for the patient?

What's happened lately though is that – because I've been watching it happen. When they have been around other physicians that have the fire in their belly about this stuff, they're getting very excited. I think we're going to see a little bit of a wave front now that is gripping the field. My expectation is that people will take more and more advantage of it, but right now, relative to the overall experience it's a small number.

Adam Pick: Got it. I could go on and on about your use of this. You're using this today with your patients. Is that correct?

Dr. Marc Gerdisch: Yes, absolutely. At this point we're doing it on some patients. As people always tell you, I do a lot of things for my patients and I don't know how to draw the line. How do you know – how do you know when somebody's not going to benefit from something? How certain can you be? I think that we're becoming more liberal with it in the sense that we want to make sure we're optimizing for every patient. As technology advances, becomes more rapid turnaround, I think that's going to happen in a lot of places. We do use it in our patients. We've been using it more and more. Any time we see any potential fallibility or any question, then we just do it.

Adam Pick: I'm so thrilled to hear all the great things that you're working on. Let's get to some of the patient questions. Dr. Gerdisch, I'm going to ask you to rapid fire these, because we have got a lot that have come in. We're going to get to as many as we can for all the people that are on the line.

Interventional cardiologists are looking at, or is this – are we in the infancy here of the utility of this technology? It seems like you got upside for durability, modeling, long-term performance, lifelong plan of valve therapy. I'm really just beyond excited for what this means to the industry.

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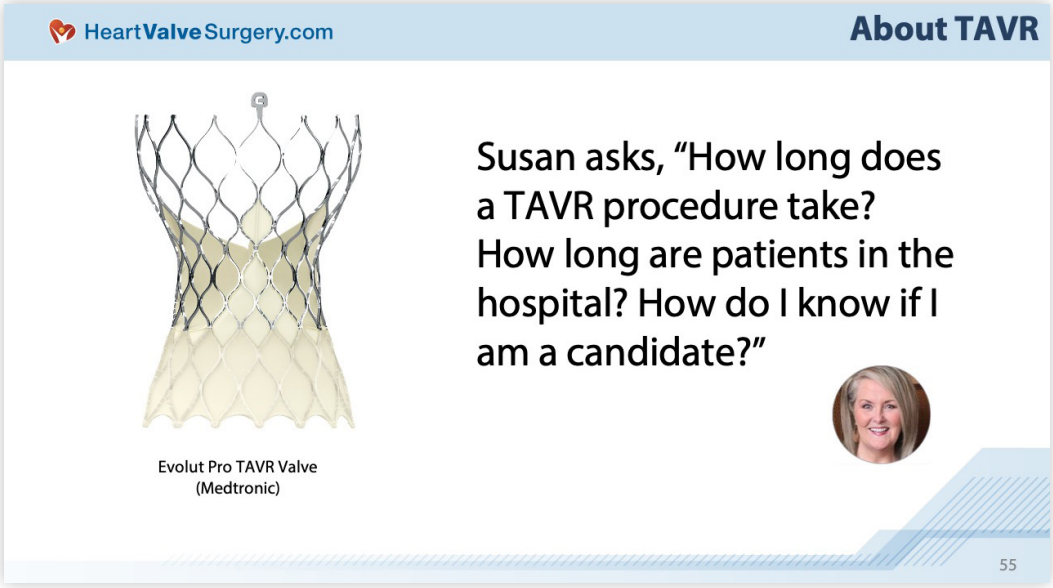


Let's start with Susan's question that came in. She asks, "How long does a TAVR procedure take? How long are patients in the hospital? How do I know if I'm a candidate?"

Dr. Marc Gerdisch: Perfect questions. Let's start by how long does it take. It's pretty fast. It's an hour of real doing it time. It takes some time to get you in the room and get everything set up, get you out of the room, but it's pretty fast. People don't have to go on the ventilator 95% of the time. We can just sedate them. Hospital time is going down. Most people go home the next day. Some folks are going home the same day in some places now. We're probably going to start working our way toward that a little bit. Again, you're not coming in for a haircut, so there's still things that can happen, and they can happen within that first day.

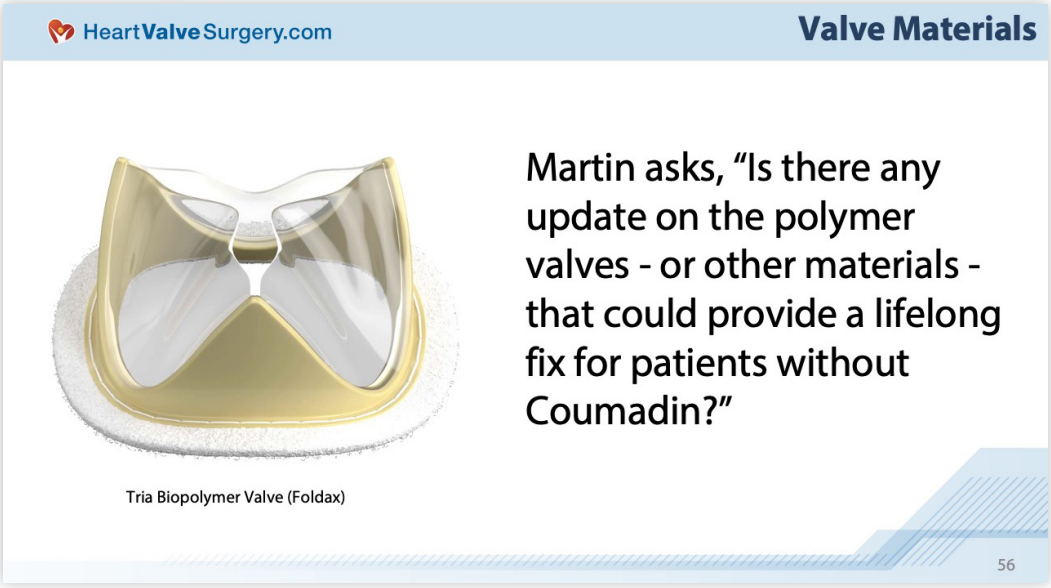
We're progressing toward that a little bit, but I think the fact is that the vast majority of people go home the next day, certainly if you don't need a pacemaker. The pacemaker are still the Achilles heel. I have to say that with DASI and our ability to implant higher more safely, that I think is starting to take a fade as well, for everybody. Everybody will say, we don't really have a – we don't put many pacemakers in. Now everybody says that. The national data is that overall, transcatheter valves are still associated with about a 10% rate of pacemakers. That's something we're trying to make go away, nationally.

How do you know if you're a candidate? Great question. I guess in a sense, everybody's a candidate. You can have the conversation. The better question is what makes the most sense for you? What's the long game? What's your anatomy look like? In other words, if I have a transcatheter valve, which valve am I going to get? How big is it going to be? Am I going to be able to get another valve inside of that one later? If that's her in the picture there, she might need three. People live a long time now. That's the real conversation. Everybody's a candidate for everything.

You might think it might make more sense to get a minimally invasive surgical valve. If you can get a nice sized surgical valve, then you've got a nice platform for transcatheter valve later if you need it. Also, you get all that leaflet tissue out of there, so you have normal sinus anatomy. Then minimally invasive aortic valve – I've sent people home day two now often. We have a guy in the hospital right now going home day two. You're not stuck in a hospital for a long time. You're up and around right away – a few days in the hospital. Those are the things to think about anyway.

Adam Pick: I've never heard of a day two go home on any form of open heart, Dr. Gerdisch. That's incredible.

Dr. Marc Gerdisch: It just started for us. I think it has to do honestly with – we're using a new drainage system. People are just up and ready to go faster. We can get into the details of that sometime. This is a new thing for us too actually.

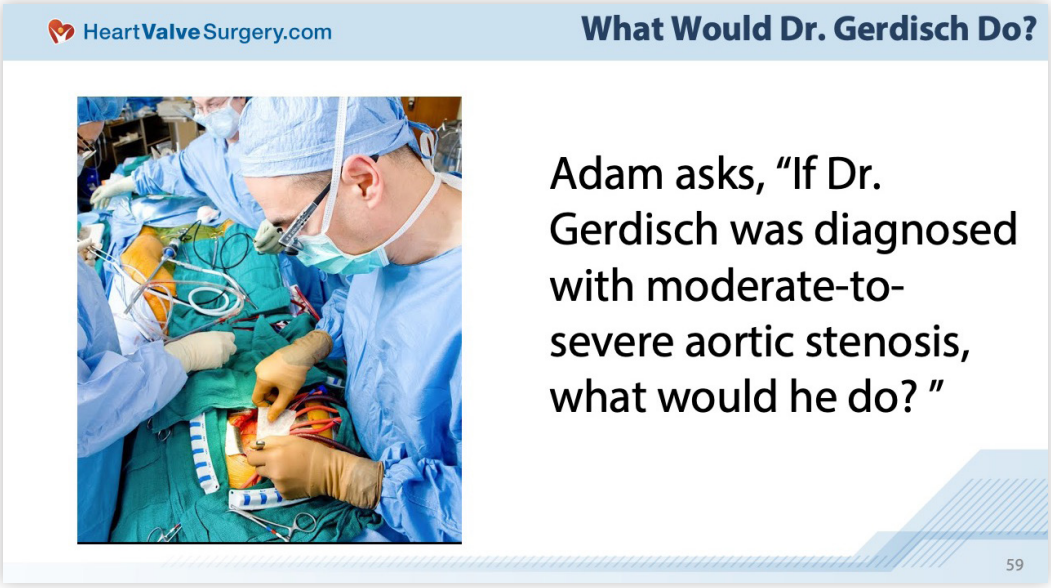


Adam Pick: I know you do a lot of research on materials. You and I have talked about extracellular matrix. Martin asks, "Is there any update on the polymer valves or other materials that could provide a lifelong fix for patients without Coumadin?"

Dr. Marc Gerdisch: Every once in a while I go back and read about the Foldax to see where they are. There's an interesting device. They have stuck with it. They've been able to keep the valve coming. Nobody's had to break through yet. It's probably not too far off. There are two different approaches. One is this, which is the concept of a polymer that is so benign, let's say, that it's indistinguishable, and the body doesn't recognize it and it doesn't attack it, and you don't get calcification or changes in it.

The other is what we've been working on, as I think you know, for well over a decade, which is a matrix valve which is actually tissue that we process so that – and it's pig tissue that we process and take all of the antigen out of it, all of the antigenicity out of it, and then we build a valve out of it. Then the person's own stem cells populate that framework, and they grow a valve.

We're not perfect on that either. We are in an FDA study with it. We've been at it for a decade. We've got that valve going in as part of an FDA study, only in the tricuspid position. I would say that we're inching toward this. I wouldn't expect a revolutionary change in the next few years or several years, but I think within our lifetime, my lifetime, we're going to get to that. If we look at the two sides of it, the one side is engineering this, and the other side is can we change the way we manage our current valves? Are there things that we can do to them or for the patient that will allow them to last longer? That's a little bit – that's lower hanging fruit. We talked about some of that at the beginning.



Adam Pick: On behalf of the patients, thanks for the research that you're doing, Dr. Gerdisch. I'm going to go to a question that I think is really important and really personal to you, which is – let's pretend, Dr. Gerdisch, you were diagnosed with moderate-to-severe aortic stenosis. You know a lot. What would you do if you had to go about the process of selecting a valve and think about the lifelong plan, given your age?

Dr. Marc Gerdisch: We have longevity in my family. My grandmother on my dad's side died when she was 106. My other grandma died, she was 100. I'd prefer to select them as opposed to the men who died younger. I'm pretty healthy. I do think I'll probably live well into my 90s, especially the way life is now. I pay attention to things.

If I had that right now, moderate-to-severe, first thing I would do is tighten up my window of evaluation. I'd be looking for any signal. Is my left atrium getting bigger? Do I have pulmonary hypertension? Have I gotten any tricuspid insufficiency? Is the circumferential or longitudinal strain in my left ventricle changing? Is it getting thick?

There are some amazing patients that I see that have these really bad looking aortic valves. They have these tissue valves that have just – they have been kicking it for a long time. Their ventricles are normal. Their hearts are normal. There are other people I'll see with the same process, and their hearts are really rough looking and they're in trouble. The important thing is to look. If I had moderate-to-severe right now, I'd be doing echoes every six months and just looking for subtle changes.

Then you asked me what valve would I choose. To be honest, I would probably take an On-X valve and hope that the Eliquis trial pans out. We're not finished with it yet. I really would prefer just to have one procedure and take my medicine. I'm okay taking medicine. I don't mind taking medicine. It's fine with me. I don't mind being on a blood thinner. Other people, they can't, because they – whatever, they ride motorcycles or something – or I might consider a Ross procedure. I'm a little old for it, but I am pretty healthy. There are issues related to that operation that I could dive into, but the reality of it that survival has been really superb in very healthy people. Those are probably what I would look at.

I don't think I'd take a tissue valve right now, because I do think I'm going to live to be well into my 90s. If we look at the data, the data tells us that if you're over 65, that a tissue valve is the smart move, but remember that that is looking at everybody. You fit into a continuum somewhere. Just be honest with yourself and what you want and what your outlook is.

Adam Pick: I love your response. For new patients who are newly diagnosed, just want to let you know, the On-X valve that he's referring to is a mechanical valve. Just so you know, Dr. Gerdisch, I'm now on year 16 with my Ross procedure, and so I can say I'm a little biased when it comes to that. These are all unique. Let's talk about a really big question. This is something we get all the time here, which is – Dana puts it perfectly. "Will there be no more open-heart surgery in the next 10 years?"

Dr. Marc Gerdisch: Dana, I love this question, because I've been getting asked this question for 30 years. When I finished training, people said to me, what are you going to do? Heart surgery's going to be gone. I just keep getting busier, so obviously heart surgery's not going away. What does that mean? It means a couple of things.

First of all, heart surgery has adapted in a couple of very important ways for human beings, for us to live well and to be well. One is we have mastered minimally invasive surgery, and that changed the experience for the patients so dramatically that it became a neck-in-neck between anything else that could possibly come up, so small incision, rapid recovery, and rapid recovery in general.

So even for, as you know, Adam, folks here – I'm sending a guy home day two who had a sternotomy – had a tumor resection and a sternotomy – is going home day two. Why? Because of the way we close the chest and the way we manage their drainage – so evolution in the technology, evolution in the procedures, surgeons being focused on the skillset, and specialization. There are fabulous coronary surgeons. There are fabulous valve repair surgeons. They might not be the same person.

The other is that surgeons have been able to nurture their skillset with respect to doing complex reoperations. Today, I did a third time redo, ascending aorta hemiarch – massive operation. Sometimes we have to do those because people get infections. Sometimes we have to do those because their valve wore out. Sometimes we have to do them because they developed an aneurysm they didn't have before. Reoperations will remain the purview of heart surgery forever, and that includes transcatheter valves that fail or get infected or whatever the next technology is.

We published a paper on failed MitraClips and doing minimally invasive surgery for those. I think MitraClips are fantastic. I think they have a real role. There was a surgeon I trained with by the name of Henry Sullivan. He looked at me once and he said, "Gerdisch, we're the caboose on the train." What he meant by that was, you go – you can run through all the cars. Eventually, you got to get to the caboose. Heart surgery's going to be around for a long time, Dana. I hope that we're always around to help people out. Thank you for the question though.

Adam Pick: Dr. Gerdisch, on that note we're going to come to the end of this webinar. For the folks on the line, please don't hang up just yet. I personally want to extend a humongous thank you to all the members of the community. We got questions coming in left and right, still. Because of your interest in being educated and empowered, we get to do these really great events together. Thanks so much for being a part of our community.

The other person I got to thank right now is Dr. Gerdisch. As always, you bring a unique perspective to heart surgery that helps us learn how to take the best care of our heart valves and our hearts. Dr. Gerdisch, thank you so much for sharing all of these incredible insights today.

As we wrap up, I'd like to thank everybody. I'm going to put up a quick survey on the screen. If you could please complete it, that'll help us improve all of our future webinar events. Thank you, Dr. Gerdisch. Thanks for doing the survey. Take care, everybody. Bye-bye.

Dr. Marc Gerdisch: My pleasure. Bye, everyone. Thanks for joining, everybody.

Patient Resources

Since 2006, HeartValveSurgery.com has developed several resources to help you better understand your diagnosis, your treatment options and your recovery.

Listed below, please find resources created exclusively for patients and caregivers. We hope they educate and empower you.

- Adam's Free Patient eBooks - Download 10+ free eBooks about heart valve dis-ease and treatment options for aortic, mitral, pulmonary and tricuspid valves.
- Heart Valve Learning Center - Visit the Heart Valve Learning Center to access over 1,000 pages of educational information about valvular disorders.
- Patient Community - Meet people just like you in our patient community. There's nothing better than connecting and learning from patients who are sharing their stories in our community.
- Surgeon Finder - Find and research patient-recommended heart surgeons that specialize in heart valve repair and heart valve replacement procedures.
- Heart Hospitals - Learn about medical centers that have dedicated teams and resources that specialize in heart valve therapy.
- Adam's Heart Valve Blog - Get the latest medical news and patient updates from our award-winning blog.
- Educational Videos - Watch over 100 educational videos filmed by the HeartValveSurgery.com film crew about heart valve surgery.