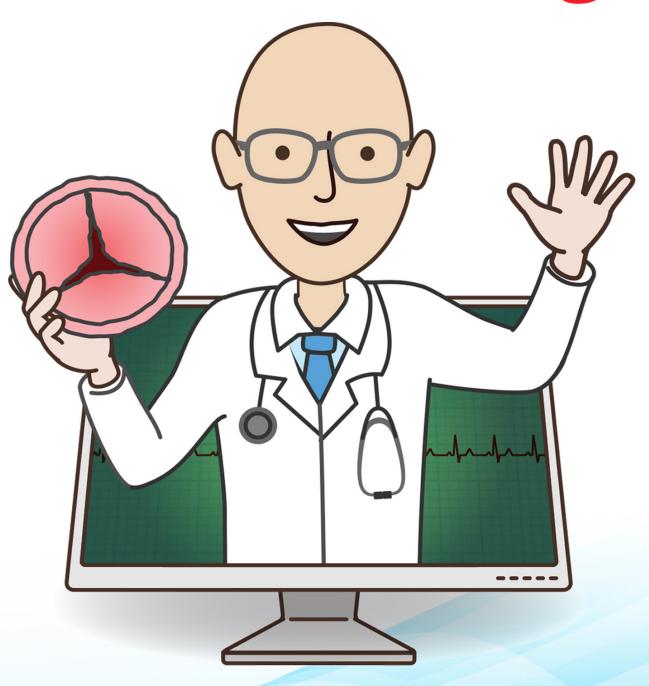


The 5 Myths of Heart Valve Surgery







Featured Speakers



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



Adam Pick
Patient, Author & Website Founder
HeartValveSurgery.com
(888) 725-4311
Learn More.





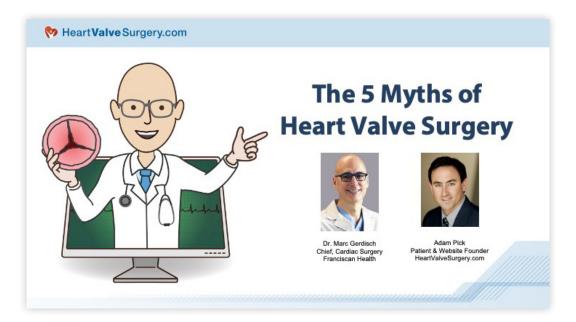
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Introduction



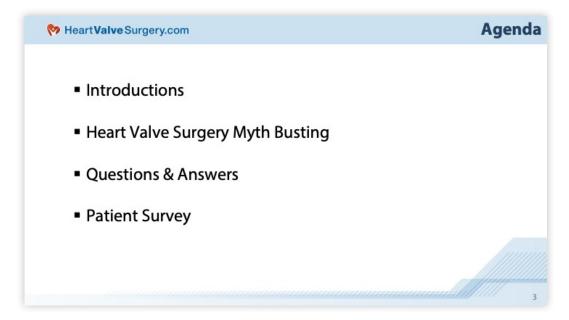
Adam Pick: Hi, everybody. My name is Adam Pick. I'd like to welcome you to the webinar, "The 5 Myths of Heart Valve Surgery". If I have yet to meet you, I'm the patient who started HeartValveSurgery.com all the way back in 2006.

Our mission here is simple. We want to educate and empower patients with heart valve disease. This webinar, which has had over 680 patient registrations from countries all over the world, was designed to support that mission. During the webinar, you're going to be in "listen-only" mode. I'd encourage you to submit your questions in the control panel that's on the right part of your screen because we're going to have a Q&A session.





Agenda



Adam Pick: Speaking of the agenda for today, let's go ahead and get into that. We're going to have some introductions. We're going to introduce Dr. Gerdisch. We're going to then get into our "Myth Busting" session. We're going to have those a live Q&A session, and then we're going to do a very quick five-question survey. That will help us enhance these events in the future.





Featured Speakers



Adam Pick: It's time to introduce the featured speaker for today. <u>Dr. Marc Gerdisch is the Chief of Cardiac Surgery at Franciscan Health in Indianapolis, Indiana.</u> He is our "Chief Myth Buster" for today and with great reason. He has performed over 6,000 cardiac procedures, of which more than 4,000 have involved some form of valve repair or valve replacement.

He is a researcher. He is an innovator, specifically in the field of minimally invasive heart valve surgery. Yes, his license plate is "HRT VALV". We share a similar obsession, and that is helping people with heart valve disease.





Patient Success Stories



Adam Pick: For Dr. Gerdisch, that obsession has yielded a tremendous benefit to the community at HeartValveSurgery.com. I've been fortunate to know Dr. Gerdisch now for about ten years. I consider him a friend. What I love about him most, not just that he is a great person, is the results that he gets for the patients all around the country and at our website. He was one of the first surgeons at HeartValveSurgery.com to have over 100 patient success stories.

Here you can see several of those patient success stories - whether it's John Pershinger or Angie Gregory, Tim Derloshon, Matt Shutte, Timothy Kennedy, Todd Runnebohm, Linda Kincaid and Nina Bamford. It is no doubt a huge honor for me personally that Dr. Gerdisch has taken time out of his very busy schedule to be with us today. With that, I'd like to introduce to the webinar, Dr. Marc Gerdisch.





Dr. Gerdisch's Welcome Message



Dr. Gerdisch: Good evening. Thank you, Adam, for that very kind introduction. It's absolutely my pleasure to be here. Of the lectures that I give, I think lecturing with patients is probably my favorite because they're the most invested and eager to learn. We thought that this was a good format because these are five of the things that are often presented to us as challenging concepts for patients. We could probably generate five more, but these are pretty common and interesting to people, so let's see what we have.





Myth #1: Mechanical Valves Are Not As Good As Tissue Valves



Dr. Gerdisch: Number one, mechanical valves are not as good as tissue valves. It's been an interesting process.





Over the past decade or so, there's been a very prominent drive toward tissue valves, moving toward valves that are not made of carbon, like the valve you see on the left, which happens to be an <u>On-X valve</u>, but for valves that are made from animal tissue. That includes <u>transcatheter valves</u>. The surgical choices are mechanical and tissue valves that are implanted surgically, of course, and then transcatheter valves. Let's look a little bit deeper.



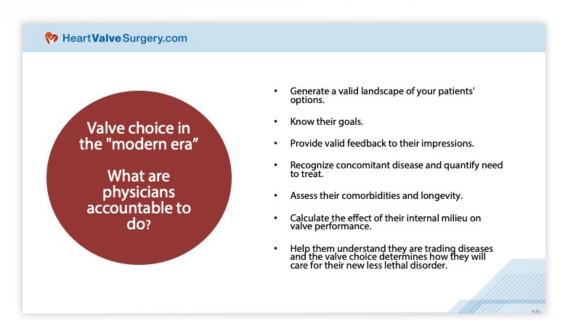


Like politics, medicine is local.

Patient management will differ in both subtle and obvious ways across institutions and even within them.

It's very important in all of these conversations about valve choice that people understand that medicine is local. Doctors and institutions behave differently across the nation. If you look at, for example, the likelihood of getting a tissue valve on the East Coast versus the West Coast, they are substantially different and different when you go south. Those subtle differences exist not just across the nation, but even within one hospital. You might talk to different physicians that have different perspectives on things. It's important that you learn what you want and that you understand what the choices are.





These are the goals that when I talk to other physicians that we have to recognize as important for the patient. What do we have to do in the modern era to be sure that we're giving the patient a full perspective? I'm just going to take a minute for this. We have to develop a landscape for the patients' options. We have to really understand the patients' goals and provide valid feedback to their impressions.

People come in with things they've learned on the internet. They've heard from friends. They've heard from other patients. We also have to recognize the concomitant disease and quantify the need to treat. This is going to come up later in the talk as well.





In other words, what are the other aspects of the patients' condition that need to be understood with respect to their impact on the person then and their longevity, and how it should be treated. Assess their comorbidities and their longevity. Put the picture together for them. Then calculate the fact of their internal milieu and the valve performance.

The type of human being that you put the valve in actually impacts the durability and the function of the valve. You have to take that into consideration. Help them understand that they are trading diseases. When we replace a valve, not when we repair them, but when we replace a valve, we are taking the really bad problem you have with the bad valve and replacing it with an artificial valve that has its own issues attached to it. It's a new disease that has to be managed.



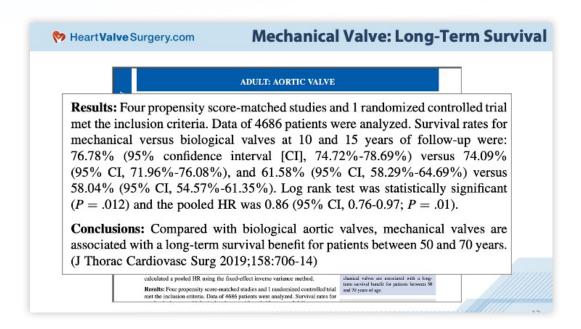


Match the long-term performance of the device with the longevity and personal vision of the person.

What do we know?

We have to match the long-term performance to the device with the longevity and personal vision of the person. That sounds simple and straight forward, but it really turns out to be something that has a lot of nuance. What do we know?

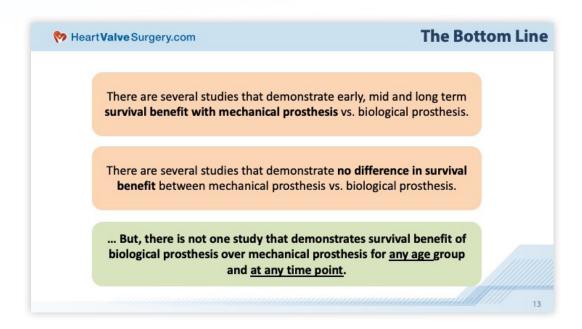




Because I'm not giving a lecture specifically on mechanical valves, which I could give an hour lecture on, I chose a meta-analysis. This is a recent study that looks at all the studies that were legitimately performed comparing mechanical and bioprosthetic valves. Let's see what they came up with.

The results from this propensity, score-matched study used the best studies they could find. When they were comparing biologic aortic valves to mechanical valves, the mechanical valves were associated with a long-term survival benefit in patients 50 to 70. If you slice that up that data a little bit and you change it to looking at just 65 to 70 or 60 to 70, you get into some gray zones.

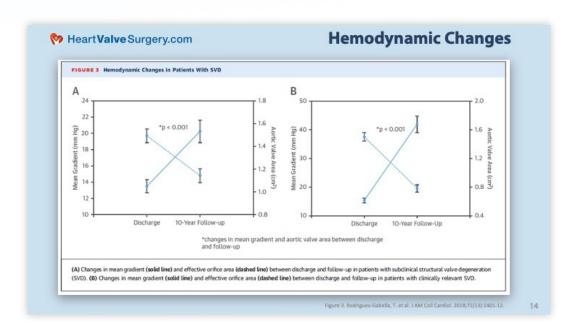




Overall, when we look at all these studies that have been done – remember, as a surgeon, I'm okay with whatever we decide, all the valves that are on the shelf. I can put a tissue valve in. I can put a mechanical valve in. We just have to come up with the right choice. Several studies have demonstrated benefit of mechanical valves in younger patients.

Several studies have demonstrated no difference in survival. There's never been a study that shows a survival benefit for tissue valves in younger patients. That's all there is to it. We can't do anything about that. We recognize that the technology is evolving. We recognize that there's opportunity in the future for things to change. The truth is we don't have a study that shows us that.

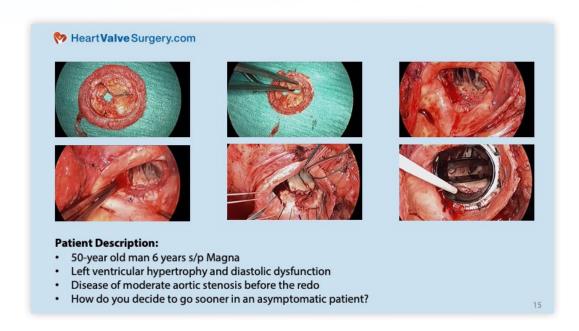




What is happening to valves? What happens to tissue valves? When a tissue valve goes in, as soon as it goes in, it starts to change a little bit. It starts to be affected by the body. This is a study showing us on the left subclinical and on the right clinical changes, meaning that on the left the patient has not become symptomatic. On the right they are symptomatic.

What it's showing you is that during that period of time the valve is changing. It's becoming less pliable. The valve has become stiffer. You have to recognize that when the valve goes in, it doesn't just perform the same way for the next decade. It changes over time. That's okay if you keep an eye on it and if you are committed to having that valve and you are well managed.



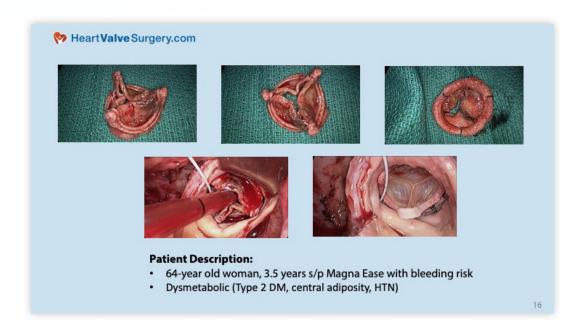


Here's an example. This is a 50-year-old gentleman. Six years prior he'd had a tissue valve implanted, a perfectly good tissue valve. He had that valve stiffen over time. He was in his 40s when it was implanted.

The younger you are when you get a tissue valve, the shorter it lasts. There are two main drivers of tissue valve durability; age and the internal milieu of the patient with respect the inflammatory activity in the body. If you get it when you're young, it may not last. There are people in their 40s that get tissue valves and they don't have another operation until they're 60. That happens.

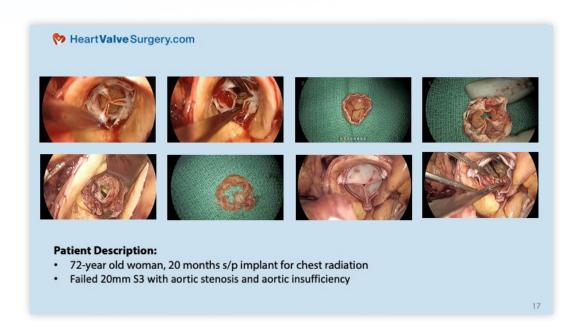
Sometimes they burn out a little bit earlier. You can see how stiff these leaflets are. You can see that the leaflets become stiff and immobile. Recognize that the patient had to deal with the valve not being great for awhile before he had surgery.





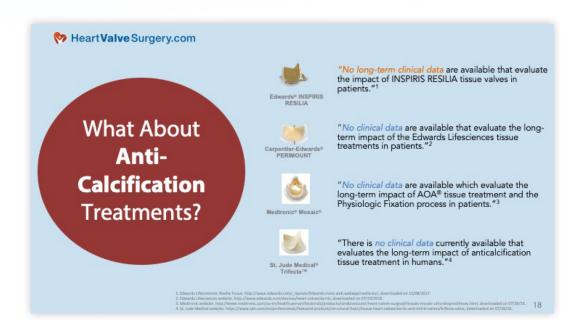
Here's another example. This is a woman who three-and-a-half years prior had a valve implanted. She had to have a tissue valve because she had bleeding issues. It's important to recognize that because of her dysmetabolic syndrome, she had a lot of inflammatory condition. It led to early demise of the valve.





Here is a lady who had a small transcatheter valve implanted. She was 72 years old. It had been implanted at another institution because they didn't want to operate on her because she had chest radiation, which we commonly do operate on at Franciscan Health. I understand their hesitancy. That valve 20 months later, we had to take it out and replace it with a standard tissue valve. It's a dynamic process that involves changes in the valve while they're in the person.

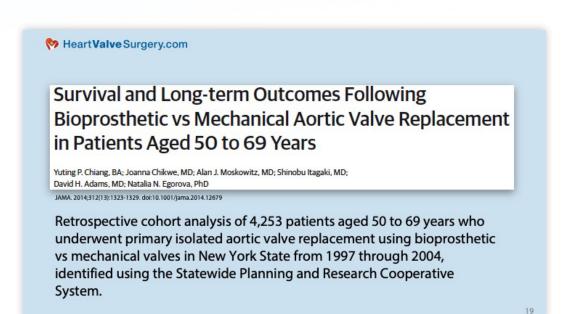




What about anti-calcification? As you know, we now have the <u>INSPIRIS RESILIA valve</u>, which I use when younger folks get tissue valves because it is promising. It looks like it may not calcify as rapidly in sheep. It does not calcify as rapidly as its predecessor valve did.

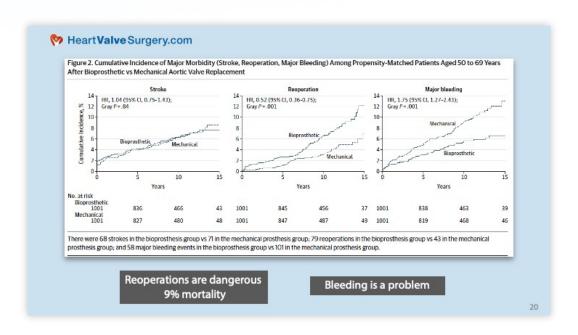
We've had other types of anti-calcification processes over the years that promise to avoid it. I don't think this is going to be a silver bullet. It's not going to make calcification go disappear. I do think it will slow it down. That is promising.





This is an important paper because it's an example of the type of thing we see commonly when comparing those valves.





This is kind of the punch line slide for all of the things we look at with mechanical and bioprosthetic valves. On the far left, all replacement valves are associated with some incidence of stroke. In the middle, bioprosthetic valves have more reoperations. One the right, mechanical valves because they have to be on blood thinner, have more incidence of bleeding.

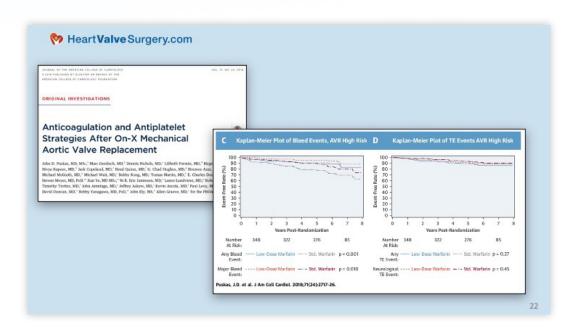
We know that bleeding is a problem. We also see the reoperations are kind of risky because the mortality is high. That makes me pause to say one thing about that; if you get a tissue valve and you need a reoperation, you go to somebody who does a lot of aortic valve reoperations. For those folks, the incidence is not bad. It's closer to a standard first-time valve.





This mechanical valve, the On-X valve, we did a study.





For this specific valve, because of the properties in the valve and because of the material performance of it, we are able to lower the dose of the blood thinner. We are able to lower the dose of the blood thinner so much that – let's go back two slides. This image on the far right disappears in the sense that the bleeding goes away. You see there's still some bleeding with bio prosthetic valves because people with bioprosthetic valves sometimes still have to be on blood thinners.





We now are doing the <u>PROACT Xa study</u> where we're looking at the use of Eliquis with the On-X valve. That would be a game changer because you don't have to worry about what you eat. You don't have to check the blood thinning level. You just have to take the pills. That's the next generation of mechanical valves.





Myth #2: Leaking Aortic Valves Should Be Replaced



Dr. Gerdisch: Myth #2 - Leaking aortic valves should be replaced.

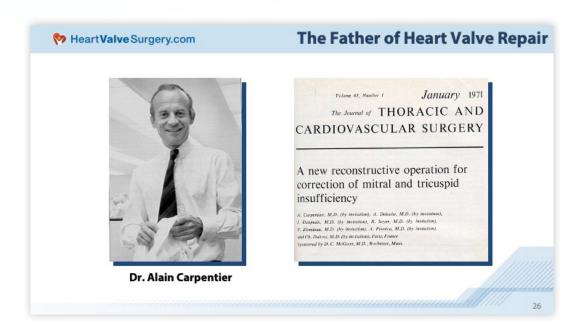




I love this video. I'm one of the last surviving human beings with this video. I got it when I was a resident. This is 30 years old.

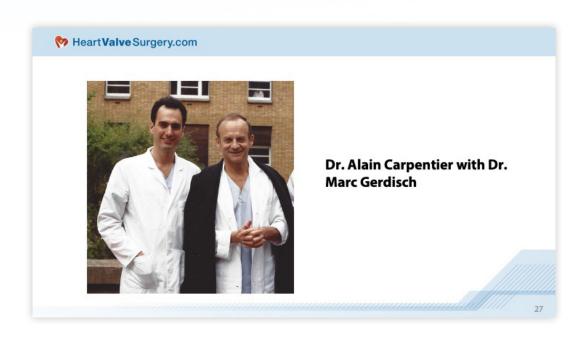
It's at the University of Minnesota, using clear blood... You're standing in the apex of the left ventricle looking up at the valve. The bad aortic valve is the valve on your left. As you can see, the tissue is soft. It's pliable. It belongs to the creature. It happens to be a pig, but it would be obviously in a human. The key to the element there is that there's opportunity with any leaking valve, whether it be mitral, tricuspid, aortic to not sacrifice the valve, but to restore it to function.





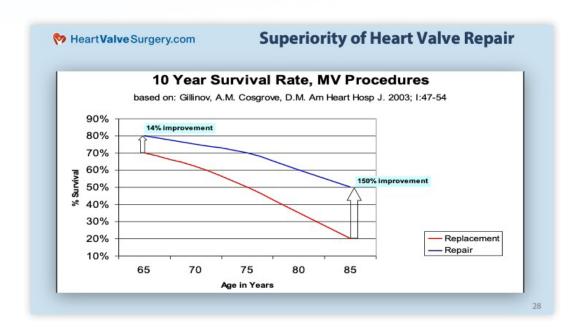
As we know, Dr. Alain Carpentier, in a 1971 paper, told us that we could repair mitral valves. That became our mission. Everybody knows that a leaky mitral valve should be repaired. You need to be in a center of excellence for that.





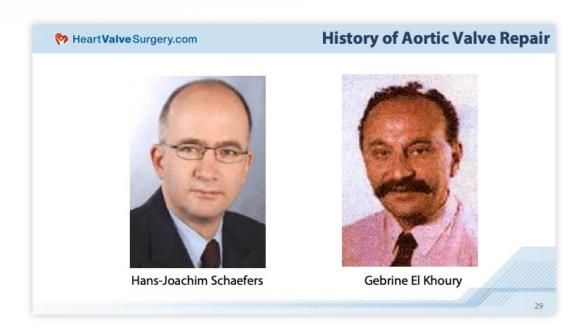
That is Dr. Carpentier and me when we both had hair. I spent time, almost 30 years ago in France, and I learned the value of preserving tissue.



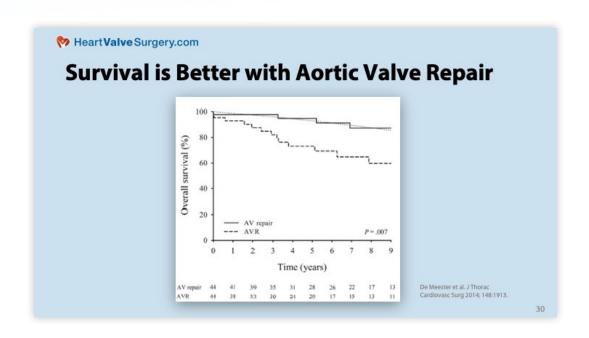


What about that is so important? The important thing is that if we look at the survival of repair versus replacement, it's dramatically different. In fact, mitral valve repair patients overall have a survival similar to people who don't have mitral valve disease if it's repaired at the right time.



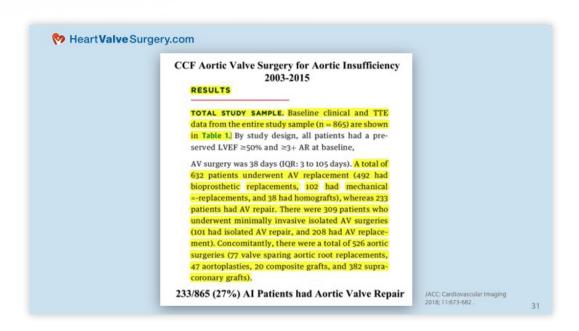


What's the message there? The message is aortic valve repair is a possibility too. Aortic valve repair hasn't moved along at quite the same pace, but it did start almost 30 years ago. These fellows for the last 20 years or so have really advanced the game for us, especially Dr. Schaefers on the left, whose techniques we now use to reestablish the normal geometry of an aortic valve.



In fact, we saw the same thing. This is a paper from his group. Other papers have been published with the same findings. When an aortic valve is repaired, the survival is better.





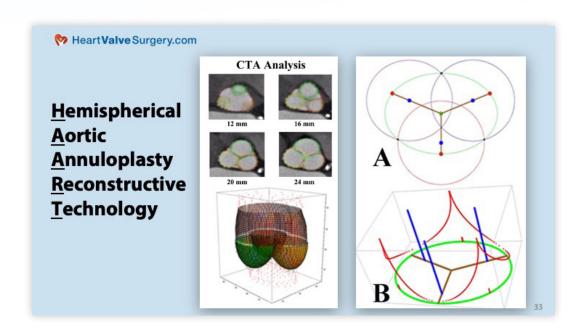
One of the dramatic findings though is that even in centers of excellence, the likelihood of an isolated <u>aortic valve insufficiency</u> or leaking aortic valve of being repaired is low. It's about maybe a third of the patients, close to maybe 25% of the patients. What can be done about that?





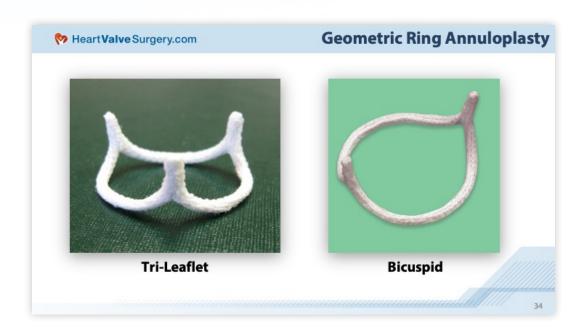
As it turns out, something can be done. This is Scott Rankin, also a legendary heart surgeon, who developed a device that coupled with the techniques of Schaefers allow us to expand our ability to repair aortic valves





Using CT angiography and point-by-point reconstructions, he built a device that would allow us to assign normal geometry to an aortic valve.





This is the <u>HAART device</u>, which comes in two versions, one for normal or standard three leaflet valves and another for people with <u>bicuspid valves</u>.





We then recently presented, and I presented this paper, at the American Association of Thoracic Surgeons. The important thing here isn't that I presented the research. The important thing is that we've got multiple centers across the nation - with 70 cases that we generated in a relatively short period of time - showing that we could apply standardized methodology to fixing aortic valves.





This is an example of one. I'm going to click along here to like a minute here. You'll see us repairing the valve. This actually was a fairly complicated valve repair. You can see we size it. This isn't a bicuspid, it's a unicuspid aortic valve.

It's one of the most unusual types of aortic valves. We can use that ring to now take this valve, which has abnormal geometry, and plant that ring. The ring goes in.

Then once we have the ring in, we tie it into place so that the leaflets come together. Then we start to interrogate the valve and make changes to the leaflets until we have accomplished our goal, which is to create normal geometry to the valve and get the patients' own leaflets working. I personally would rather have my own leaflets, even if they're abnormal, than the tissue from a <u>cow valve</u> or a <u>pig valve</u>. You can see that valve is going to work fine.



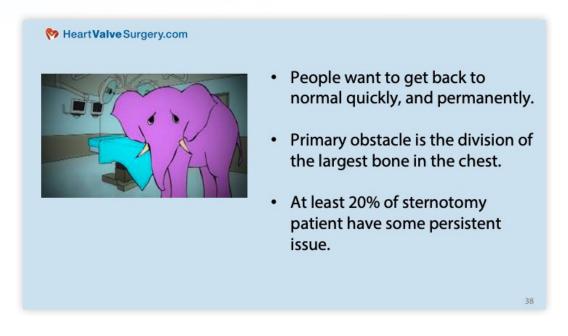


Myth #3: Sternotomies Always Heal



Dr. Gerdisch: Myth #3. Sternotomies always heal.





People know this is a pet project for me. The elephant in the room when we're talking about people getting better from surgery after heart surgery if they have a sternotomy is the vision of the largest bone in the chest. At least 20% of people with sternotomies have some persistent issue with that aspect of the operation.

What can we do? One thing we can do is not make a sternotomy.





You can see this fellow I did his surgery through that little incision under his right nipple.

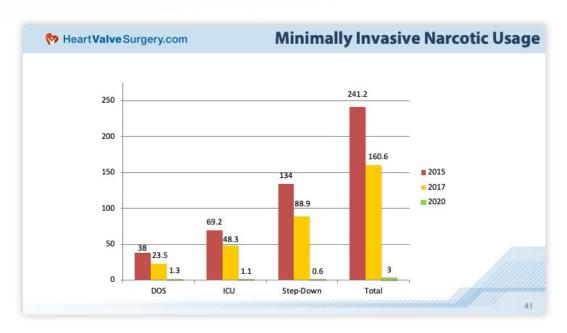
If we don't make a sternotomy, we get this where people can be back in normal activity, stay away from the limitations of the sternotomy, and in fact, with the use of a special type of technique we use to create a block of the nerve, we can eliminate their pain for the most part, and they're ready to go back into action right away after surgery.





In fact, the impact of that was so dramatic, that for minimally invasive surgery, we eliminated the use of narcotics. So you know nationally, we're trying to get away from the use of opioids. We have eliminated it for minimally invasive surgery.





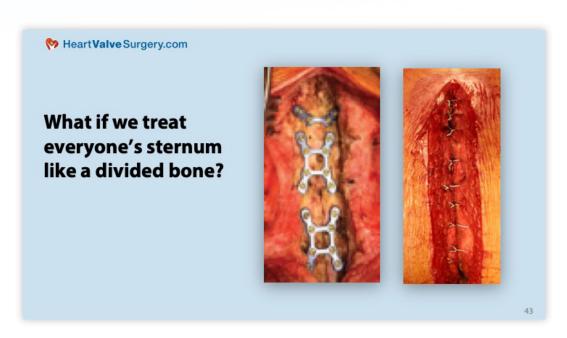
Still, what do we do for sternotomies? How can we make the sternotomy equivalent to our minimally invasive techniques?





How about if we approach every sternotomy like a divided bone?





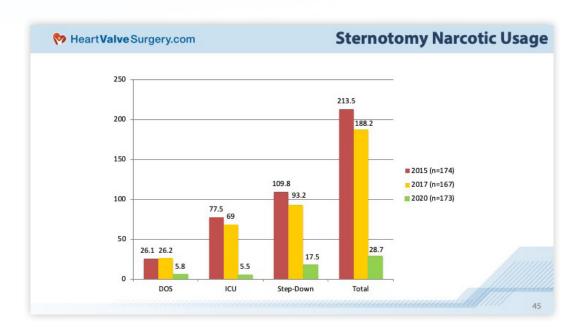
I know that sounds silly, but think of it this way. Let's say you're in an automobile accident. The only thing that happens to you is that your sternum is split right down the middle. You go into the hospital. The surgeon takes you to the operating room. He puts your bone back together with some baling wire, and he sends you home. Would you feel okay about that? You had a traumatic division of your bone and all they did was use wires. The answer is no. Heart surgery is the holdout for how you treat a divided bone. In our practice, everybody who gets a sternotomy gets rigid plate fixation, which means they get an orthopedic repair. Why?





Because we did a randomized control study. That is the highest standard of medicine and science, and we proved better bone healing, fewer wound complications, better upper extremity movement, less pain, fewer days in the hospital, and it was cost neutral in 60 days because of the lack of complications and the lack of need to send even frail patients to extended care facilities.





We saw a similar effect – this is just the most dramatic thing - almost accidental. 87% reduction in the use of narcotics for patients with sternotomies. Only 10% of our patients even go home with narcotics prescriptions



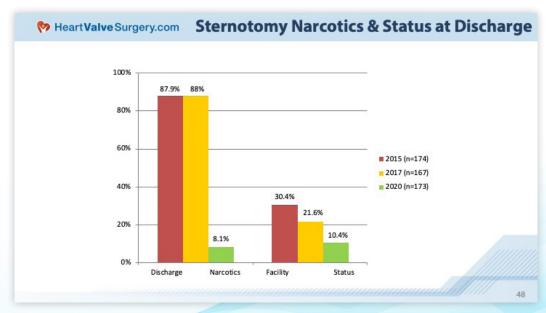


Here's some cool examples. 82-year-old woman, day two after having her aortic valve, ascending aorta replaced. Goes home day five. Goes back to work three weeks later. 68-year-old gentleman had a huge operation, a redo operation. You can see the mobility he has, good to go. He also went home in a few days and back in action.





I want you to tell me which one of these patients had a sternotomy three weeks ago? Which one had a minimally invasive operation. The guy on the right had a sternotomy hitting fast pitch. I know those are dramatic examples, but like I said before, now only 8% of our patients go home with narcotics, and only 10% of our patients, including the frail or older people, have to go to extended care facilities. People go home.





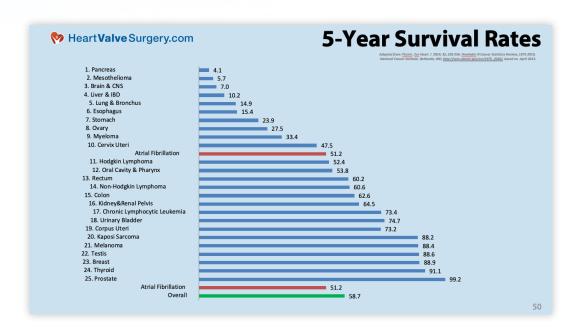


Myth #4: Not All Atrial Fibrillation Is Important to Treat



Dr. Gerdisch: You guys know that I'm a little manic about this. You've probably heard me talk about it before. This doesn't require a lot because I'm going to tell you ahead of time <u>atrial fibrillation needs to be treated</u>.

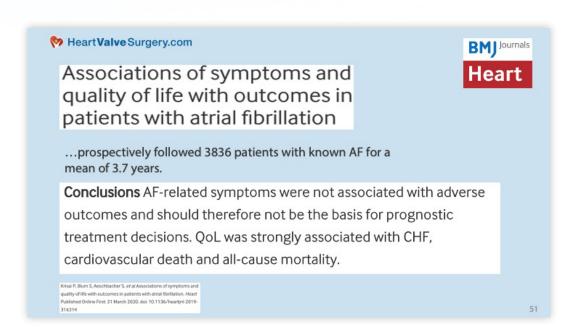




The message of this slide is the impact of atrial fibrillation. When a patient is first diagnosed and admitted for atrial fibrillation, their 5-year survival's only 50%. It's worse than most cancers. Atrial fibrillation is a serious disorder.

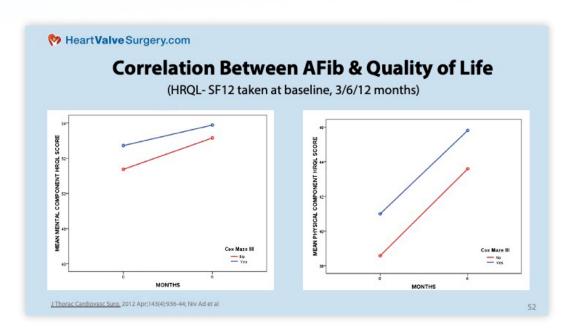
We know that you don't have to have palpitations to have the consequences of AFib. This was an important paper because they recognized that it was more about the quality of life than it was the symptoms of palpitations, and so, "What happens if we get rid of atrial fibrillation in somebody who has heart surgery?"





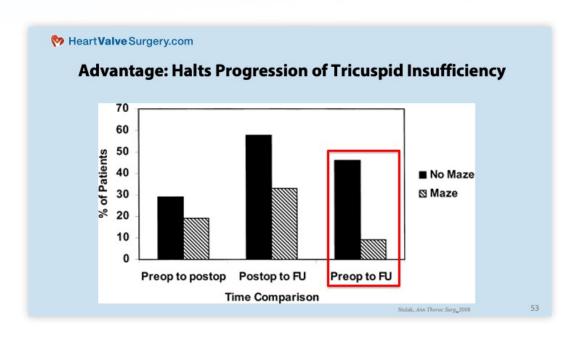
My friend Dr. Niv Ad answered that question, so you can see what happens. Mental health, their physical health both improve dramatically with the elimination of atrial fibrillation. Those are quality of life parameters. That's not just whether you're having complications. Those are quality of life parameters.





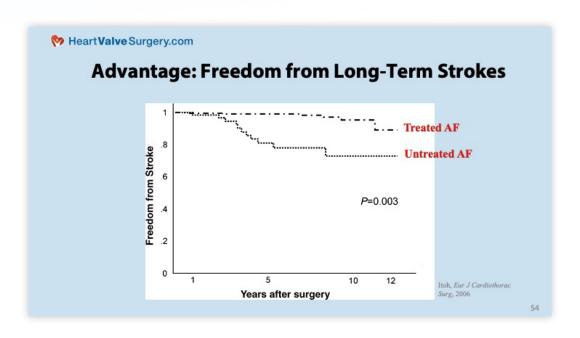
It also keeps you from developing worsening valve disease which comes with atrial fibrillation and stroke.





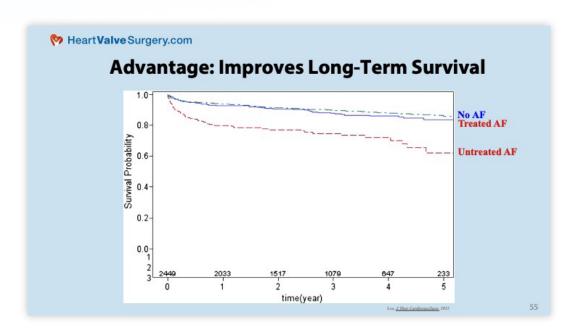
Stroke is the greatest, most devastating complication of atrial fibrillation. We know that treating atrial fibrillation is important for that.



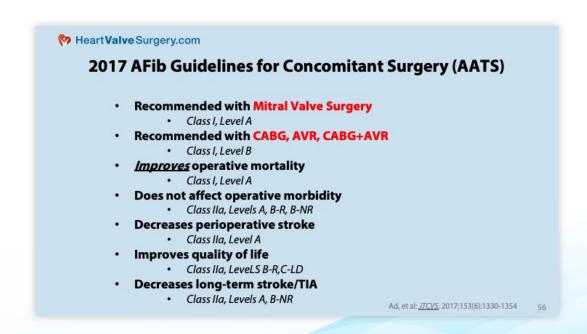


The difference in survival. This is a great paper. This was from Northwestern several years ago. You want to be on the top line, the long-term survivors, right? The people who didn't have their AFib treated were more likely to be dead.





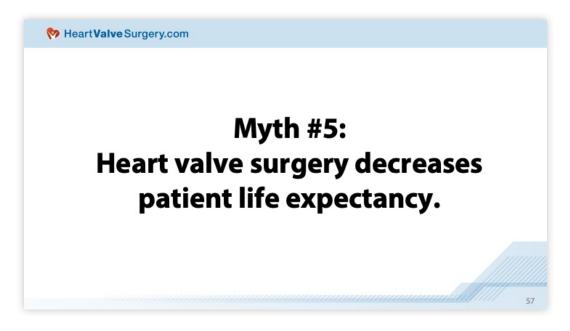
For all of these reasons the AATS, the American Association of Thoracic Surgeons, says you must assess, you must consider treating atrial fibrillation whenever it's present in a patient. There's no such thing really as a little atrial fibrillation because atrial fibrillation begets atrial fibrillation.







Myth #5: Heart Valve Surgery Decreases Patient Life Expectancy



Dr. Gerdisch: Life expectancy has become a hot topic. It is because patients are doing the math. They're reading. They're learning. They're trying to understand their own disease process, and that has called attention of the medical community to it.

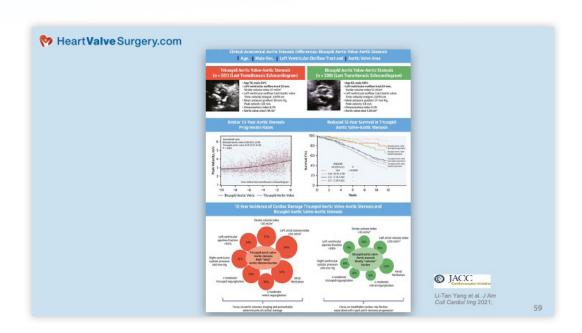




These are two fresh off the press papers, and I love them both because they explain some of the things that I've been trying to explain to patients for a long time.

The first is this paper looks at the difference between bicuspid and tricuspid valves. Bicuspid, congenital abnormal valve, versus three-leaflet tricuspid valves.





This next slide is a little confusing and you can always go back and look at this. What you have to focus on is on the left side of the slide. If we go to that second component where the red line is, it basically shows you that the progression of disease is similar for these two disorders. The tri-leaflet valves start a little bit later in life because of age-related deterioration of tri-leaflet valves. Bicuspid valves start a little earlier in life because they're abnormal to start with and they're vulnerable to change.

The graph on the right, on the same level, though, shows us at the top – the top line are bicuspids. The bottom line are tricuspids. There's some differentiations in there. I won't get into the subtleties, but the point is if we go down to the bottom of this diagram, the picture on the left with the orange, those are trileaflet valves, and all of the things that are associated with morbidity and mortality with valve disease are happening more with them. In the bicuspid valves you see less of it.



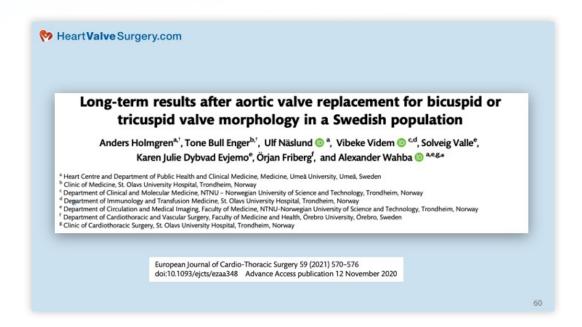


Let me try to make this clear for you. It's a little bit of a granular concept. Trileaflet aortic valve disease – you're born with a normal valve, but it gets sick over time.

For some people, there is some genetic component to that of calcification of a three-leaflet valve, but there are a lot of other influences, diabetes, inflammatory conditions, hypertension, smoking, central adiposity, all these things that favor atherosclerosis.

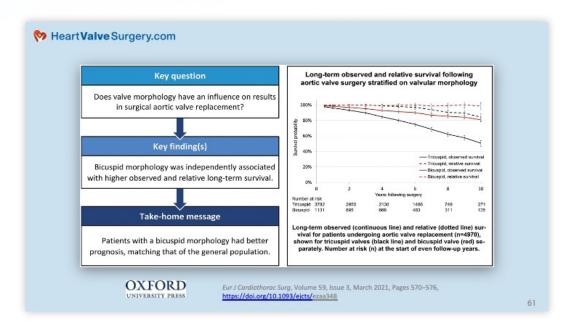
The same folks who get coronary disease, often will have some disease of the aortic valve because there's some relationship there. If we move over to the right, bicuspid disease is largely related to the fact that it's an abnormal valve from birth, so if you want a focus on bicuspid disease just avoiding things that just accelerate the deterioration of a valve specifically, whereas with trileaflet disease you really want to try to manage the patient very globally with respect to those risk factors that advance tri-leaflet disease.





Let me show one more paper. It delivers the same message with survival data. This is in Sweden. I love Swedish papers because they have such great healthcare, they're always able to follow their patients well, so we get very good data.





What we see here, the very important finding here is that when they look at their population of people that were treated with valve replacement for three-leaflet and bicuspid valve disease, the bicuspid valve patients had a better survival.

Although the disease onset might be sooner, the survival improves because it's a function of that bicuspid valve. It's true that the majority of those patients that had their surgery with bicuspid disease were treated earlier so they got mechanical valves, they were standard therapy so there can be some bias built into that. But the fact is that the bicuspid group had a improved survival. That points to the fact that and likelihood that the tricuspid valves tend to have a more constitutional disease that can contribute to their demise.





Dr. Gerdisch's Advice for Patients

Meart Valve Surgery.com

Live long and well with valve disease.

- Create a map of the future together with your cardiovascular team.
- Include your hopes and dreams.
- Plan your personal path to influence your long-term outcome.
- Understand the science as dispassionately as possible.
- Ensure all aspects of your condition are addressed afib, aortic aneurysm

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Dr. Gerdisch: Let me finish with live long and well with valve disease. Create a map of the future together with your cardiovascular team, your cardiologist, nurse practitioners, your primary care physician, and your surgeon. Include your hopes and dreams. Just tell them what you want. How do you want to live, and let's figure out how to get there. Plan your personal path to influence your long-term outcome. In other words, I have patients where we spend a lot of time just figuring out what it is about their lives that we want to be sure to influence and emphasize so that they get to live their lives well.

Understand the science as dispassionately as possible. Super important. You don't want a horse in the race. This is not about I like tissue values, I like mechanical valves, I like – this is about science, and you have to be dispassionate about it. Ensure all aspects of your condition are addressed. If you have atrial fibrillation, if you have an aortic aneurysm, if you have other valve disease, all of those things, coronary disease, whatever it is, it all should be addressed at the same time.



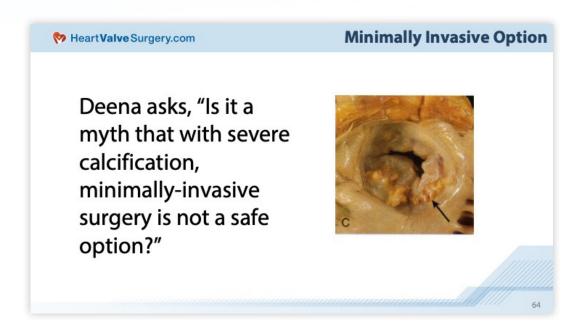
Questions & Answers



Adam: Dr. Gerdisch I can't thank you enough for not only presenting the myths that you see in your practice talking with your patients, but then going and busting them to elevate our consciousness, not only on an actionable level of the next steps for taking care of our valve disease as patients but also bigger picture. What do we need to think of after that perhaps first intervention? How do we need to think about this maybe more strategically as we are all living longer lives? Thank you so much for that. I really appreciate it. We have had question-after-question coming in during this webinar, and I think we can just real quickly if you're okay shift gears and go right into the Q&A. How does that sound?

Dr. Gerdisch: That would be great, and I love your word strategic. That's what we have to be. We have to be strategic.

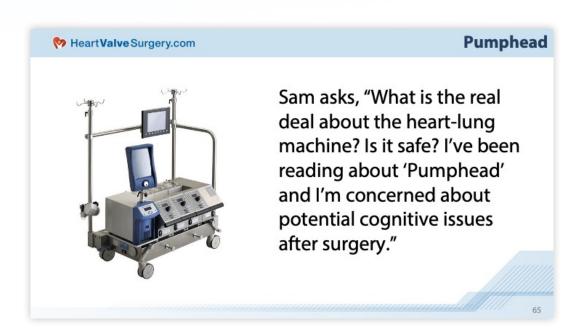




Adam: Great. Let's get to the Q&A. This was interesting. Deena asks, "Is it a myth that with sever calcification, minimally invasive surgery is just not a safe option?"

Dr. Gerdisch: It's a very good question, and it actually depends which valve and how extensive the calcification. Calcified aortic valves can absolutely be treated almost invariably minimally invasively without even touching the sternum between the ribs. Mitral valves, if there's extensive calcification of a mitral valve, it penetrates the wall of the heart. That requires major basically excavation in order to create new space, whether the valves can be repaired or replaced. Those normally will have – usually will have to get done with a sternotomy, with a standard approach.





Adam: Great. I hope that helped you, Deena. Let's move on to a very, very big topic in our community, Dr. Gerdisch, and I want to just take a breath to make sure everybody has the time and space if you're considering a valve surgery to focus on this question. It has to do – Sam asked it, and it's about the heartlung machine. He asked, "What is the real deal about a heart-lung machine? Is it safe? I've been reading about 'Pumphead', and I'm concerned about potential cognitive issues after surgery." Before you answer his question, can you maybe, Dr. Gerdisch, just share what the – for someone who's never even heard of a heart-lung machine, what is it, and then address Sam's question so that we get a full rounded picture here.

Dr. Gerdisch: Right. Yeah, good point. When people have heart surgery that requires us to stop the heart or even beating heart surgery where we have to get inside of the heart, the patient is put onto a heart-lung machine where deoxygenated blood, blood that's already been used by the body and the oxygen's been taken out, is sent through a cannula, a tube to the heart-lung machine, which then oxygenates the blood, puts the oxygen in that your lungs would normally do, and then pumps the blood back to the body. Meanwhile, we



keep the heart isolated, and we feed the heart separately. We take care of the heart separately while we're doing our work, and the body is being profused by the heart-lung machine. Is that pretty clear then you think Adam?

Adam: Yes.

Dr. Gerdisch: Recognizing that – and Sam's question is really super important, so I would say a few things. First of all, cardiopulmonary bypass has definitely evolved. Techniques have evolved. As part of our enhanced recovery after surgery program and practice, we have a process that we call goal directed profusion. When we use the heart-lung machine, every time a person's on the heart-lung machine, like every aspect of the operation, we want that patient to have the experience that we would want for ourselves or our loved ones.

With goal director profusion, we are constantly assessing and tweaking the parameters that ensure that the body is experiencing as close to normal blood flow as possible. That is all about oxygen delivery and the pressure of the blood as it reaches the tissues. We constantly monitor that and adjust it. The concept of pumphead – I have to say that most of the studies, the large studies that have been done it the past decades have shown us pretty clearly that within a few months, patients are back to their normal cognitive baseline. That said, nobody wants to not have their normal cognitive baseline at any point, so there are some things that we do.

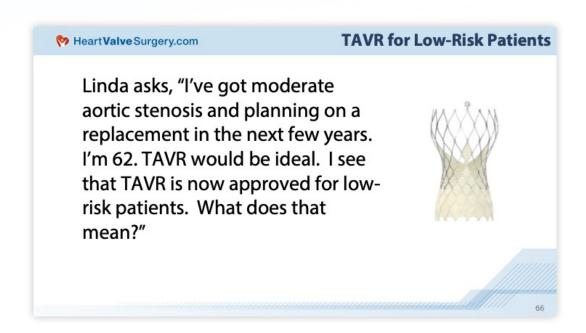


There has been recent data looking at preemptively influencing the level of inflammation in the body, and there are two things that I found in the literature. This is my own personal hunt. One is patients should always have their influenza vaccine before having heart surgery. The reason I say that is I took that out of the cardiology literature when they saw that patients who had had coronary stents would have a higher incidence of major adverse events if they hadn't had their influenza vaccine, so I dug a little deeper, and I found that once you have your influenza vaccine, it lowers the level of inflammation in your body, so you're set up to tolerate cardiopulmonary bypass better. There's one paper – I don't know if it got published to tell you the truth, but there was one paper that showed that indeed people who had had their influenza vaccine had lower inflammation on cardiopulmonary bypass.

The other thing is we use – even in folks that don't need them otherwise, we actually put patients on statin drugs coming into operating – before surgery, and we do that because statins also lower the overall level of inflammation and we think might avoid some of this early cognitive impairment. That cognitive impairment appears to be not – it's not strokes. It's not stuff going to the brain. It's this kind of general inflammation in the body that we try to obviate.

The other thing that we do – this is obvious from all the things I've said is that we stay away from a lot of medications and things that make people foggy, so we get people snapping to right after surgery. If you're awake and alert well after surgery and well rested, a lot of that stuff goes away. It's a multipronged approach, goal directed profusion being the key element that when you're on the heart-lung machine, somebody knows how to manage it, and then there's not being on a heart-lung machine all day, being with a surgeon who can move the operation along and get things done for you. Long answer, but it's an important question.





Adam: Yeah, very, very helpful, and for everybody in the line who – Dr. Gerdisch very quickly talked about the rapid recovery protocol that he uses at his center. You can go to heartvalvesurgery.com, type it in. You'll see a really great play by play of how he describes what that is. It's fascinating to learn about that. Let's move on to Linda's questions. This is a great one. I get this all the time. Linda says, "I've got moderate aortic stenosis and planning on a replacement in the next few years. I'm 62. TAVR would be ideal. I see that TAVR is now approved for low-risk patients. What does that mean?"

Dr. Gerdisch: Yeah, this is such a great question, Linda. It's a great question for a number of reasons. First, I would take you back to my very first slides where I said that valve therapy is both nuanced and varies on where you are. You could walk into one hospital and say I'm 62. I want a TAVR, and they'd say no problem, ma'am. Walk this way. You might walk into another where they're going to sit you down and have a long conversation, so I think that what data we have would dictate that in a 62-year-old person who's genuinely low risk – in other words, you don't have some other comorbidity – if your long game is 20, 30 years, if you get a transcatheter valve, the likelihood of getting real durability out of that valve is limited.



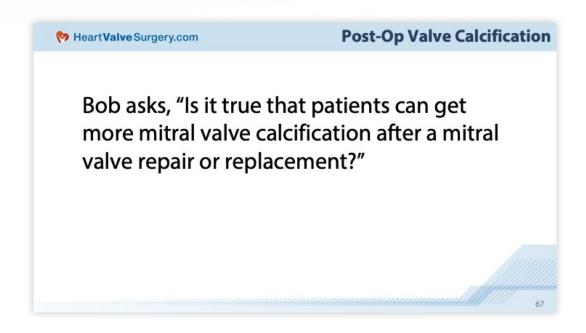
There's a recent publication actually from Germany looking at a multi-year experience in 1,800 patients, and for those patients that they could match – they could directly compare surgical to transcatheter valves – it was a limited cohort – it was obvious that the surgical valve patients were getting better survival. I think that we don't know enough yet to start putting these valves in people that young. What we do know is that if you decided you want a tissue valve at 62 or 65 or whatever it is, you can have that valve implanted without anybody touching your sternum, going between your ribs.

You can have a surgical valve that we know has durability, and this newest generation of surgical valve may have increased durability, and you can be set up to have a valve in valve later with a TAVR, which we do all the time. I think that logic would prevail and someone who's 62 years old, otherwise healthy, that that person – that person has a long game, logic would prevail that it would make sense to have a minimally invasive surgical valve with a plan perhaps for a transcatheter valve in that valve later in life. I hope that answers your question.

Adam: Thank you. Great, great answer. I'm just curious to know off-hand Dr. Gerdisch. You are a minimally invasive specialist. About what percent of your procedures these days that are valvular are being done minimally invasive by you and your team?

Dr. Gerdisch: If it's a single valve, it's essentially all of them. When we move up to two valves, it becomes a little bit less, and it depends which valves they are. If it's mitral and tricuspid, it's most of them. If it's aortic and mitral, it's less. Then when it becomes more complicated operations where maybe three valves or two valves or reoperation or valves and bypasses, those kinds of operations we do through a sternotomy, and as I mentioned, all of those patients get rigid fixation so we can restore them to full activity, but anybody who has a single valve, unless here's some contraindication based on their body habitus or something, the vast majority of those are done through – without touching the sternum.





Adam: Got it. Let's move on to the question here from Bob, and he asks, "Is it true that patients can get more mitral valve calcification after a mitral valve repair or replacement?"

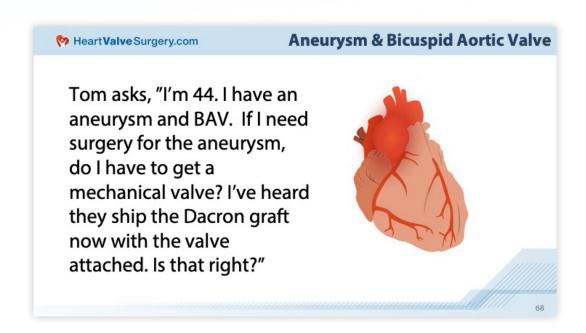
Dr. Gerdisch: Another great question. Bob, that's a great question. There are two ways to look at that. One is if you have a valve replacement and it's a tissue valve, the valve will calcify. Eventually, you live long enough, the valve will stiffen and calcify. I would add an aside to that and some people might take issue with it, but I personally believe that if a mitral valve is replaced, you should favor a porcine, pig, bioprosthetic valve because that valve is made from actual leaflets from a pig, and the mode of failure is different. I can get into the details of this, and I'm happy to talk to people about it, but it comes down to stiffening in pericardial valves and failure of porcine valves not by stiffening but by tearing.





It becomes complicated, but the mode of failure is better in the mitral position in my opinion with a porcine valve, but they will also calcify over time. If you have a mitral valve repair with your own tissue, the only reason for that valve to calcify is if you get really old and you develop senile calcification in the valve. That would be unusual. Most people with degenerative mitral valve disease that get a valve repair will not develop senile calcification, will not calcify the valve. Good question.





Adam: Dr. Gerdisch you're not alone in that opinion about porcine valves in the mitral position. I was talking to Dr. Vaughn Starnes, my surgeon the other day, and he echoed your opinion which was fascinating to hear you guys both concur on that. Let's move on to aortic aneurysms, which we haven't talked a whole lot about here, but Tom has a great question. He says, "I'm 44. I have an aneurysm and a bicuspid aortic valve. If I have to get surgery for the aneurysm, do I have to get a mechanical valve? I heard they ship the Dacron graft now with the valve attached. Is that right?"

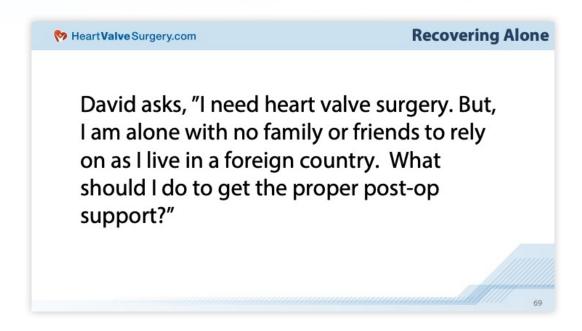
Dr. Gerdisch: It is true. I would tell you this. First of all, it doesn't matter what they make now. In the past, if we had to replace an aortic valve and replace the entire aortic root and ascending aorta, we just fabricated the combination in the operating room, and I still do that when I need to, so yes, you can get prefab, you can fabricate it in the operating room. It really, quite honestly, is irrelevant. If you have a bicuspid aortic valve, though, and that valve can be repaired or is not leaking and just needs to be tuned up and you're 44 or 50 or 60, you should keep your valve. You should keep your bicuspid valve.





I would rather have a well-functioning bicuspid aortic valve than a replacement valve. My well-functioning bicuspid aortic valve does not carry the risks that a replacement valve, whether it's tissue or mechanical – it does not have those risks. If possible, keep your valve, keep your bicuspid valve, and just replace the aortic root and ascending aorta. Admittedly, you have to have a surgeon who can do that, who can replace the root and save the valve, but there are plenty of us, and wherever you are I could find somebody near you. You just have to be with the right person to keep your valve if it's still working. If your bicuspid valve is stenotic, if it's become calcified and has to be replaced, then you could have either a tissue or a mechanical valve, whatever makes the most sense for you, and have the Dacron that kind of graft to replace your ascending aorta. I hope that answers your question, Tom.





Adam: Great answer, Dr. Gerdisch, and again, I'm just going to echo what we've heard a lot about today, a lot of advantages for repairs. We talked about with aortic valve, also there for the mitral valve as well. This is a fascinating question that comes in from David who's in Thailand. He says, "I need heart valve surgery. I am alone with no family or friends to rely on as I live in a foreign country. What should I do to get the proper post-op support?"

Dr. Gerdisch: David, it's in important question, and so I think that, obviously, you're going to find the surgeon and team that you're comfortable with, and you get that great care in the hospital. When you leave, if there's any chance – while you're in the hospital if there's any chance at the end of your operation that they'll give you – that they'll do rigid plate fixation of the sternum, and I mean an actual – not just one plate but three plates, implanted properly, that will allow you to when you leave just go back to your life.

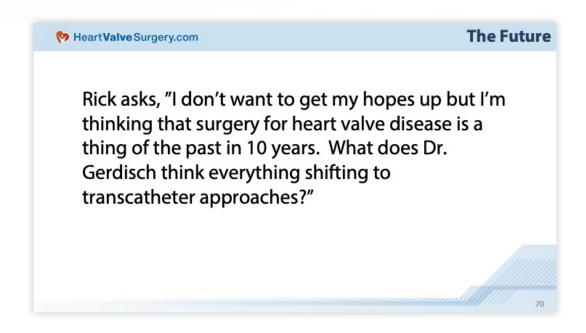
You'll be able to – for our patients, we let them lift 15 pounds the day after surgery, 20 pounds when they leave. We show them how to get up and out of their chair, up and down from the commode, in and out of bed, so they can go home and





live alone. I think that if there's any way – and I don't know what the situation is there, but if you can get it, that would solve a lot of your issues because you'll have mobility. I'm sure they'll have a nurse that'll come and visit you at home if you need to, check your meds, check your blood pressure, etcetera, but if you don't have friends or family around – and many people don't even here – then it's ideal if you can get rigid plate fixation so that you can have full mobility when you leave the hospital.





Adam: David, I really – I've seen your comments online. I've seen you in the community. I really hope you take those very important words from Dr. Gerdisch all about rigid sternal fixation, and if you go to the website again, you can just type in rigid sternal fixation, and Dr. Gerdisch has a really nice piece in which he describes how that device can help patients during their recovery. Let's move on to the future, Dr. Gerdisch. I know you are an innovator. You're always looking out. What can we do next to help patients? Rick asks a question I've heard several times. He says, "I don't want to get my hopes up, but I'm think that surgery for heart valve disease is a thing of the past in 10 years. What does Dr. Gerdisch think about everything shifting to transcatheter approaches?"

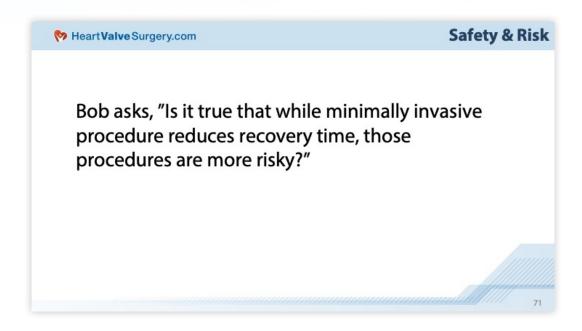
Dr. Gerdisch: First of all, I think it's super exciting. I love the engineering. I really think transcatheter interventions have broadly expanded the people that we can take care of, right? I can tell you that in our institution, while heart surgery has only grown – we're actually having our biggest year ever – we also are expanding a great deal in transcatheter. I see patients from all walks of life, from all over the country, and some of those patients I shift directly into thinking about transcatheter approaches.



That said, all of this stuff has to be tailored based on the entire human being. It has to be tailored on all the things that person needs, and furthermore, there are plenty of patients that still are going to need second operations for different conditions and problems that they have with either prior operation surgery of the valve or additional problems, so I think that heart surgery isn't going anywhere. I think surgery's only going to expand, and as we refine, especially in minimally invasive techniques, we're going to find a dovetail. We're going to find a merging or a blurring even between what is surgical and what is transcatheter. Incisions get smaller. The devices get better. We start to do hybrid procedures where we combine therapies. I have done them.

I have taken a person a few years ago who simply couldn't have either and I did a minimally invasive beating heart mitral valve repair on a patient, and then through his carotid artery replaced his aortic valve with a transcatheter valve. All of this stuff is – these are just tools for expert clinicians to be able to serve patients better. I think that a decade is a short time and a long time. It's a long time in the sense that the engineers are moving at a very rapid pace. You're going to see better technology, but it's also a short time in the sense that our lives move along so quickly, and you have to make decisions based on what's available to you at the time. I wouldn't expect the earth to shift in one direction. I think there will be a progression. We have to be serious about the decisions we make because when we change something, it has implications for the future of the patient, right, years down the road.





Adam: Yeah, Dr. Gerdisch, one thing I know about you and I hear from your patients is not only do you just include them in the treatment selection process, it's great to hear this other side of you today talk about how you include everybody on the quote unquote heart team there at Franciscan Health all for the benefit of the patient. I'm thrilled, and we have one – time for one more question. I can't think of many people besides you, Dr. Gerdisch, who can answer this one. It's about safety and risk. Bob asks, "Is it true that while minimally invasive procedures reduces recovery time, those procedures are more risky?"

Dr. Gerdisch: It's actually a very insightful question, Bob, and they – an operation becomes more risky if someone tasks more risk. Let's look at it this way. A patient has degenerative mitral valve disease. Their heart is still pretty healthy. The patient's pretty healthy. The access is good. There's no – there's nothing that favors a sternotomy, right? You'd look at the patient. There's nothing that says a sternotomy will be faster, better, cleaner – there's nothing better. That patient definitely is minimally invasive, but there is a gray scale, so as we move toward multiple valves, as we move into sicker patients, if we move into more complex scenarios and reoperations, then they have to be fit together based on the nature of the





operation, the expertise of the surgeon, and what the goals are for the patient.

I put the incision very low on the – even though I do so much minimally invasive surgery, I put the incision very low on the scale of things that are important to me because the most important thing is a perfect operation. I actually was just having a conversation with a patient in my office today, we talked about which approach we were going to use, and he looked at me and said "Look, I just want success. I want my heart to be well." He's an athletic guy, rode his bike a ton, needed two valves and a maze, and so we talked about all of those aspects.

First of all, minimally invasive surgery should only be done by minimally invasive surgeons, number one. Number two, don't risk anything for an incision. Like I said earlier, if you get a sternotomy, get rigid plate fixation, and it's hard to tell the difference between those patients. Finally, don't take any component out of the operation just to make it minimally invasive. If the operation's going to be done minimally invasively, you have to get the entire procedure. I hope that's clear to you, Bob. Minimally invasive surgery is a lower – shorter recovery time. It is better for the patients when it can be delivered under the appropriate – in the appropriate context with the right patient. I don't think it's ever worth an incision – changing the size of an incision to compromise an operation. You have to have a perfect procedure. You have to have a perfect operation.

Adam: I just love that response, Dr. Gerdisch, focusing on the perfect, safe operation that's going to provide the long-term result for the patient. With that, we're going to go ahead and wrap up this webinar, but first off, don't hang up and don't end it just yet. I want to extend a huge thank you to everybody in our community who has joined us today. It is always great to be a part of your life and to help educate and empower you in any way possible. I also want to, of course, have to thank Dr. Gerdisch for taking the time to share all of his clinical research, all of his expertise to help us live better lives. Thank you, Dr. Gerdisch for being with us today.





Dr. Gerdisch: Thank you so much for having me. It was very fun, and I appreciate your and the audience's enthusiasm. I hope I can – I hope I shed some light on things, and I'm always available.





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

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- <u>Heart Valve Learning Center</u> Visit the Heart Valve Learning Center to access over 1,000 pages of educational information about valvular disorders.
- <u>Patient Community</u> 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.
- <u>Surgeon Finder</u> Find and research patient-recommended heart surgeons that specialize in heart valve repair and heart valve replacement procedures.
- <u>Heart Hospitals</u> 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.
- <u>Educational Videos</u> Watch over 100 educational videos filmed by the Heart-ValveSurgery.com film crew about heart valve surgery.

