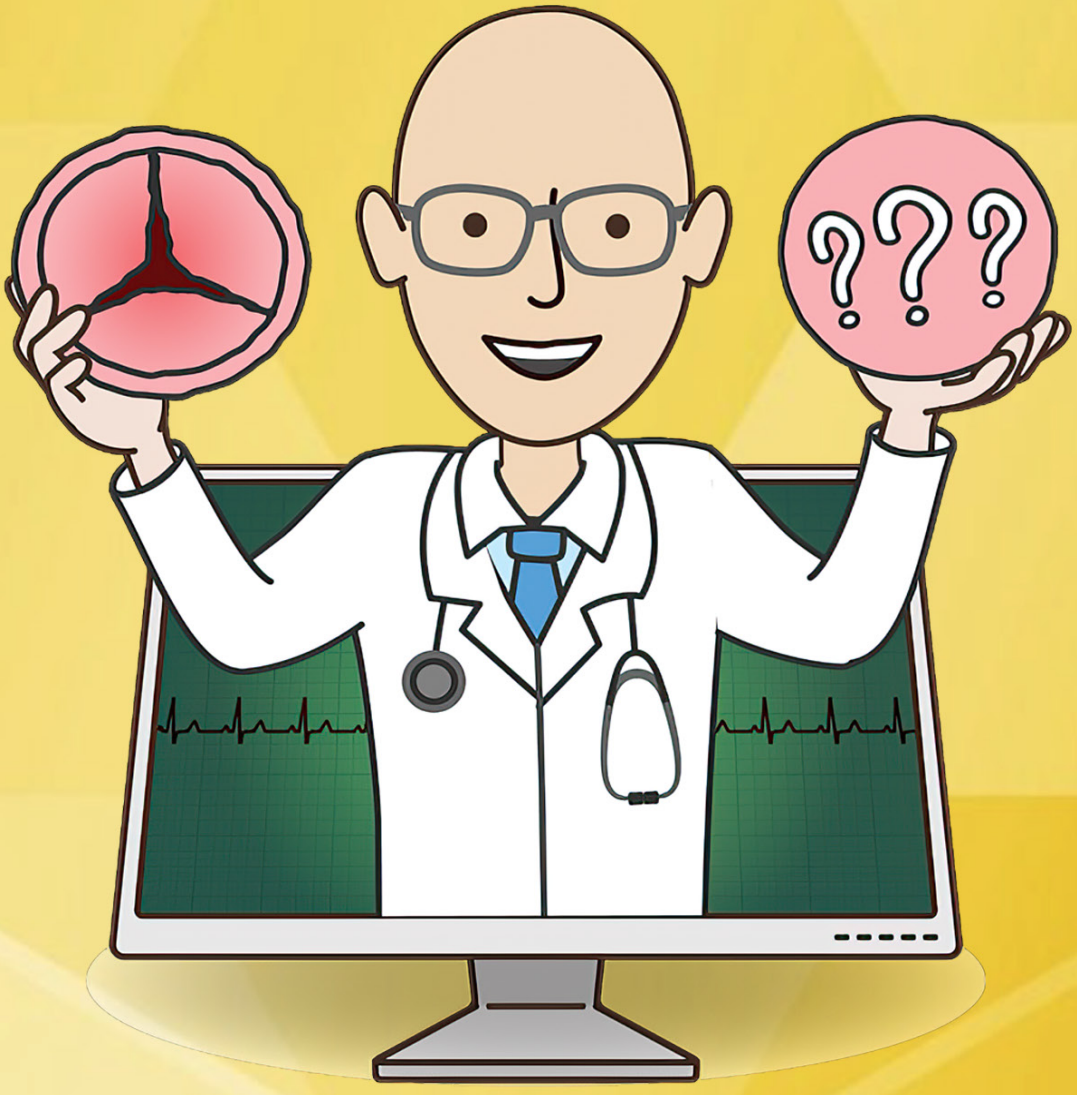
HeartValveSurgery.com

# ASK DR. GERDISCH ANYTHING



Franciscan HEALTH

# Featured Speakers

## Dr. Marc Gerdisch

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Learn More.

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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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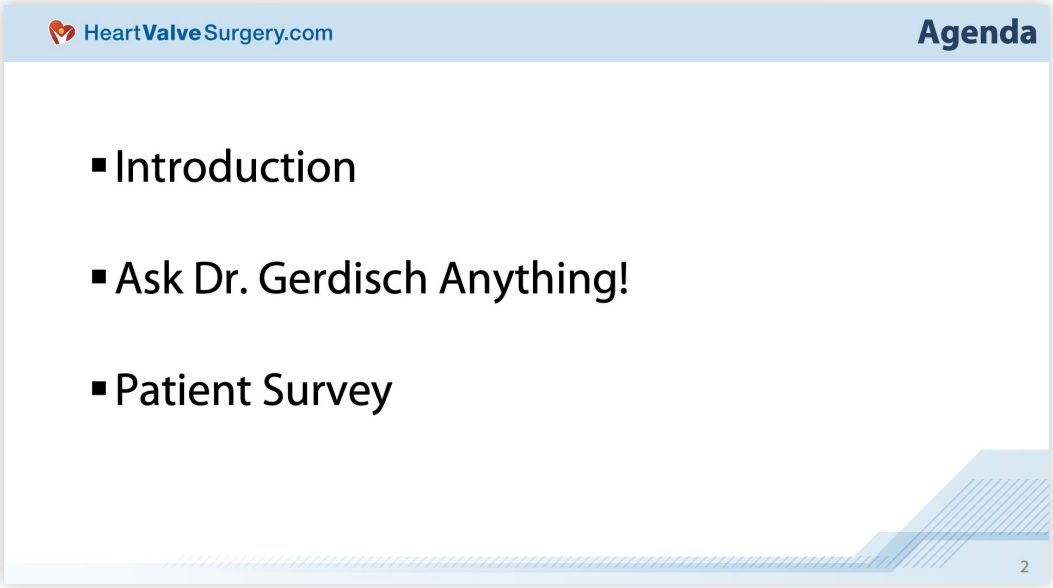
# Introduction

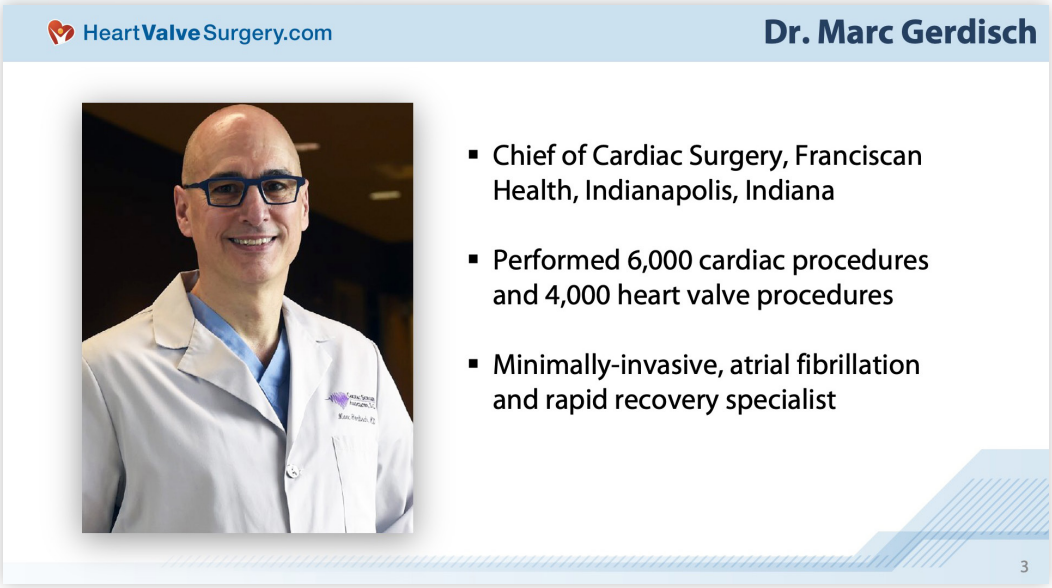

**Adam Pick:** Hi everybody, my name is Adam Pick. I'd like to welcome you to the webinar titled, "Ask Dr. Gerdisch Anything". If I have yet to meet you, I'm the patient who started HeartValveSurgery.com all the way back in 2006. The mission of our website is really simple. We want to educate and empower patients just like you. This webinar - which has had over 675 registrations from patients in countries all over the world - was designed to support that mission.

Throughout the webinar, you're going to be in what's known as "Listen Only Mode" but I encourage you to submit your questions to Dr. Gerdisch throughout this webinar.

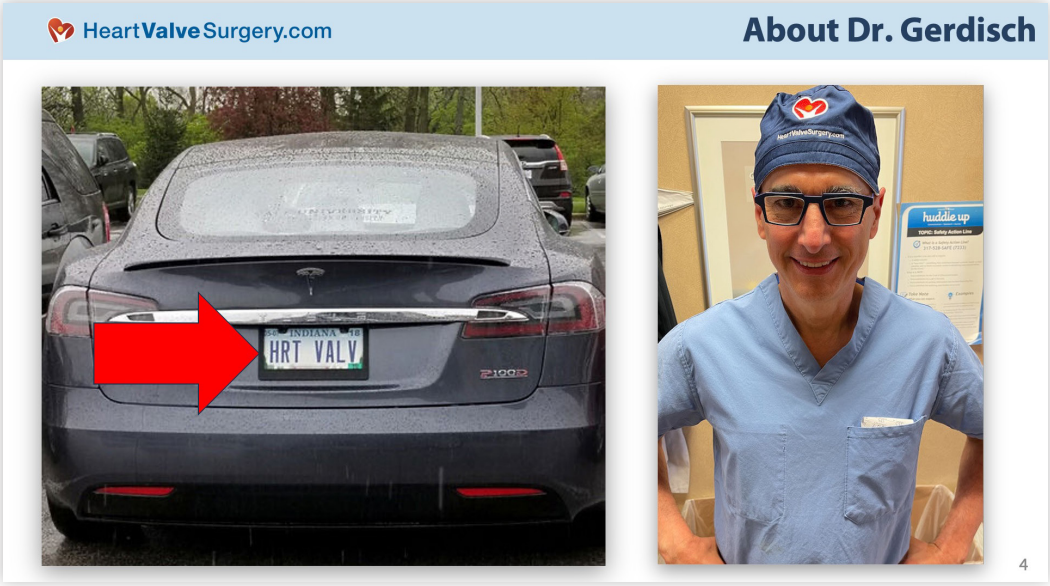



Let's look at the agenda for today. I am going to introduce our featured speaker, we are then going to get very interactive with a "Q&A Session", and then I'm going to ask you to complete a very quick five question survey as we wrap up the webinar.

When it comes to the featured speaker, I am humbled that he is taking time away from his very busy practice in Indianapolis, Indiana.




Dr. Marc Gerdisch is the Chief of Cardiac Surgery at Franciscan Health in Indiana at Indianapolis. He's performed over 6,000 cardiac procedures. When it comes to valve surgery, Dr. Gerdisch has performed over 4,000 heart valve repair and heart valve replacement procedures. He is focused on minimally invasive techniques, atrial fibrillation and he has a very deep understanding of rapid recovery protocols. Why? Because he wants to get his patients back to their normal life as soon as possible.




When I talk about Dr. Gerdisch to people, I often talk about his commitment to valve disease. You might be wondering how committed is he? Well, his license plate reads, “Heart Valve”. When we came out with our scrub cap, who was one of the first people to put it on and take a picture, it was Dr. Gerdisch.

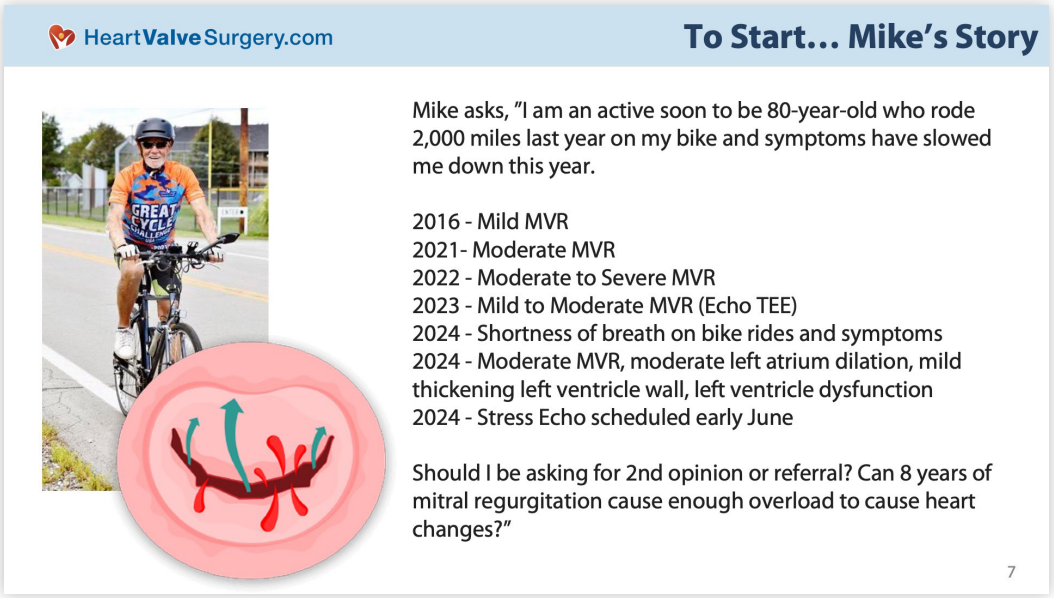
I don’t know where HeartValveSurgery.com would be without him, because he has been so responsive, so proactive with our community.  Whether it is creating educational content with us in articles or videos. If I ever need anything, Dr. Gerdisch is there to help. He’s not just helping me. This is what I think is most important about Dr. Gerdisch… It’s the results that he gets for who?


For all the patients in our community. What you see here are actual patients from HeartValveSurgery.com who have found their way to Dr. Gerdisch, whether it's Linda or Todd, or Tim or Janelle or Nina. He's got over 130 reviews and testimonials from patients at our website.

This is why I just I've loved working with you, Dr. Gerdisch, and I can't wait for today's webinar to share all the good information that you have. On behalf of our community, I'd like to thank you for being here.


**Dr. Marc Gerdisch:** Thank you so much, Adam. It's a lovely introduction. It's my pleasure. This is my favorite talk that we do because it tests my knowledge a little bit. I don't have to prepare because we're not talking about one topic and I really enjoy experiencing the depth of understanding actually that folks have about their own conditions and how they explore their conditions. I'm glad to be here. Thank you.

# Mike's Mitral Valve Story




**Adam Pick:** Let's not waste any time because we only have so much of it today. I thought Dr. Gerdisch, this would be a great question to set the context and the tone for today's session and for valve disease in general. This comes in from Mike. He says, "I'm an active soon to be 80-year-old who rode 2000 miles last year on my bike, and symptoms have slowed me down." You can see here over a period of about eight years, he's gone from mild to moderate and now his doctors are saying, "Hey, you know something for that mitral valve regurgitation. Let's get a stress echo to learn a little bit more." He's asked the question, "Should I be asking for second opinion on referral?" I think another great question he asks is, "Can eight years of mitral regurgitation cause enough overload to cause heart changes?"

**Dr. Marc Gerdisch:** Very good question and really great information because we have a timeline. That's super useful to us in this conversation. We also have a picture of a guy that looks better than I do. On this thing, when I get on a bike and I'm near 80, I want to be anything remotely like that. There's so many interesting facets to this. One is folks who are in really good shape tend not to get symptomatic very early because they have a lot of reserve. It's almost a challenge in people that are very healthy, have good muscle strength, they have great aerobic capacity. It takes a lot to set them back and it's important to do what they've been doing with Mike, which is to monitor and look regularly. You can see once they identified moderate in 2021, they stepped it up. Then you've got this unique scenario where in '22, moderate to severe, mild to moderate in '23. Why is that? You have to assess that. You would want to look at the two studies closely.

Then in '24, now he's got symptoms and his symptoms are going to be real because this is a very fit person who knows his own physiology. His most recent echo shows us moderate mitral regurgitation, moderate and larger than left atrium. The things that I'm most concerned about are the words left ventricular dysfunction. That in and of itself, is likely an indication to fix the valve. In moderate mitral regurgitation, some of this is a little bit in the eyes of the beholder. I mean, you try to measure it. There can be multiple jets, there can be reasons that it quantifies in the moderate range and doesn't quite crest into severe. In severe mitral regurgitation, we're always looking at other indicators. Does a person develop atrial fibrillation? Do they have tricuspid insufficiency? Do they have elevated right-sided pressures or do they have dysfunction of their heart, their muscle? He's probably already ready to have surgery based on this. I'd have to see the images and look at the jets and understand the anatomy.

I think a stress echo is a perfectly reasonable thing to do though, because it will establish what happens to the amount of mitral regurgitation when he exerts himself and put the equation together where the exertion increases the MR, makes him symptomatic.

As far as second opinion, I think they're doing a pretty solid job but it does look like this is matured to a situation that needs to be addressed. It reminds me, I had a guy about eight months ago, 94 years old bike rider. To be honest, because he was 94 people weren't ushering him into therapy. When I met him I said, "Well, let's just fix your valve." We did a minimally invasive mitral valve repair and he is riding his bike again.

Chronologic age, certainly obviously in this case is not the issue. It's a matter of just deciding whether the regurgitation is quantifiably bad, which it looks like it probably is, and if there is an impact and it does look like the left ventricle is starting to have dysfunction, so probably time to do something.

**Adam Pick:** Dr. Gerdisch, I'm sure many people on the line like me are curious to know. You mentioned a 94-year-old. Do you know offhand what is the oldest person that you've performed cardiac surgery on?

**Dr. Marc Gerdisch:** Yeah, I think 96 was the oldest person. It was actually a girl and she was aortic valve and bypasses. Again, chronology isn't the key. It's this full assessment and it's also somebody's drive and what their interest in staying alive is and how in the game they are. It gets weighed against the complexity of the operation, the morbidities, the potential complications, but age is relevant but it isn't a final determinant.

# FiberTape and Rapid Recovery Protocols


**Adam Pick:** This is a great question coming in from Jerry. She says, I'm a 64-year-old woman and I work full-time. I have severe aortic stenosis, a narrow or blocked valve. I have allergies to metal. Is there a non-metal closure? Have you heard anything about Arthrex fiber tape?

Dr. Gerdisch, I had to show some of these videos of your patients. I think they're in their early recovery - maybe post-op day zero. I know that this is near and dear to your heart. Maybe we can talk a little bit about your protocol as well.

**Dr. Marc Gerdisch:** Of course. Actually I should be carrying my phone around every day because every day I'm amazed at what people are doing. As many people know, we have been extremely aggressive about absolutely stabilizing the entirety of the sternum when we have to do sternotomy, when we do sternotomy, because minimally invasive surgery is wonderful. I do it all the time, but we still have to do a lot of surgery through a sternotomy. Our goal was to level the playing field, that the experience would be the same whether a person had a sternotomy or they had minimally invasive surgery. That way we were always sure we were doing a complete operation, we were always sure we were giving them the full operation and they would have the same experience. We're actually working on the incision now too.

This is a great question because it layers into a couple of important things. When we made this shift several years ago, we saw a steady decline drop in how long people stayed in the hospital. We saw essentially an elimination of the use of narcotics and we saw a dramatic decrease in the number of people that had to go to extended care facilities.

This lovely 82-year-old woman here who's post-op day two and goes home, post-op day four went back to work three weeks after surgery. She didn't go to a rehab center. We're very driven to make sure that people are back in action.

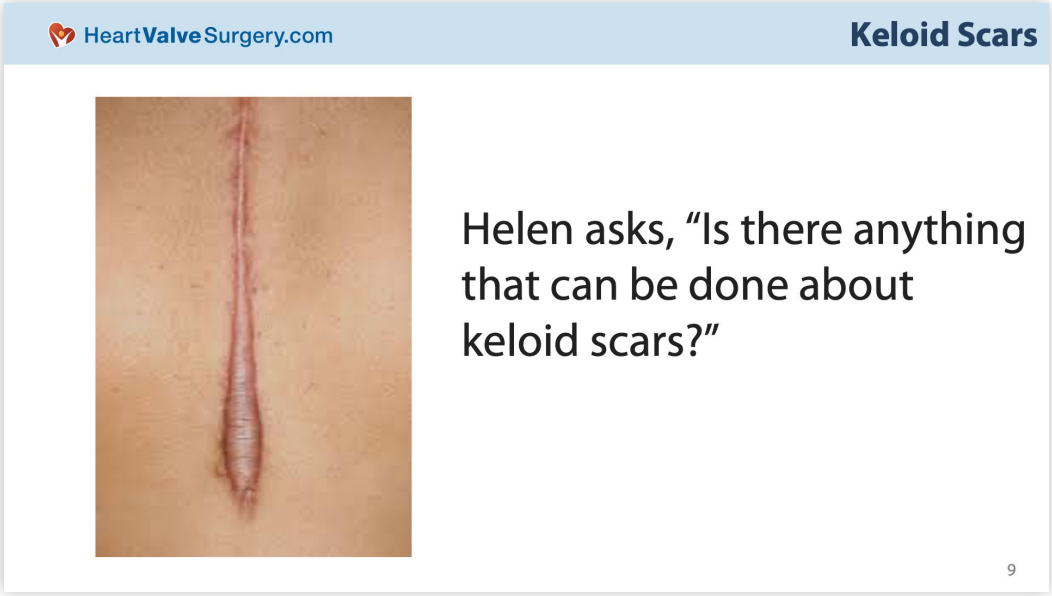
Fiber tapes are super cool. We've started using them the last few months. I've developed a relationship with Arthrex. I like those things so much. We're actually looking at new platforms for sternal stabilization and one of those platforms

is absent any metal, but the fiber tapes are definitely a very good adjunct to sternal closure. For us, it wouldn't be all we would do because we always do rigid fixation. We always completely fix the sternum so that it can't move with an orthopedic repair.

Fiber tapes versus standard wire cerclage is a big upgrade. The tapes are wider, they don't cut through the bone, they get better compression, and they lie flat. There's no twisty things on the wires to stick up and get in the way and for people to feel they're very flat. As is mentioned, there's no metal. Now, I would advocate though for Jerry that she be sure that she has a reaction to titanium.

Titanium is incredibly inert and the plates and screws that we use at present are titanium. I would even say that if Jerry were to get a sample, she could come in contact with it, maybe put it on her wrist or something and just spend some time with it there and see how she feels about it because it is that dramatic an improvement in recovery if you can get an orthopedic repair. If you can't do that, fiber tapes alone done well is a very nice step up from standards cerclage. Bravo to you for even knowing about it, Jerry, because we've just started to explore this and it's being used now. It's starting to pick up some steam, but it's just being used in a few centers around the country.

# Keloid Scars




**Adam Pick:** The next question is from Helen. I probably get this Dr. Gerdisch about 50 times a year. Helen asks, “Is there anything that can be done about keloid scars?”

**Dr. Marc Gerdisch:** This answer has two parts. I'm interested in this too because it's the last hurdle. If we can make the scars disappear or we can make them so subtle that you can barely see them, then we really do change the entirety of the psychological impact of the operation because we've already dealt with the pain, we've dealt with the mobility, people are able to go back to work, they're able to do this and that, even when we do a sternotomy but they still have a scar. There's just a little, it's not a traumatic; it's not a huge trauma but there's still some opportunity there to do something better.

Keloids are particularly challenging. There is a genetic component to keloids, so some people are going to get keloids no matter what you do. The question is, "Can we do a better job of healing incisions overall?" The answer to that is yes. I mean, look at plastic surgeons. What do plastic surgeons do? They have all kinds of gimmicks and devices and tension releasers and things that they put on incisions. Now we can't do exactly what they do because we have to think about reentry and the size of the incision and tension on the tissue but that doesn't exclude us from making steps.

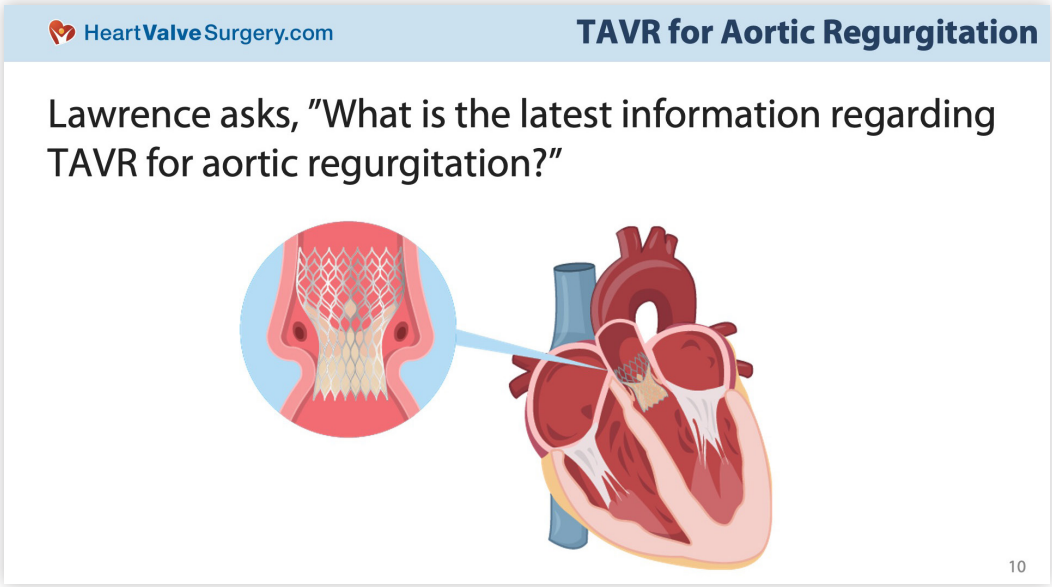
The things that we've done so far to try and make the soft tissue part better is we use a special type of suture that is a barbed suture that actually when it goes through the soft tissue, which would be the fat and muscle, that you can't back out. First thing we wanted to do is get all those layers to be really close to each other. Then for folks that would tend to hollow out that tissue, we actually use a powder that acts as a glue, so then now we've built up.

Now we're building up from the bone. We've got that bone stabilized, we're building up for the bone going through the soft tissue. We get to the skin now. The skin, we're actually looking at some technology now, and is actually related to Arthrex.

The same company has a type of skin closure patch at the end of the case that really looks like it enhances tissue healing, diminishes the risk of scarring and diminishes infection risk. It's got everything you want. Actually, it has a charge to it. It has an electrical charge to it that's chemical and it appears to stimulate the healing of the tissue. We're looking at that now. We're looking at that last hurdle, and it may help with folks who tend to form keloid.

The things that you have to do to diminish keloid scarring are you have to get the tension off the incision because any tension causes to spread a little bit and form the keloid. The other is to just diminish the inflammation there and that's part of what our goal is with that process. Then if somebody has a scar that's really driving them crazy, I don't think it's inappropriate to seek, if it's late in the game obviously, to seek input from a plastic surgeon and see if they want to optimally treat the skin, because now everything else is healed so if they want to optimally treat the skin.

# TAVR for Aortic Regurgitation

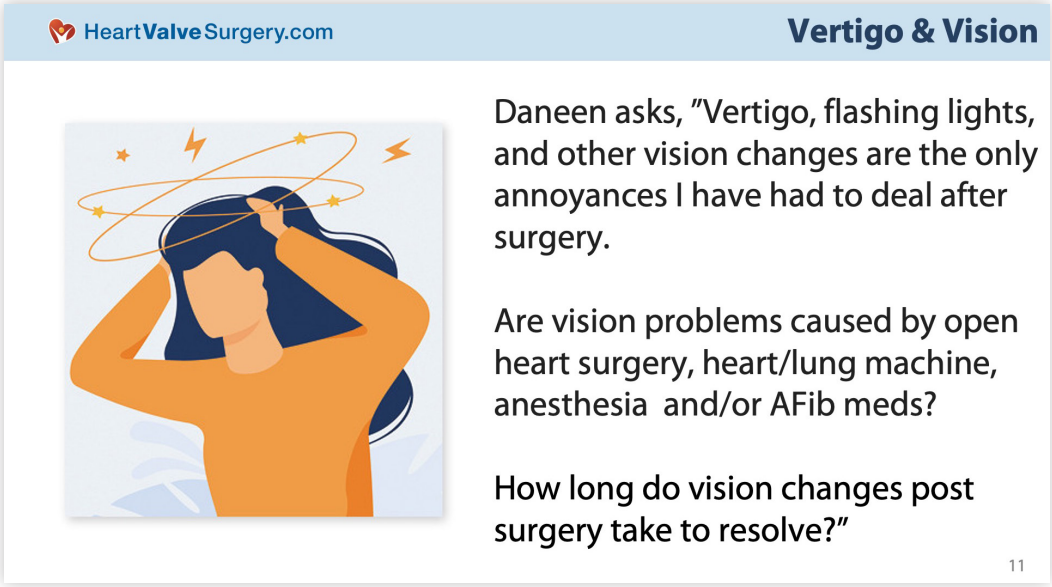



**Adam Pick:** We've seen this tremendous increase in the use of TAVR over the last 15 years or so. I think cases have gone from about 4,000 in 2012 to over 100,000 last year. That's really, as far as I know, been for aortic stenosis primarily. Lawrence asks, "What is the latest information regarding TAVR for aortic regurgitation?"

**Dr. Marc Gerdisch:** An important question because we haven't heard much lately. Yeah, it's true the TAVR ride has been a wild ride. It's been amazing, the explosive growth of the devices. I actually spoke to Dr. Steve Yakubov, who is a cardiologist in Riverside recently actually getting caught up on this because it's still a study valve. The one that's been in the study in the US is called the JenaValve. It's actually spelled with a "J" from Jena Germany. That valve is a very elegant device that when it's dropped in, it nestles into the valve and it grasps the leaflets. It has to be positioned perfectly. When it is seeded perfectly, when it's deployed perfectly, it works very well. It has some very particular constraints with respect to the fact that it's delivered in a large tube, larger than we presently use for transcatheter valves, which is usually not a problem to people who have aortic insufficiency ("AI") because they tend not to have vascular disease. The angulation of the aorta, the position of the aorta can make it tricky to seat. Then it only goes up to a certain size of the annulus. People with AI typically have big annular. Those are all things that will strict the ability to implant the device.

After several years, they finally enrolled 180 patients in the study. That data was presented recently at the TCT meeting and it looks pretty good. It's not ideal. You have a little bit of a high pacemaker rate because the aortas could be frail in these patients. They had a couple of people have aortic injuries that were important but they're definitely headed in the right direction. Presently, they're moving toward getting it cleared for use by the FDA, but the FDA, of course has to assess all these properties of the devices and it will stay in limited release for a while but eventually I think it's going to make it to the market. There's another one called the J-Valve. There's the JenaValve, which is Jena, and the J-Valve. That valve is just getting into the US market. I think it's an Asian product. It has some properties that might make it easier to implant. That's where we are. It took a long time to enroll the patients. The AI isn't as frequent. Most of those patients are good surgical candidates, but it is making progress.

# Post-Op Vertigo and Vision




**Adam Pick:** Daneen asks, "Vertigo, flashing lights, and other vision changes are the only annoyances I have had to deal with after surgery. Are vision problems caused by open heart surgery, heart lung machine, anesthesia, and or AFib meds? How long do vision changes post-surgery take to resolve?"

**Dr. Marc Gerdisch:** Something happens. It was temporally related to the operation. I didn't have it before. I've got it now, so probably it's related to what that patient just went through. Let's face it. Heart surgery is a big deal. That's true you're on the heart lung machine. It is not terribly uncommon for people to have a little bit fuzzy vision right after surgery. It doesn't have a lot, but it happens.

I think most of that is actually driven by edema. You have some extra fluid in every part of your body, and it resolves on its own. That's typically what we see.

A persistent vision change has to be evaluated by an ophthalmologist, especially being accompanied by flashing lights. What could flashing lights be? Flashing lights could be retinal detachment. Flashing lights could be mini strokes. I know that sounds terrifying and alarming, but the truth is flashing lights can be those things. Probably aren't in her case, but can be those things.

Then vertigo, vertigo is a really tough thing to deal with because you have to be able to winning it down to the mechanism. Vertigo can be due to low blood pressure that you're not aware of, your blood pressure drops, or changes in your heart rhythm that you're unaware of. Vertigo in and of itself has its own algorithm for management, for assessment and management.

Daneen is going to have to get all of those. The relationship to the surgery is a little bit hard to tag on because this is an unfortunately, or I should say fortunately, it's a very rare scenario. I have to say that Daneen's going through, but clearly she has to deal with it. Do I think it's specifically from one aspect? I really couldn't say, and I don't know.

AFib meds, no. Only though, got to look at the rhythm. If you're on AFib meds, are there times when your heart rhythm is changing, causing the vertigo? I assume if you're having AFib meds that you're on a blood thinner. If you're not on a blood thinner, the flashing lights could be thromboembolic events from atrial fibrillation.

First thing for me would be to converge on looking at the things that could really be devastating to me that could drive this, could be the rhythm thing. could be the AFib, and then expanding into assessment for each of these as a separate component until you narrowed it down and treated it. Vision changes.

# Scar Tissue on Heart Valve Replacements


**Adam Pick:** Karen asks, "I received a cow valve replacement in 2019, which only lasted three years. Scar tissue was found. The doctors were not able to do a TAVR valve-in-valve. The valve was re-replaced again in 2023 with a cadaver valve. Please explain the development of scar tissue after a heart valve replacement. Is it the biological valve or the patient? What are the odds of me forming scar tissue again?"

**Dr. Marc Gerdisch:** This is a great question. That valve actually probably has a combination of scar tissue and then deterioration. You can see the calcification in the leaflets and actually a perforation leaflet. Also, if we flipped it over, you would probably see some scar tissue that developed underneath it.

If we're speaking specifically about the scar tissue, we generally refer to that as pannus ingrowth. It happens as tissue encroaches from the annulus underneath the valve. We could have a very long conversation about this because it's super interesting. I'm going to try to narrow it down to just a few components. It is a fairly common occurrence. I have seen it with tissue, surgical valves, and TAVR. It is a process whereby that tissue, that scar tissue grows in until it gets onto the leaflets, and then it prevents the leaflets from moving. It's happening on the underside of the valve.

There are two things. One is just that cut edge of annulus, which is debrided tissue, it's active, it's inflamed, and it may promote the growth of tissue from it. The other is that typically when we implant a valve, we use a little bit of a Teflon pledget. We use very, very tiny ones. Some surgeons use very big ones. Those pledgets engender inflammation and probably promote some of that panacea growth in just some people, but it does happen.

If we can minimize the amount of material on the undersurface in the annulus, then we might diminish the panacea growth. We've actually been looking at that lately by even redesigning the sutures so that we can get purchase of the tissue. We have the support like we do with a pledget, but we have less of that bulk and less of that material there that might promote it.

Now, the fact that I've seen it in a TAVR means it's not just that, because TAVRs don't have any sutures or pledgets. That means that there's active growth from the tissue. That's partly the biology of the person. It's partly how big the valve is. It's partly how the annulus relates to the valve.

For example, you've heard me talk about the On-X mechanical valve, which we've done a lot of studies with. One of the advantages of that mechanical valve is that it has a skirt of pure carbon that drops down through the annulus of the valve, and it excludes it. The annulus, if it tried to grow pannus in, it would have

to grow it down, and underneath the skirt, and back up, which is extremely unlikely. There are some aspects of valve architecture that could support not developing pannus ingrowth.

It's an interesting choice to go on to a cadaver valve, and I'm sure there was a reason for that. They perform really well hemodynamically. They're a little bit challenging as you get remote from the implantation with respect to how you manage them if you need another valve, but they are hemodynamically beautiful. We use them almost exclusively for endocarditis patients who have infections. But I've never heard of pannus ingrowth in a cadaver valve of a homograph. I've never heard of that. That is a way probably to solve that particular problem.

**Adam Pick:** Dr. Gerdisch, quick follow-up. We get a lot of questions from patients. A lot of them normalize around the question of durability of a bioprosthetic valve. How long is a pig valve going to last? How long is a cow valve going to last? Here, Karen had a situation that was only three years because of the scar tissue. Is this an anomaly? Is this an outlier? Does this happen regularly?

**Dr. Marc Gerdisch:** It is a little bit of an anomaly. If we look at valve durability, it's definitely a bell curve. You've got this tail on the short-term end that there's just a few, there's a smaller number of patients. Then we have the center, and the durability center of tissue aortic valves is 10 years.

Now, remember that whole thing shifts based on the person's age and their biology. A person who is young and/or has cardio metabolic disease would have a shorter lifespan for their valve. Also, it shifts based on the size of the valve. If you have a big valve relative to your body surface area, then the valve tends

to last longer. You get more time with the valve because as it stiffens or fails, it takes longer for it to get to a point where the hole is actually small based on your body surface area, which is why we try to always upsize, always put a valve in that's a little bit bigger than the patient actually needed. That's true obviously for tissue valves.

Now, pig versus cow tissue, this is a tug of war that we've been going through for a long time. I think now, the real importance is decision-making that tailors the long-term plan for the patient. In some folks, a cow or pig tissue valve, they're going to behave a little bit differently biologically, perhaps, but they are really neck and neck with their durability.

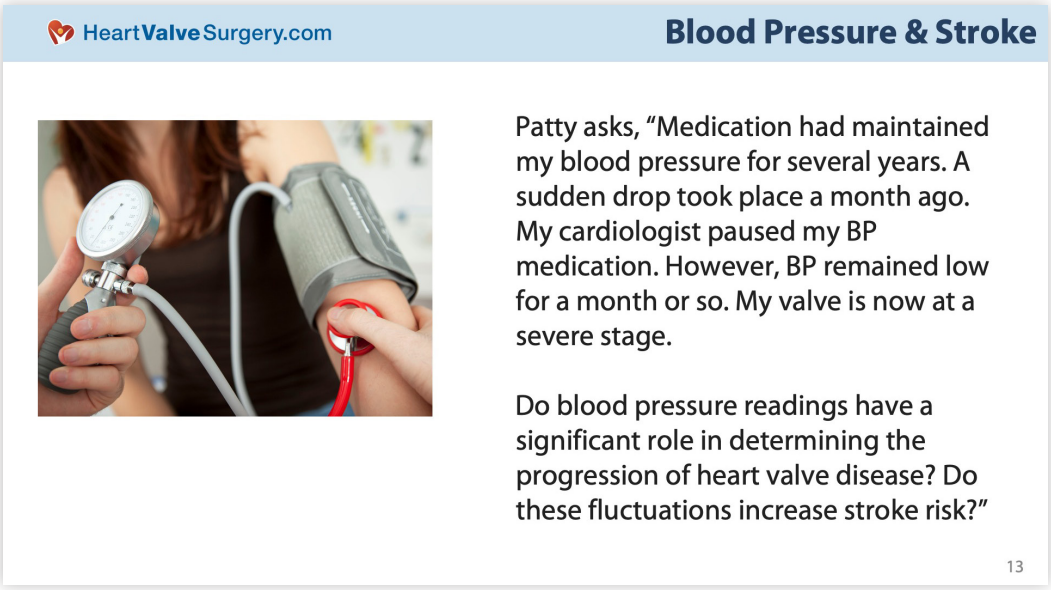
Now, we do have some newer technology that folks think is going to last longer. We haven't proven that yet in the pericardial valves. We also have some advancements in the pig leaflet valves that have to do both with durability and with the opportunity to do a valve-in-valve later. That overlaps with the architecture of the aortic root.

When we talk about all of this, it has to be folded into what the long-term plan is for the patient. For example, somebody is 70, and this is easy, they're 70 and they're getting a tissue valve. They have longevity in their family. They're 70, so they might get 14 years out of that valve. Now, they're 84. They need another operation. This is a good valve-in-valve. If you put a big valve in there and they have room in the aortic root for it, which one would they have gotten? Which tissue valve?

Depending on the aortic root, that might actually make a difference because the porcine leaflets, the pig leaflets, when we put a valve-in-valve inside them, those leaflets stay a little bit lower. That actually makes it a little bit easier to be sure that we have blood flow to the coronary arteries when we do the valve-in-valve. Whereas the bovine or the cow tissue, it sits a little bit higher when we put a valve-in-valve. It may have no consequence if they have a generous aortic root, but if they don't, it can have consequence.

Therefore, we see patients that – now it's time for their valve-in-valve, and we look at the architecture. There's no room, so they get another operation. It really depends on all of those components. I don't know which horse is the winner. I know what makes sense when planning the long-term framework for the patient's life. Sometimes it's not a tissue valve. Sometimes it's a mechanical valve.

# Blood Pressure and Stroke




**Adam Pick:** Patty asks, "Medication had maintained my blood pressure for several years. A sudden drop took place a month ago. My cardiologist paused my blood pressure medication. However, my blood pressure remained low for a month or so. My valve is now at a severe stage. Do blood pressure readings or have a significant role in determining the progression of heart valve disease?" Another common question is, "Do these fluctuations increase stroke risk?"

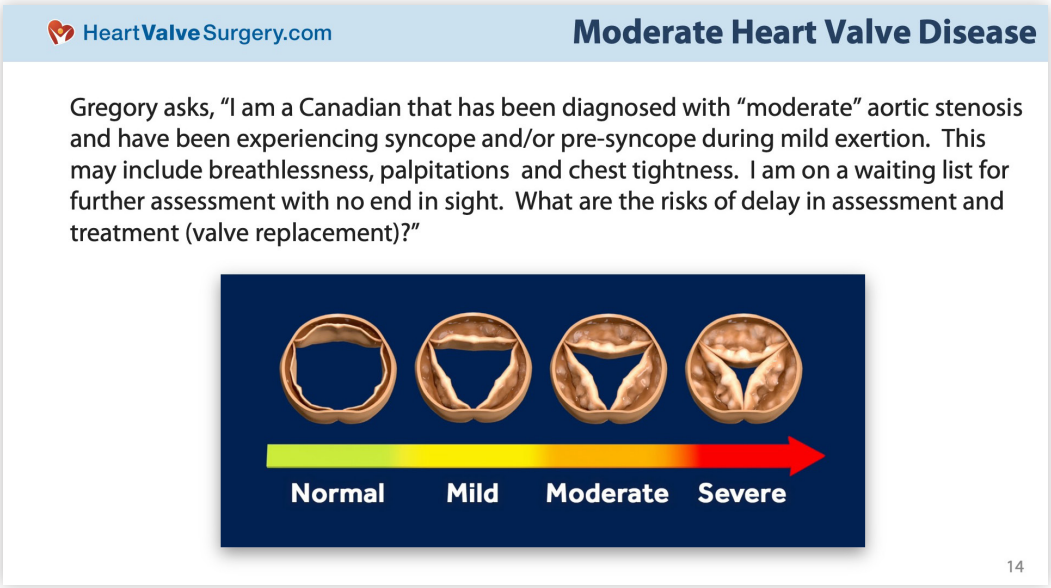
**Dr. Marc Gerdisch:** Good questions. Having your blood pressure drop during the progression of aortic valve stenosis, it can actually be a little bit ominous because – I don't want to alarm Patty. She probably feels okay. Think of it this way. Your blood pressure is a measurement of two things, the forward flow of blood out of your heart, and the resistance in your vascular system.

As your valve is getting more blocked, you might have some diminution, some decrease in the amount of forward flow, and the system, your vascular system will tighten up a little bit to compensate. If you need blood pressure medication, and then all of a sudden you don't, what's going on there? Your vascular system didn't change. You still have the same blood vessels that you had, but your aortic valve has gotten tighter.

Your heart is no longer driving the pressure as much. It's not an alarm like, oh my gosh, I need to go to the hospital. It's a, let's do a very nuanced evaluation of the echocardiogram. Let's understand how the ventricle is functioning. Try to really assess the cardiac output.

Then probably, you already know the valve is severe. Maybe step up the pace a little bit in evaluation and treatment for this valve now that you've had a blood pressure change. I think this is a little bit of a signal that it's time to be very serious about it. As far as stroke risk, no, unless your blood pressure really drops, and that precipitates the lack of blood flow to the brain, obviously.

# Moderate Aortic Stenosis




**Adam Pick:** We talked a little earlier on Mike's story about moderate mitral regurgitation. This is another topic in the moderate realm, but moderate aortic stenosis. I've been getting several more questions about this lately. This one comes in from Gregory who says, "I'm a Canadian that has been diagnosed with moderate aortic stenosis and have been experiencing syncope and/or pre-syncope during mild exertion. This may include breathlessness, palpitations, and chest tightness. I am on a waiting list for further assessment with no end in sight. What are the risks of delay in assessment and treatment, meaning valve replacement?"

**Dr. Marc Gerdisch:** This is a very timely question, because we have some recent studies looking at moderate aortic stenosis and the implications of treating it earlier. Whereas I become a little concerned when we talk about treating moderate aortic stenosis because I don't want everybody who has moderate stenosis to rush in and think they need their valve replaced, or fixed, or whatever.

I don't want clinicians to abandon our history of management of aortic valve stenosis in favor of moving on them earlier for everybody with moderate aortic stenosis.

That said, someone who has moderate aortic stenosis and is symptomatic almost definitely, unless there's some other reason for them to have pre-syncope, almost definitely needs a valve treated now, not tomorrow, but in the next several weeks, or maybe a couple of months. I give you a couple of months. But syncope is not – that's not something you play with.

Syncope, folks, is passing out. If it's not driven by something other than the valve, then the valve needs to be treated. This also comes on the heels, though, of, like I said, a couple of other recent studies looking at very large populations of patients, trying to understand the impact of moving earlier on moderate aortic stenosis.

There was an interesting study came out of Cleveland Clinic, looking at, I think, 1,400 patients. They found in 1,400 patients with moderate aortic stenosis, is how I remember it, about 22% of those patients with moderate stenosis had had their aortic valve replaced, 75% of those were SAVR, surgical valves, 25% were TAVRs.

Then they looked at how the two groups behaved, if they had their valve replaced with moderate aortic stenosis, or if they were followed for their moderate aortic stenosis. It's a 10-year study with about a median follow-up of about six years. That six years is a pretty good chunk of time. Survival was better for the people who had their valve treated.

That's an overall look. You would have to drill down on specifics of what actually drives that. One of the things they recognized was that the people who had their valve treated had improvement in their left ventricular ejection fraction. They had a decrease in their right sided pressures. Those are signals that that means that there was already impact on the heart. It just wasn't recognized that it was just that valve.

For example, right now, an indication to do aortic valve replacement in severe aortic stenosis reads severe aortic stenosis with symptoms or severe aortic stenosis with a decline in left ventricular function. If the people who had their valve fixed had an improvement in left ventricular function when their valve was fixed, it means they had a decline in ventricular function back here.

It's going to be these subtle changes, looking at the dynamics of the ventricle, how thick it is, how well it relaxes, what the performance parameters are. Are there any changes in that? That's why their current recommendations for moderate aortic stenosis are an echo every two years. I disagree. Moderate aortic stenosis gets an echo every year, because we want to know if we can, we want to know about the changes in the heart.

My response to Gregory is that if indeed these symptoms are related to the valve, it needs an aggressive assessment now in consideration for intervention because syncope is – we see syncope for aortic stenosis, we treat it. Then there's this broader swath of patients with moderate aortic stenosis that we just need to keep an eye on to make sure we're timing things properly.

# Mechanical Valve Replacements


**Adam Pick:** Jerry asks, "Are mechanical valves taking sort of second place in the world of heart valve surgery?"

**Dr. Marc Gerdisch:** Folks are asking these questions that are so timely. For a heart valve enthusiast, they really are the things I like to talk about. If we were at a cocktail party, we'd be talking about the same stuff, my poor wife. The reality of it is that it's true that if we look at overall what's happening in valve management, there's been a shift toward tissue valves. There's an explosive growth in transcatheter valves. We can talk about that and the consequences of having to take some of those out.

Then there has been an overall decrease in the use of mechanical valves. It hasn't been quite as dramatic as you might think, though. There are still mechanical valves going in, of course. Roughly, 20% of my patients that have aortic valve replacement still have mechanical valve implanted. One of the reasons is this valve. The On-X valve, we just published data for both one year and five years of registry data for the On-X valve. Before that, we had 10 years ago, a decade ago, we finished a study to show that this valve could be run at a lower dose of Coumadin.

What's the problem with having a mechanical valve? The problem that people worry about is bleeding because you're on a blood thinner. There are two things. One is you have to check it. There's a little bit of annoyance. There's something you have to do. You have to take a pill. You have to check the blood thinner. But the real thing people are worried about is bleeding.

In the PROACT study, which we did 10 years ago, we showed a 65% reduction in bleeding events by managing this lower dose of blood thinner with no increase in other risks, no stroke increase. In the registry, we had an 87% reduction in bleeding risk, again, with no increase in stroke incidents or complications.

Fundamentally, what we have here is a valve that potentially lasts your entire life. It lasts your whole life unless it gets infected or some other catastrophic event happens. That we can run at a lower dose of blood thinner and almost eliminate the bleeding issue.

They have taken the second place, but I think we're seeing a little bit of an inching back for two reasons. One is we're learning that maybe planning tissue valves, and doing transcatheter valves, and tissue valves, and younger patients. As a society, we've paid a little bit of a price.

It's not devastating, but the redos, the valve-in-valves, the data, the follow-up on those and recognizing that, and some of these folks, these folks especially who have longevity. For example, bicuspid valves who don't have anything else wrong with them. People with bicuspid valve disease tend to live a long time, and they might be best served with a valve like this as long as they're willing to manage the anticoagulation. We're seeing a little bit of a swing back, and it's based on this data, and the opportunity that this particular valve provides.

**Adam Pick:** Mark asks "Will a surgeon prefer a particular type of mechanical valve simply because they are more familiar with it, so they can install it quicker, which means less time on bypass?"

**Dr. Marc Gerdisch:** Good point. My answer to that is the same always, which is that a heart surgeon should be able to implant a heart valve. It's true that, for example, the On-X valve is a little bit more – one surgeon once told me, and this is a surgeon that I love, he's a spectacularly talented surgeon. He said they could be finicky.

He's right, there's a little bit of attention to detail. There are some things with sizing. There are some considerations with respect to the implantation technique, which we who implant – I've only implanted this valve for almost 20 years. It's the only valve I've implanted.

Honestly, I'm a good surgeon, but I'm not. I'm just a heart surgeon, just probably only as good as the average heart surgeon. It's just a matter of knowing the details of the implantation. Could it take longer? It might, but it's on the order of minutes, several minutes maybe. I think that if somebody just familiarizes themselves with the technique, we who implant them all the time are always available to talk to surgeons that they should be all very comfortable in planning the valve.

It is also true that that was one of the things that led to resistance to this valve dominating as mechanical valve implantation. But slowly, that's turned as patients have become aware and surgeons have become aware that you can run it at a lower dose of blood thinner.

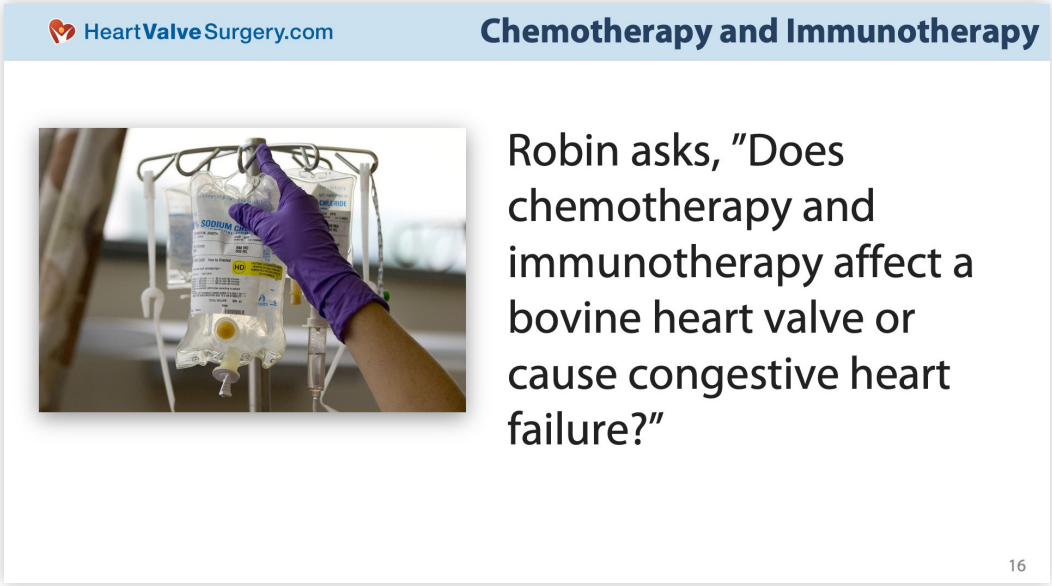
**Adam Pick:** Dr. Gerdisch, I know you're a very humble guy calling yourself an average heart surgeon specific to heart valves. I just want to ask you the question. How many heart valve procedures did you do last year?

**Dr. Marc Gerdisch:** Last year, probably just about 250. We have a broad spectrum of, from minimally invasive to multi-redo, multi-valve stuff. That's all I do except for some aortic work that is not valve-related.

**Adam Pick:** Correct me if I'm wrong, but getting back to your averageness, the average number of heart valve procedures, I believe, in particular, the mitral valve, as indicated by the STS, Society of Thoracic Surgeons is 5?

**Dr. Marc Gerdisch:** Yeah, so 5 to 10. Aortic valve is a little bit more. Folks have a little bit more experience with aortic valves, but mitral valve surgery, it's true. In general, a lot of surgeons don't get the opportunity to operate on them. But it's also why we have centers of excellence and places that focus on this approach of really being able to globally manage everybody with aortic valve disease or valve disease rather.

# Chemotherapy and Immunotherapy




**Adam Pick:** Robin asks, "Does chemotherapy and immunotherapy affect the bovine heart valve or cause congestive heart failure?"

**Dr. Marc Gerdisch:** Wow. Again, very timely. In the last several years, there has been this focus, and it's not just about valve disease. It's the focus on understanding the impact of chemotherapy and immunotherapy, cancer therapy at large on cardiac performance. One of my cardiologists that I work with very closely, Dr. Vijay Rao, is a world authority, a global authority on this, and has developed a program that has been recognized internationally for managing folks who suffer the consequences of, or preventing the consequences of chemotherapy on the myocardium.

It doesn't affect the bovine heart valve directly, because the bovine heart valve is basically, it's tanned tissue. It's inert. It doesn't have cell growth. It's not being affected by chemotherapy. Chemotherapy, though, when you think about what's its job, its job is to kill cells, particular cells, but kill cells.

Meanwhile, while it's going after those particular cells that are particularly vulnerable to it, it has some global impact on the patient. When you think about, for example, the GI tract where you have this rapid turnover of cells all the time, people get a lot of GI symptoms, but it will pass because those patients are able to regenerate those cells all the time.

You think of something that, for example, the heart. Your heart cells are your heart cells. We haven't figured out how to regenerate or develop, grow new heart cells yet. We're working on it. We're actually working on it in the valve space, and we have been. We're making some solid progress there, but we haven't perfected the ability to build new muscle. Human beings don't build new heart muscle.

If the toxicity of those chemicals affects the heart muscle, then the heart muscle will become weakened and people do develop congestive heart failure from them. There's a whole branch of medicine now, cardiology, that is focused on managing this.

# CardiaWave


**Adam Pick:** Let's talk about CardiaWave. Kerry says, "I met with Dr. Gerdisch in person one week ago before the ACC conference, American College of Cardiology, and asked him about the treatment process using sound waves. I really would like to try the sound wave treatment instead of having the tavern. Does Dr. Gerdisch have an update for us?"

**Dr. Marc Gerdisch:** It's an interesting technology, developed in France and Paris. They have a very limited number of patients that have been treated. They've had some interesting success with it, though. What is this? High-frequency ultrasound has been around for a really long time. It's a way to treat tissue.

You can create scar in some tissue if you want to. You can use it to break up calcium. You can use it inside blood vessels to break up the calcium side of blood vessels to open them up. We use it sometimes when we're doing transcatheter valves to open up a blood vessel that has a blockage so we can pass through it.

This is a particular application where high-frequency ultrasound is being directed outside the patient's chest into their heart valve. It's essentially vaporizing the calcium on the leaflets. It sounds very Star Trek, and that is. The interesting things are they haven't had any major strokes from it, which is cool because you're not getting big pieces of stuff coming off.

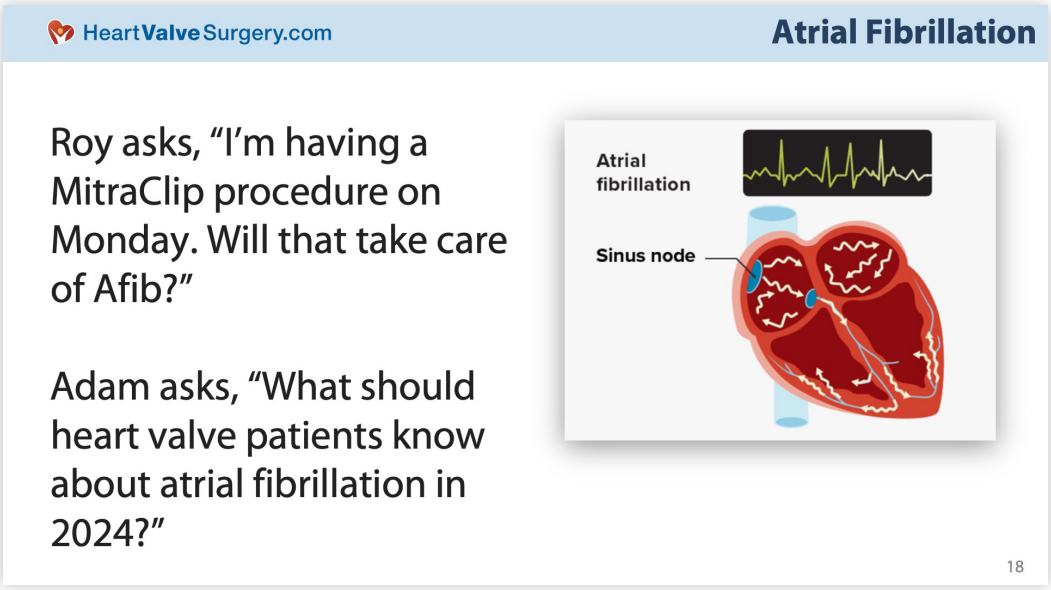
They have had some people that have gone quickly on to have surgery because maybe they develop aortic valve insufficiency or whatever. The interesting thing about this to me is that if we can get some long-term data, which is we're nowhere near it. My concern is that you morselize, you vaporize the calcium. Let's say you get a good result, the leaflets look better.

Now, how fast will they re-calcify? We don't know because that tissue is normal, and your body's already calcified it. You're going to re-calcify at some rate. I don't know what the rate is. But the really sexy concept is that if it's established as so safe that you can treat a person without any substantial risk, maybe this is what we end up treating moderate aortic stenosis with.

If somebody has moderate aortic stenosis, if it's so safe – now this is years from now, probably at least a decade, maybe 20 years from now. You go in, you get your therapy, it re-calcifies over a few years. You go in, you get your therapy. I'm just wondering if that might be something.

Its first role is going to be in folks that can't have heart surgery. That's where it might initially have a seat, or even a TAVR, whatever. Then after a while, as it gained some traction, it has some follow-up. It may become an available device, but we're way off, way, way off from this competing with our current technology, which is valve replacement or repair.

# Atrial Fibrillation




**Adam Pick:** Dr. Gerdisch, we know valve disease is often underdiagnosed. We know it's often misdiagnosed. We know it's undertreated. You can say a lot of that. Those same problems exist for atrial fibrillation, which could be a very dangerous related cardiac condition to valve disease. We got two questions here. First comes in from Roy. He asked, "I'm having a MitraClip procedure on Monday. Will that take care of my AFib?"

**Dr. Marc Gerdisch:** Roy, this is such a good question. I know I keep saying that, but again, timely. The answer is no, but I'm going to elaborate. It's a very interesting topic right now because the MitraClip, which is designed to treat functional mitral regurgitation in people who have a poorly functioning left ventricle so that we can keep them out of heart failure and out of the hospital has been expanded to use in what we would call the non-FDA approved world of using it for microaggregation that is not that, microaggregation that is degenerative, that is related to deterioration of the valve itself.

There are situations where that makes complete sense. In the course of a year, I might have a couple of patients that are elderly, very sick, very frail. We have a cardiologist at shake who can put these clips on, and I'll say, Saed, can you please just put a clip on this patient because doing surgery on this patient makes no sense? They aren't the one I talked about before. They're categorized in this other category, but they're also extremely high risk.

It has made its way into these lower risk categories. I don't know what Roy's situation is. I don't know what his ventricular function is. I don't know why they're doing the clip. Even if the mitral regurgitation is successfully treated, let's say they do the clip and they're fortunate enough not to have a leak, so you do the mitral clip, there's no leak, great. But the AFib won't be going away.

This is the same conversation we had with transcatheter valves. For example, I just had a guy in my office today, 79 years old. We evaluated him first for transcatheter valve, had severe aortic stenosis. It was an easy TAVR, but he had AFib. He had had AFib for several years, but he also remembered going into AFib and that what changed over time in his life.

We didn't do a TAVR for him. We did an aortic valve replacement in a maze for him, and I see came into my office today, basically telling me that the cardiology offices across the highway, he said, "I don't know. I was thinking about just walking over, but I couldn't find a way over." He's like, "I feel so good," because he's rid of the AFib and his aortic valve is working fine."

When we look at this now, there are ongoing studies looking at, for example, MitraClip versus their studies, looking at MitraClip versus surgery for degenerative mitral valve regurgitation that the place that surgery works so well that we do minimally invasive surgery for. That's fine with me.

But if you look at the population of people who have mitral valve disease, if you look at the MitraClip population, 67% of them have atrial fibrillation. If you look at degenerative mitral regurgitation, the folks that we treat all the time for surgery, almost 30% of them have, or maybe even 40% of them have AFib. We can't ignore the AFib. AFib decreases your cardiac output, causes strokes, causes congestive heart failure, even if your heart rate is controlled, damages your left ventricle, causes atrial myopathy, changes the architecture of your atria.

Now, there are going to be people that, yeah, maybe they're not supposed to have their AFib treated. Maybe they are so advanced and there's something going on, and there's not a reason to treat their AFib. But if you're going to fix the mitral valve, and the person has some reasonable opportunity for longevity, and they have atrial fibrillation, the surgical data, the preponderance of surgical data is so powerful that we now have a Class 1 indication in the guidelines, Class 1 indication for treating atrial fibrillation at the time of heart valve surgery. It's very hard to walk away from that.

Someone might say, we're going to put the MitraClip on, and then we're going to send them to the EP, and the EP is going to take them to the lab, and they're going to fix the AFib. Possibly if you have new paroxysmal AFib, but if we look at persistent AFib or people who have a substantial burden of AFib, they're not very successful in that realm, nor is that if we look at the data, we don't see that happening. In other words, people don't get MitraClips and then go on to the lab to have their AFib fixed.

My answer is that you have to really take a global look and decide how important the AFib is. It should be addressed at the time of the procedure if the person has quality of life that they're after and they have some reasonable chance of longevity. What patients with heart valve disease need to know in 2024 is that the Society of Thoracic Surgeons has made it a Class 1 indication that if you have atrial fibrillation at the time of going to the operating room for your valve surgery, the surgeon should treat it.

How will it be treated? That is a whole other conversation because different surgeons have different approaches to atrial fibrillation as a disorder. I teach that course over and over again, and we have these unbelievable conversations with surgeons from around the country. But it requires that you have real insight into the impact of the atrial fibrillation and it not be ignored.

The other thing they can think about with the MitraClip procedure, because now I've taken several out, is that sometimes we can save the valve and repair it, and other times we have to replace it. A valve that might have been repaired surgically, sometimes we're going to have to replace it because of the MitraClip. Those are all things to think about. This might be a perfect application for the MitraClip. I don't know the case, and it may well be that the AFib just shouldn't or couldn't be treated, but that would be the – I've given you the global assessment.

**Adam Pick:** I want to go right to Gary's question. It's incredibly specific in terms of what treatment means, because you referenced there's variable approaches to treating the AFib. Gary asks, "Is it common practice today in 2024 to close the left atrial appendage during heart valve surgery?"

**Dr. Marc Gerdisch:** Wow. I'm not even sure doctors would ask me these questions. This is something that we're looking at very intently right now. We did a study a little while ago called Atlas. We looked at the impact of closing the left atrial appendage in people who did not have a history of atrial fibrillation, but were at risk for it, so high CHAD-VASc score, factors that we recognize contribute to the likelihood of developing atrial fibrillation.

It was a pilot study to lead up to the study that is being done now, which is the LeAAPS trial. In that study, we're going to enroll 6,500 people from around the globe, and we will be closing the appendage of at risk patients in a randomized fashion, so one to one. It is not routine. It is routine for some surgeons to close all appendages. It's routine for some other surgeons to close appendage of people at risk.

There is not an indication. In other words, there is not an STS or ACC recommendation to close a person's atrial appendage at the time of open heart surgery if they do not have a history of atrial fibrillation. That recommendation does not exist. But now, there's a series of publications, including mine that have looked at that. We just published another one that Pat McCarthy's from Northwestern – I'm on the paper too, that looking at the data that exists out there in Medicare, in insurance databases for patients who had their appendage closed without a history of atrial fibrillation, and we did see an overall improved survival long term for folks who had their appendage closed. What's the mechanism for that? It's got to be related to stroke reduction.

That said, though, that is not a randomized control study. That's not going to get us across the finish line for closing the appendage and people who don't have a history of atrial fibrillation. That's why now we're doing this massive study that is going to answer the question. That's a randomization.

For folks who are having heart surgery, and if they fit into that category of risk, I would certainly would encourage them if they're at a center doing the study to enroll and study, because we don't have a hard and fast answer for this yet. We don't have an answer to enroll in the study and help us answer the question. If not, it's up to you to have a conversation with your surgeon about managing the appendage. Does it make sense? What the risks are and how does it compute into the operation? But at present, we do not have an indication for it, outside of it.

## 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 Heart-ValveSurgery.com film crew about heart valve surgery.