3 Questions To Ask Before Mitral Valve Surgery

Cleveland Clinic

Featured Speakers

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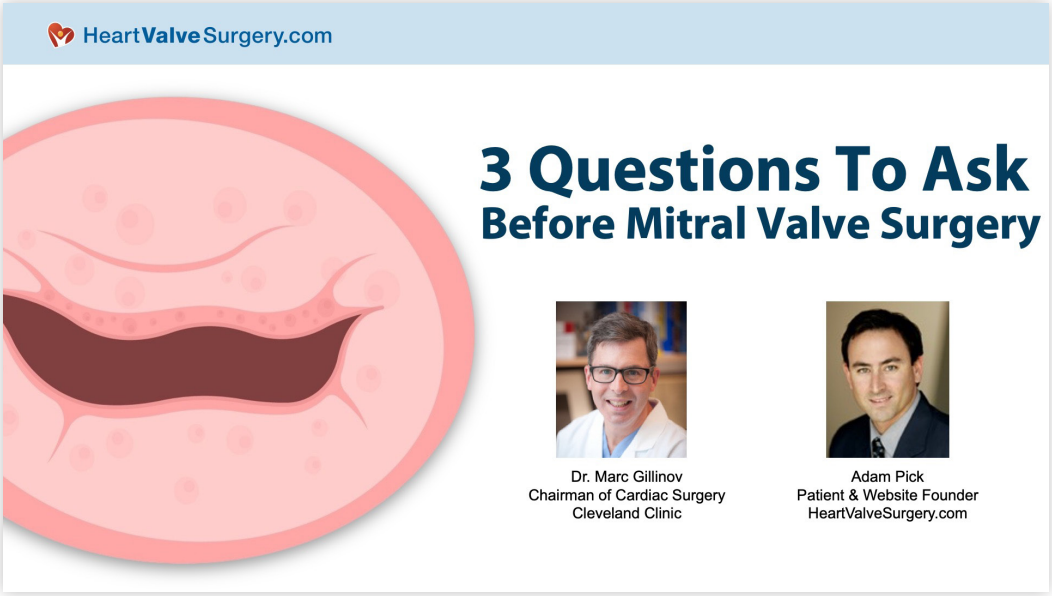
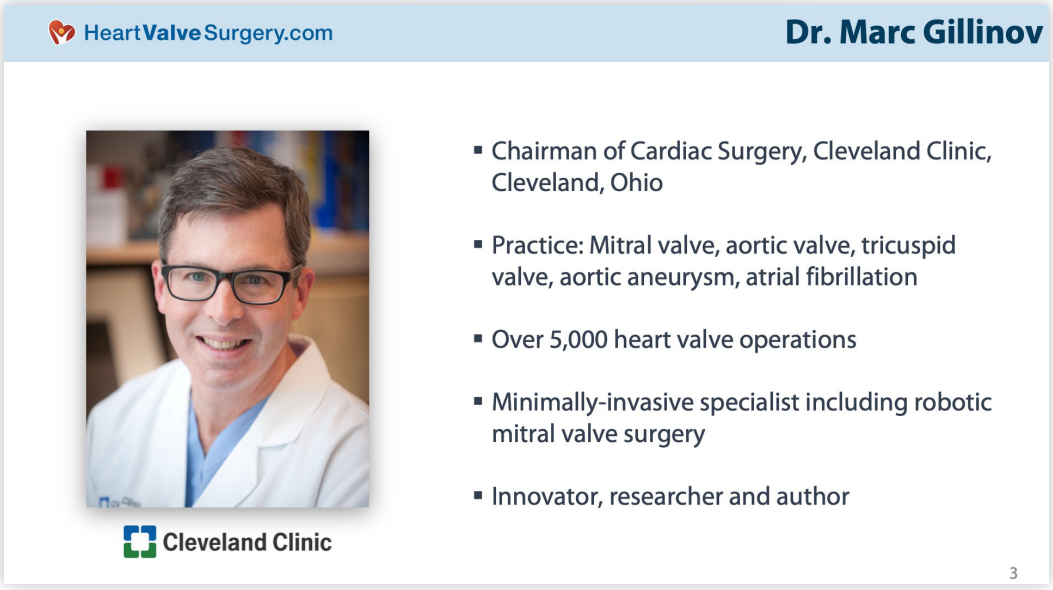
Table of Contents

Introduction



Adam Pick: Hi everybody, my name is Adam Pick. I'd like to welcome you to the webinar titled the "Three Questions to Ask Before Mitral Valve Surgery". If I have yet to meet you, I'm the patient who started HeartValveSurgery.com in 2006. The mission of our website is simple. We want to educate and empower patients just like you. This webinar, which has had over 650 patient registrations from people in countries all over the world, was designed to support that mission.

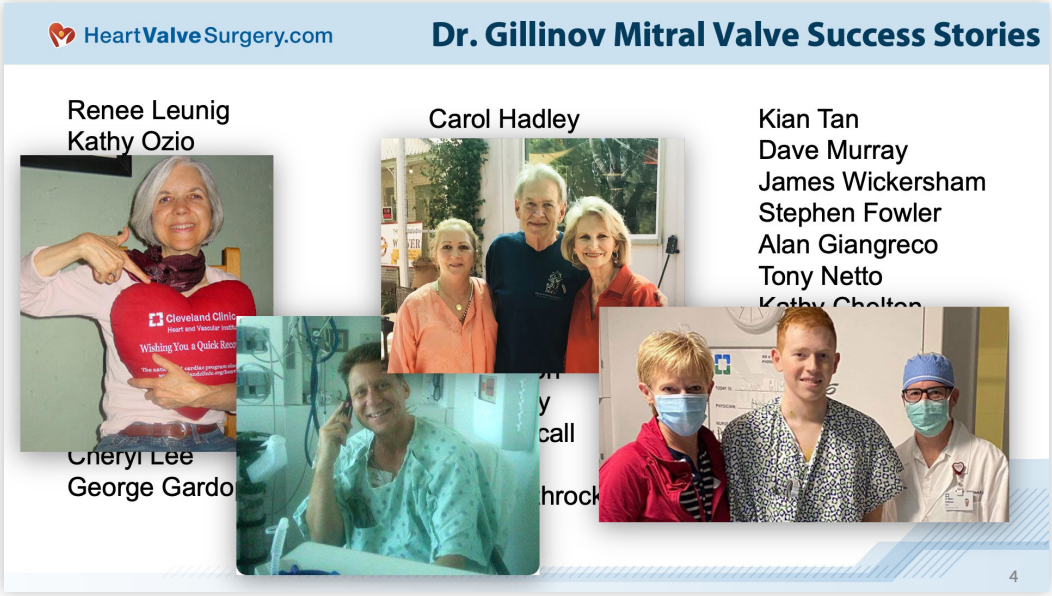
Throughout the webinar, you're going to be in what's known as "listen only mode". But, I encourage you to submit your questions in the control panel on your screen. As we look at the agenda, it'll become clear why that's so helpful. We're going to introduce our featured speaker. We're going to start the discussion with a really great patient case study to set context to the meaning of mitral valve surgery. We're going to get into the three questions, then we're going to have our own Q&A section. Lastly, I'm going to ask you to complete a very quick five question survey that's going to come onto your screen.



When it comes to the featured speaker of today, I am humbled that he is taking time away from his very busy practice. Who is he? Dr. Marc Gillinov is the Chairman of Cardiac Surgery at Cleveland Clinic in Cleveland, Ohio. His specialties are mitral valve, aortic valve, tricuspid valve, aortic aneurysm, and atrial fibrillation. I'd submit to you, he's not just a specialist when it comes to valves. He is a super specialist having performed not 1000, not 2000, but 5,000 heart valve repair and heart valve replacement procedures.

How does he do it? Dr. Gillinov is a specialist when it comes to minimally invasive techniques we're going to talk about today, including robotics. He's an inventor; he's an innovator; he's a researcher. His name is on over 400 scientific journal/papers and he's the co-author of Heart 411.

Dr. Gillinov's Patient Success Stories

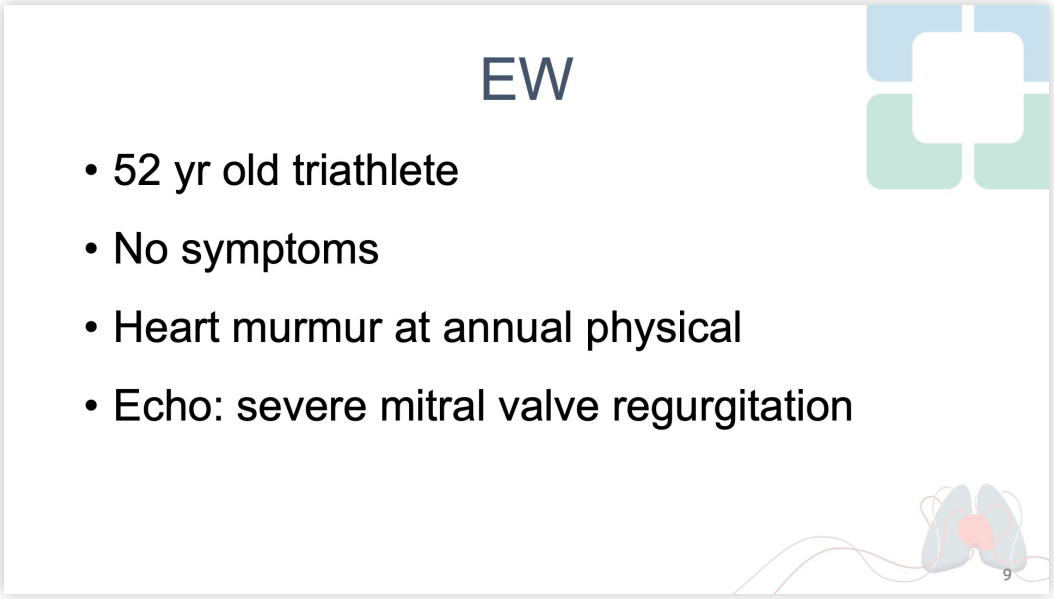


Adam Pick: To give you an idea as to how helpful Dr. Gillinov has been to our community, I went back and I looked at our database of patients. I did a search for Dr. Gillinov success stories. Here, you can see whether it's Dan Spots, Kathy Gazen, Alan G, and Greco. These are all patients from where? The HeartValveSurgery.com community who have gone to Dr. Gillinov and had successful mitral valve surgery. If the names aren't enough, how about some pictures? There's Anita Divine from New York. There's Jeff from Arkansas. Here's a patient reunion of Dr. Gillinov's patients in Austin, Texas. There's Jenny, Randy, and Lisa. Here is the mother/son story of Kathy and Carter Chelton. Yes, mother and son who both needed what? Mitral valve surgery. By who? Dr. Gillinov.

Here are more pictures. This is Dr. Gillinov in the operating room. This is him at the Robotic concil. This is Dr. Gillinov and I in Abu Dhabi celebrating National Heart Valve Disease Awareness Day a few years ago.

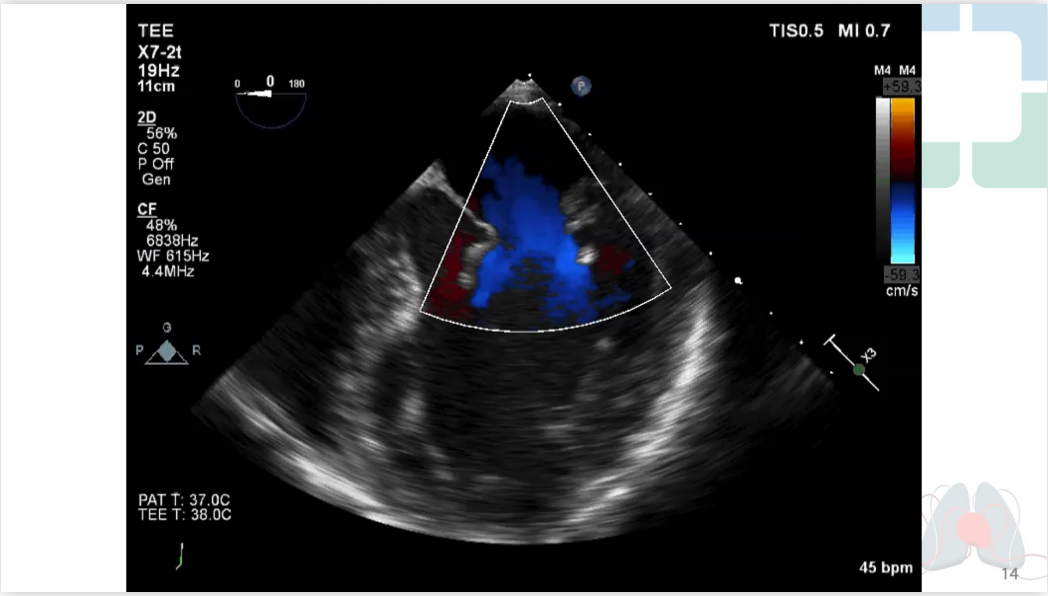
With that introduction, I just can say one thing. Dr. Gillinov, thank you so much for everything you've done to support our community over the years. I'm thrilled to have you here with us today.

Mitral Valve Patient Case Study



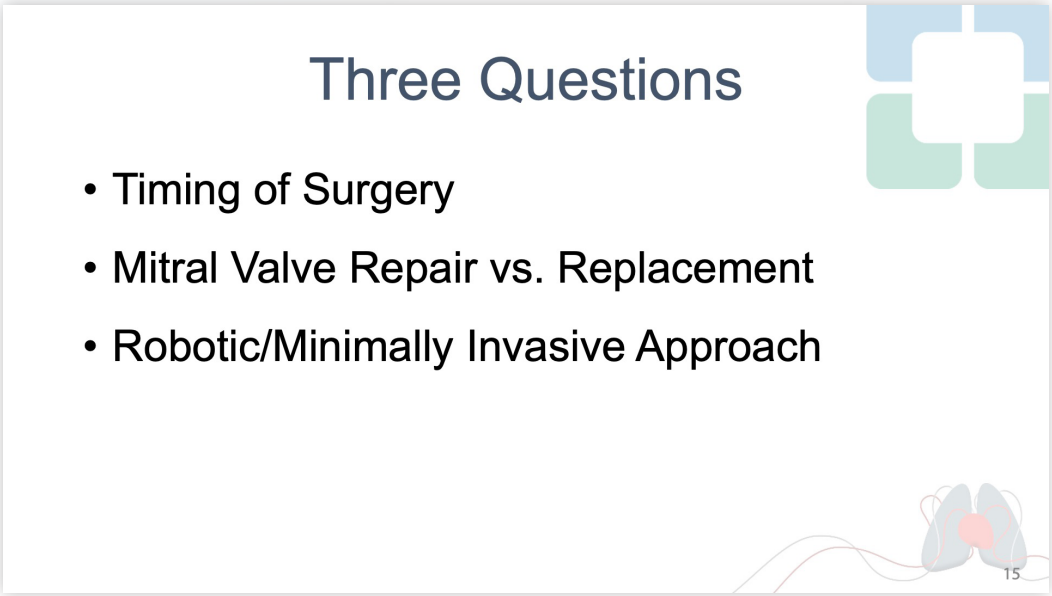
Dr. Marc Gillinov: Great and thank you, Adam. Who gets mitral valve surgery? For the most part, I'm going to talk about degenerative mitral valve disease, which is also called mitral valve prolapse, which is also called myxomatous disease. Degenerative equals prolapse equals myxomatous. But, who are these people? They are people like this, someone who is young and healthy. A 52-year-old triathlete came to me asymptomatic. This guy feels great.

He's completing Ironman Triathlons. He was found to have a heart murmur at his annual physical. He then underwent an echocardiogram which showed that even though he felt great, his mitral valve was leaking. What does that mean? It means heart surgery. Of course, that is an unexpected turn of events for a 52-year-old triathlete who feels perfectly fine. Of course, here's the reaction. "How could this be?" and "How could I be having heart surgery?" and "I have no chest pain, no shortness of breath, no swelling in my ankles. So, why do I need surgery?"



The answer comes in this echocardiogram. This is a transesophageal echo, meaning that the person has been sedated and the echo probe has been placed in the mouth and down the esophagus. The reason that works is that the heart sits right in front of the esophagus. This is an ultrasound of the heart and what you see to the right is something flapping up there. What you're going to see is the leak. This mosaic of color represents mitral regurgitation or the leak of the mitral valve. That's blood going backward from the left ventricle that's squeezing at the bottom of the screen up through the mitral valve, which in normal circumstances is supposed to seal nearly completely.

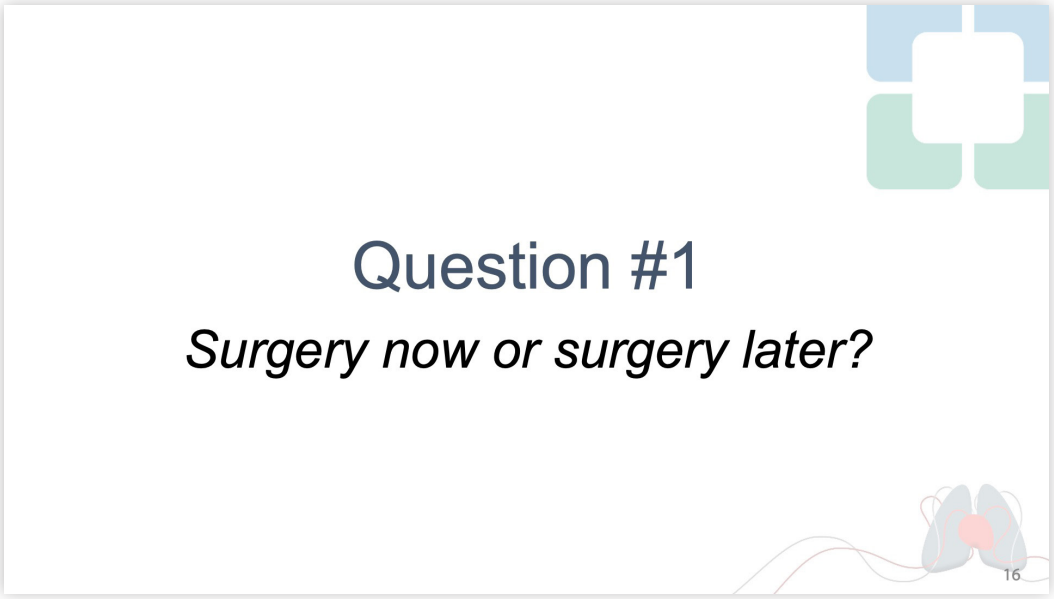
This is what we call severe mitral regurgitation. And this needs to be fixed.



He had three questions once he got over the concept that I'm a 52-year-old triathlete, I can run laps around my surgeon, and I'm going to have surgery. His three questions were the timing. Do I really need this now? The operation itself; what are you going to do to my valve? Are you going to repair it or replace it? Then, can you get that done using a robotic or less invasive approach?

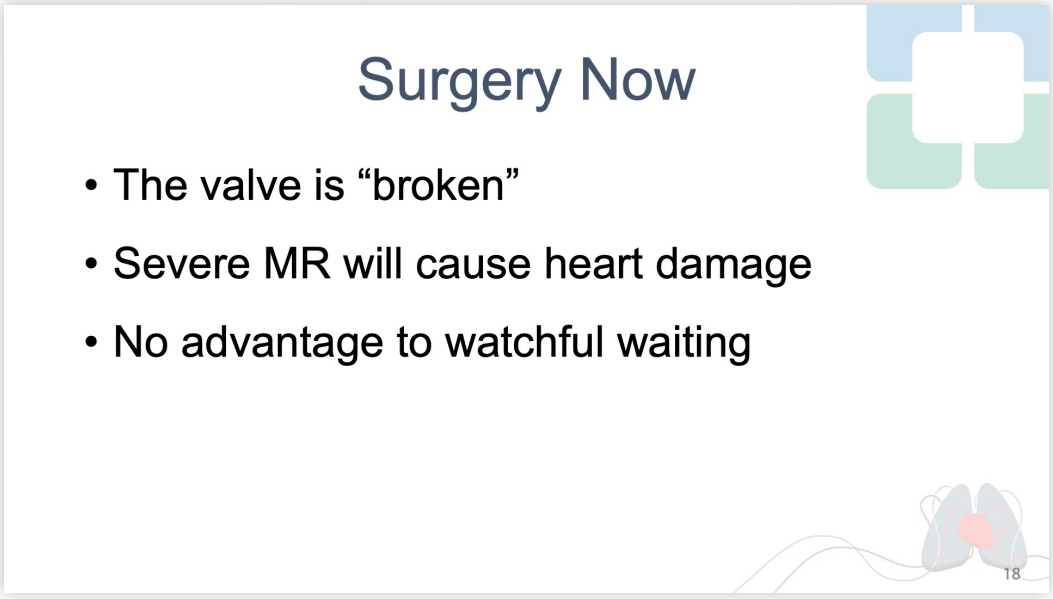
These were the big three questions he had written down on his iPhone when he me with me.

Timing Mitral Valve Surgery



Dr. Marc Gillinov: Let's talk about the timing of heart valve surgery. Should the patient have it now when he feels fine, he's young and healthy? Or, should he just wait? The answer is... Have it now.

The timing question used to be fairly controversial but not so much anymore. The valve is broken, it's not going to fix itself and it's going to cause problems if left alone.



This is what we said. Your valve is broken. You feel fine, but it’s broken and severe mitral regurgitation on a scale from zero to four… If you’ve got a four, that is inevitably going to cause heart damage. You may feel well today, but that’s not going to last.

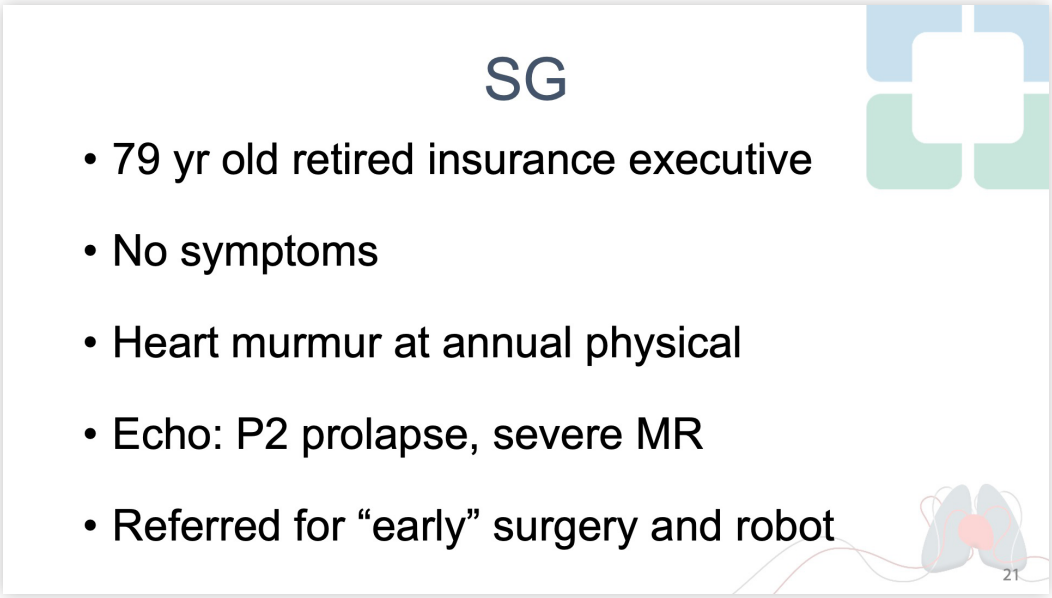
There is no advantage at all to watchful waiting.

The debate used to be... You feel fine? Okay, let's get an echo every six months. With this watchful waiting strategy, which is a bad strategy, the idea was we will do your heart surgery and fix your valve as soon as you start to have heart damage.

Who wants to have heart damage? Don't wait for heart damage. Fix it when you recognize it's broken. Next please. Again he said, can't I wait? I feel fine. The short answer is it's not an emergency. Yes, you can wait few weeks, two, three months, but not six months, not a year, not six years.

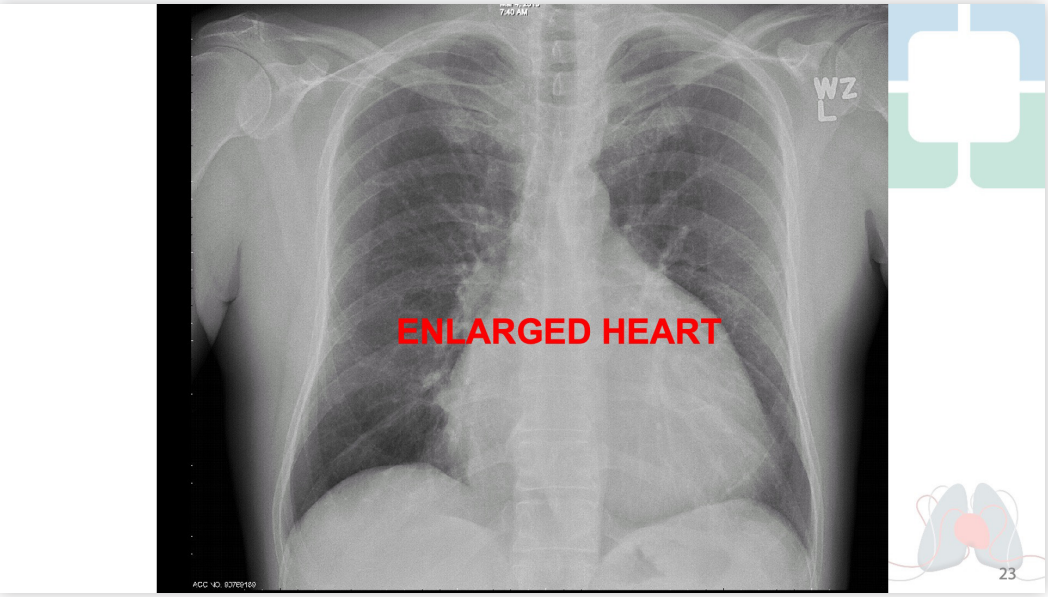
Waiting can be dangerous.

Patient Case Study: Mitral Valve Regurgitation



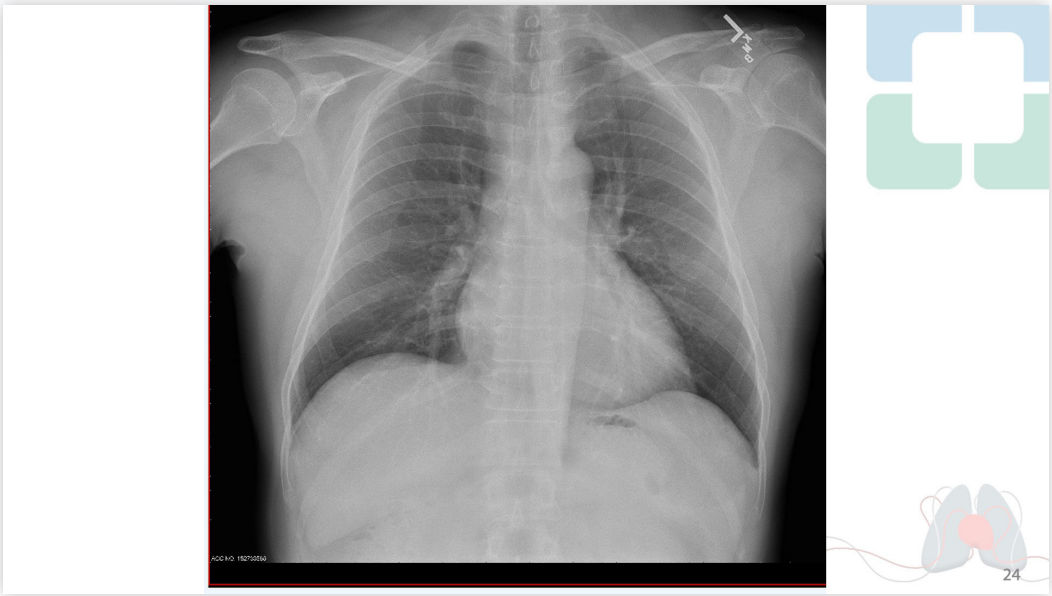
Dr. Marc Gillinov: Let me show you what happened to someone who decided to wait. This is a different patient who is a 79-year-old retired insurance executive, really good health coverage through his company, also no symptoms. He had a heart murmur hurt at his annual physical two or three years in a row. He got an echo which showed the same thing... Prolapse P2.

P means posterior; two means the second part of the posterior leaflet. This is the middle of the posterior leaflet. It’s the most common cause of a leak. He had severe mitral regurgitation. After a couple years of watching this, his cardiologist referred him for what he thought was early surgery because he said this is early in that this patient has no symptoms. He didn’t have symptoms. But, if you look at the image, you’ll see he has an enlarged heart.



This is a very enlarged heart.

Your heart is not supposed to be this big. If your heart is this big, this means his leaking mitral valve, even though he feels fine, his leaking mitral valve has already caused heart damage because you'll see on the next image what your heart is supposed to look like.



This is a normal sized heart. His was one and a half to two times as big. Next slide. He had surgery and he did well, but I cannot, no doctor can reverse heart damage that's already occurred. Don't wait. Don't be like that patient who in fairness was not advised to have early surgery. If the valve is broken, get it fixed. The second question is, what do I mean by getting it fixed? Does that mean repair the valve or replacing the valve?

Adam Pick: Dr. Gillinov, before we go on to the second question, I'm sure there's some patients on the line who are newly diagnosed, maybe they have been in watchful waiting. What I noticed in your prior slides was the use of the word severe for describing mitral regurgitation. We know this is a progressive disease, so what should patients be thinking if they've been told they have maybe just moderate regurgitation, moderate to severe? What would you recommend for them as they're thinking about timing surgery?

Dr. Marc Gillinov: That's a really good question. If the regurgitation is graded as moderate or two out of four, no surgery at this time because you can live to be 100 years old with moderate regurgitation if it stays that way. If it's moderately severe, let's call that three out of four, and we often call it three plus.

If you've got moderately severe or a three out of four, if you have symptoms or if you have any change in your left ventricle, meaning it got bigger or its function is down, you should have surgery. If you have four or severe regurgitation, that's easy, have surgery. If you've got two, waiting is a hundred percent the right thing to do. Get an echo every year. If you've got three, think about how you feel and ask the questions… How is my heart? Has my heart enlarged? Do I have any sign on your echo?

Are there any signs that my heart's paying a price for this? If your heart is paying a price, meaning it's getting damage or you are paying a price for three plus or moderately severe regurgitation, you are paying a price meaning you don't feel as good or you've slowed down. You used to run three miles, now you can't walk three miles. If there's a price being paid, you should get the valve fixed.

Question 2: Mitral Valve Repair vs. Mitral Valve Replacement

Dr. Marc Gillinov: Second question is… What does fixed mean? For prolapse, and this is not talking about people who have rheumatic heart disease and other conditions. For mitral valve prolapse, which means the valve is floppy, mitral valve repair is the gold standard. That's what you want for your valve.

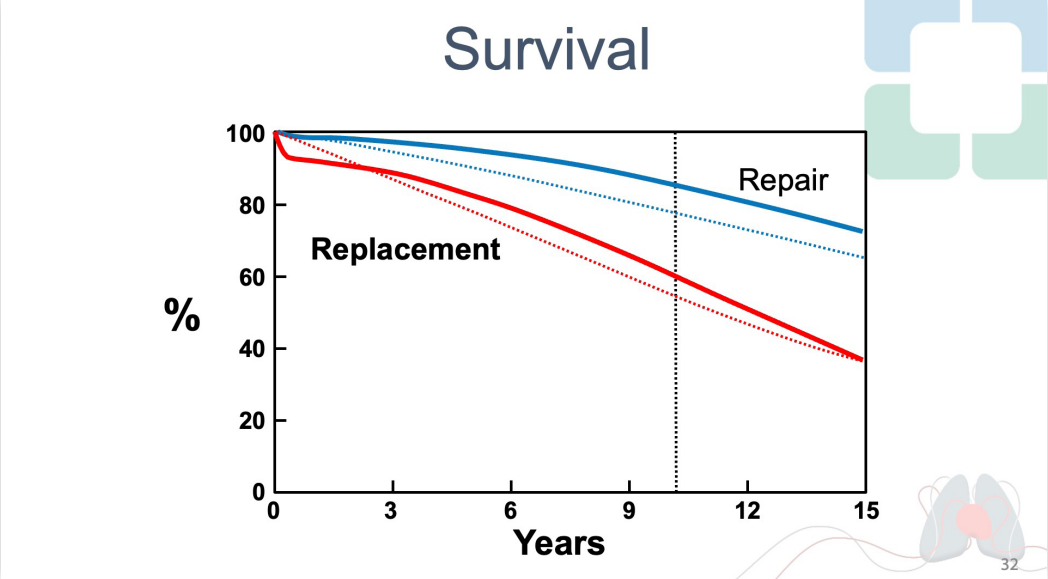
The data goes way back more than 40 years. Alain Carpentier, a French surgeon, described mitral valve repair and he called it the “French Correction”. Then, his long-term results over 20 years showed that these repairs last a long time, which was not known at that point.

Then, other surgeons found out we can repair almost all of these degenerative valves. It turns out that as Carpentier, the father of mitral valve repair said, “They last a long time.”

More recently, we found we can do most of these operations through little incisions with robotic assistance. Regardless of approach, mitral valve repair for prolapse is the gold standard. That’s what you want from your surgeon and your surgical experience.

Why do you want repair? What is the advantage? It's pretty simple. Mitral valve repair, is somewhat magical.

I'll show you why. If you get a valve repair for degenerative disease or prolapse, you have the following benefit, which is quite simply… You live longer!



This is a graph showing how long people live if they got a repair on the blue line versus replacement on the red line. You see the separation. People who get a mitral valve repair in general live longer than people who get a mitral valve replacement. This is the single reason that you should ask your surgeon, "What is the likelihood that you and your team can repair mitral valve?"

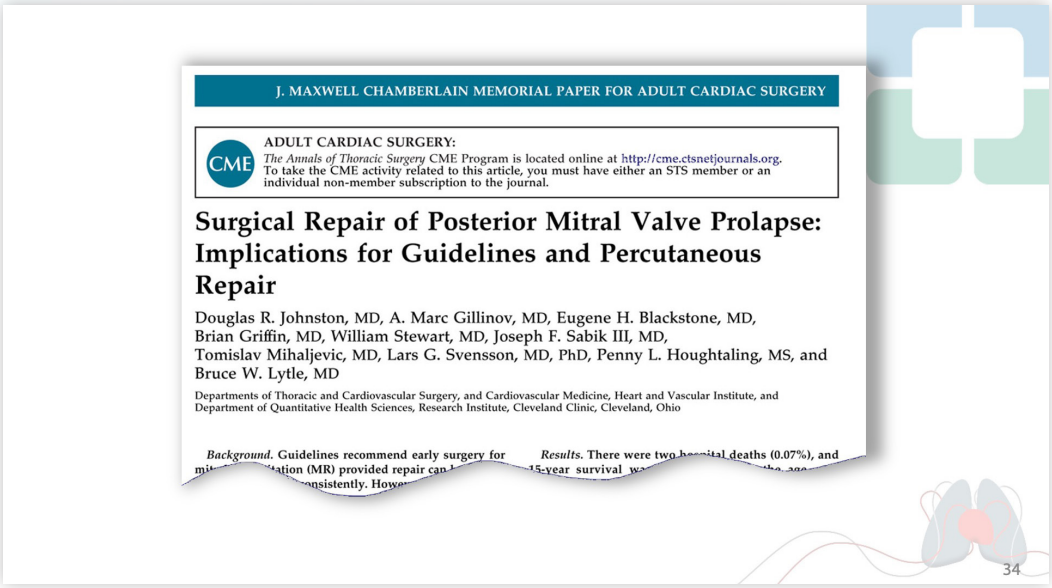
Adam Pick: Dr. Gillinov, I have to ask if you are a patient and you have mitral regurgitation, you see a physician, you've been told you need surgery and you're told that they're going to do a replacement for you, what is your advice to patients?

Dr. Marc Gillinov: Get a second opinion. I think you should always get a second opinion for something as important as your heart and it's worth your while to do so. Sometimes, it can even be just a video conference. There are a few kinds of mitral regurgitation where replacement might be a better option. But, there a select few.

If your diagnosis is mitral valve prolapse, then you should be talking about repairing. Your surgeon should be discussing repair because that's what's going to make you have a normal life expectancy.

Replacement sometimes is inevitable but repair is better and we want the best, you want the best. For this patient, a repair was perfect. This patient we presented, back to the 52-year-old triathlete who feels great, he's got what's called posterior leaflet prolapse. The mitral valve has two leaflets or flaps. One is termed the anterior leaflet, the other the posterior leaflet, and they meet in the middle like the doors at the airport.

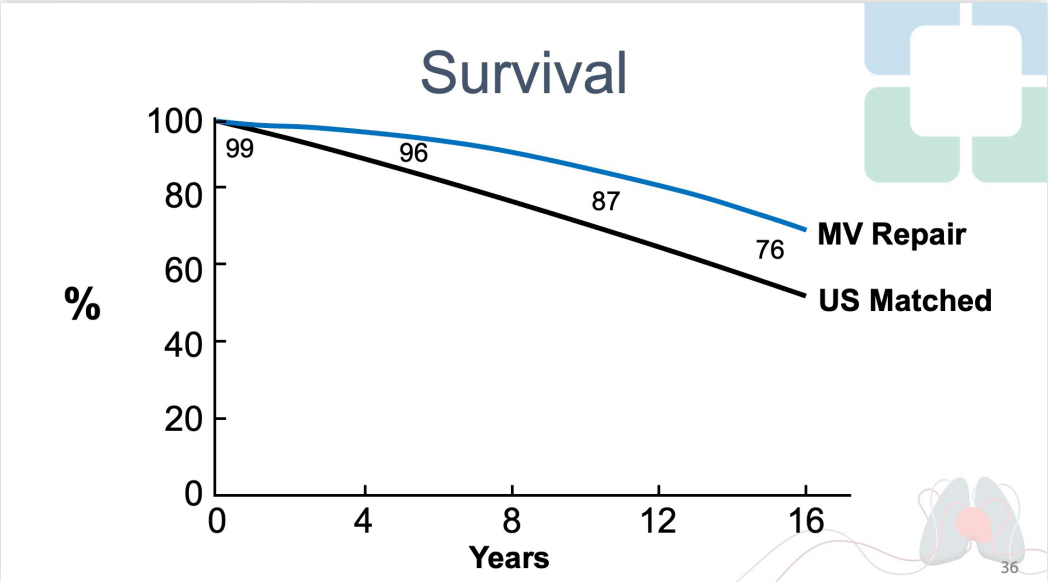
As you walk up they slide apart and then they rejoin each other. Posterior leaflet prolapse. Prolapse affecting the posterior part or back of the valve is our sweet spot. It is the easiest to repair. It has outstanding durability and the operation is incredibly low risk. It's almost like getting your appendix or your gallbladder out.



One of my friends and colleagues, Dr. Doug Johnston, when he was at Cleveland Clinic, looked at repair of posterior leaflet prolapse. This is what 70% of people have, prolapse; this posterior leaflet effect.

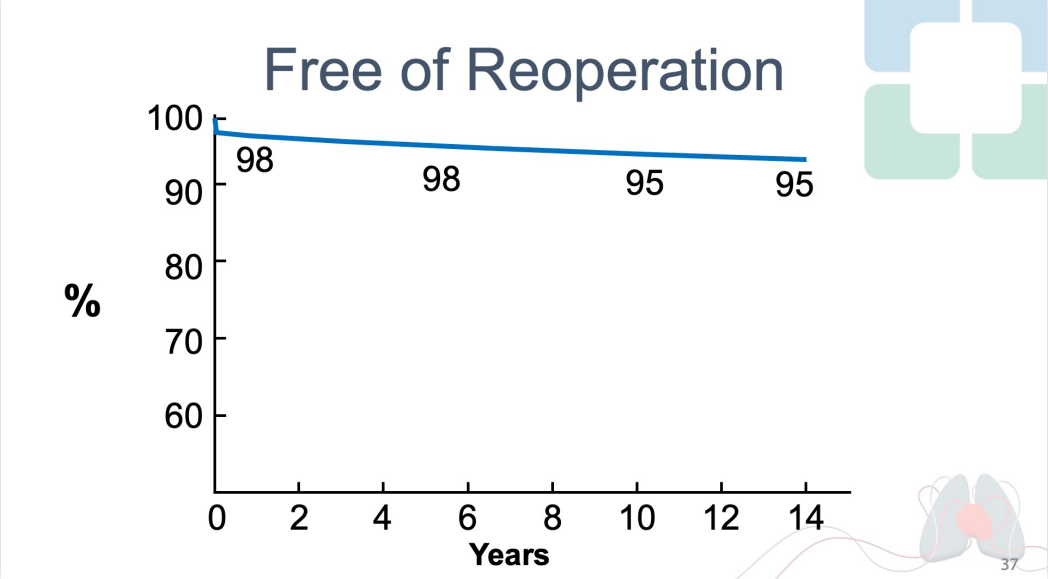
If we look at the repairs in this research, what we find is a few things. First of all, the operative risk, the risk of not getting through surgery is under one in a thousand. To flip that around, if you come in to the hospital with posterior leaflet prolapse and you're going to get a mitral valve operation, ideally repair, the risk of you dying is under one in a thousand. This is an incredibly low risk operation.

Yes, it's heart surgery, it's a big deal, but it's a very low risk heart surgery.

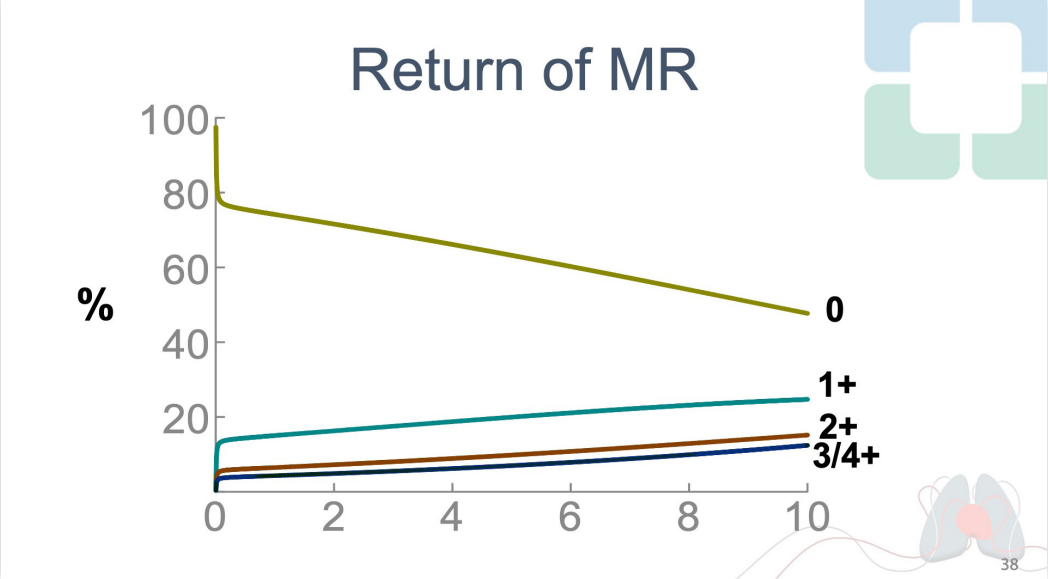


The reason we want to repair again and I want to emphasize this, that's why we've got a similar curve up twice, is these are two survival plots, meaning how many people were alive after surgery at 4, 8, 12 and 16 years. After a mitral valve repair on the blue line, you're pretty much the same as people we've matched from US Census Bureau data. What this means is if you had a mitral valve repair for prolapse, it's as if you never had heart disease. You are back to a clean slate. You're normal.

You had something wrong with your valve, it got fixed. It's like a car that was in a fender bender. It's not the whole valve just a part of it. Look what happened. You were restored to a normal life and this is why repair is so important to me and should be to you.



Now, not all repairs last forever and I just want to make that point. If you've had a repair, usually it will last forever. At 14 years, 95% of people have not required a reoperation. But, if you did get a repair, you should get an echo once a year.



On this image, what we'll see is there is some return of mitral regurgitation at 10 years. About 10% of people might need a re-operation, meaning they're on that bottom curve, meaning their return of mitral regurgitation is at a level of three or four.

However, the other 90% are at zero regurgitation or close to zero I should say because no one's really zero but close to zero. You can live with that. Ideally you're one or less, which is the majority of people. The point here is you will likely have a normal life expectancy.

364 days a year, forget about your valve. One day a year get an echo to check on it.

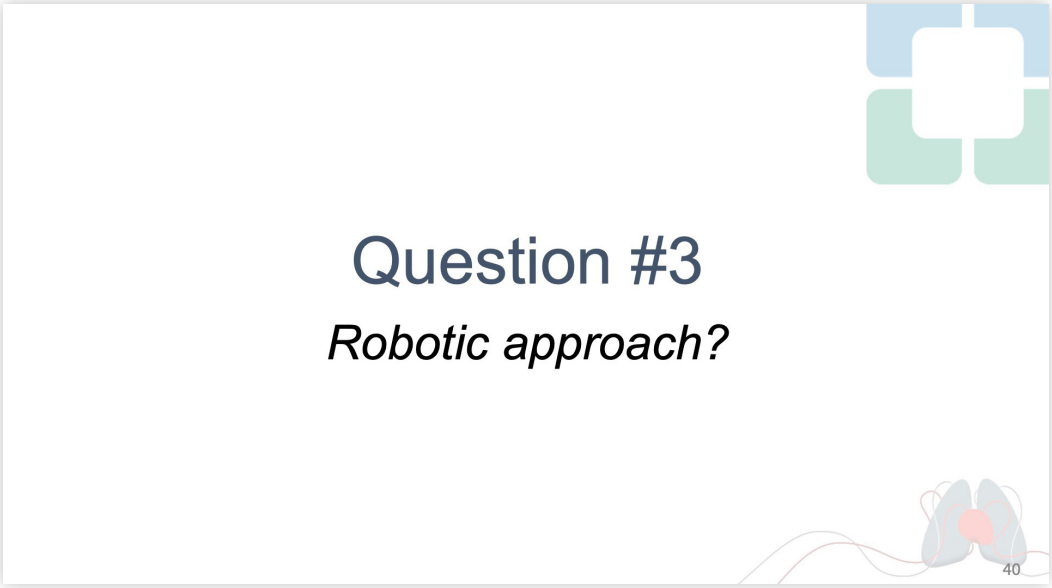
Adam Pick: Dr. Gillinov I've got to ask you, you've highlighted all the advantages here of the return to a normal life expectancy being normal, just even with this disease, the lack of mortality. I'm sure patients might be wondering does this apply to all cardiac centers? Where is this data coming from? Are you collecting it from across a massive database or is this specific to the Cleveland Clinic?

Dr. Marc Gillinov: These are the Cleveland Clinic data. However, across the country, across the entire US, in general, the risk of having a mitral valve repair is about 1% or a little bit less which means 99% success in terms of surviving surgery. That's really good.

I'd say one in a hundred people in the US won't make it through mitral valve surgery. But, at Cleveland Clinic it's actually more like one in a thousand. I think that relates to just the team that we have. I'm sure that there are some other medical centers that also have just tremendous resources in teams, but virtually everyone who goes in for a mitral valve repair should be thinking about I want an experienced surgeon and not just a surgeon, a center that does this every day, day-in-and-day-out because to your point, these are our Cleveland Clinic data with super low mortality.

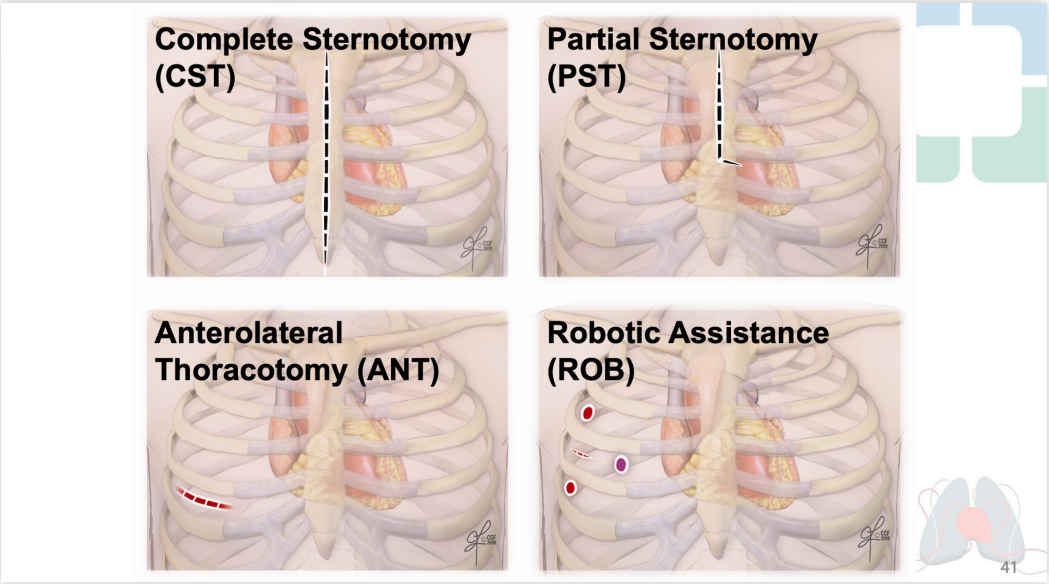
Again, it's not exclusive to us, but we are fortunate in that we do more mitral valve surgery than any place in North America. I don't play golf, but people who do tell me if you do it every day you get better at it. I would hope the same has been true with surgery over the last 40 years at Cleveland Clinic.

Question 3: Approach to Mitral Valve Surgery



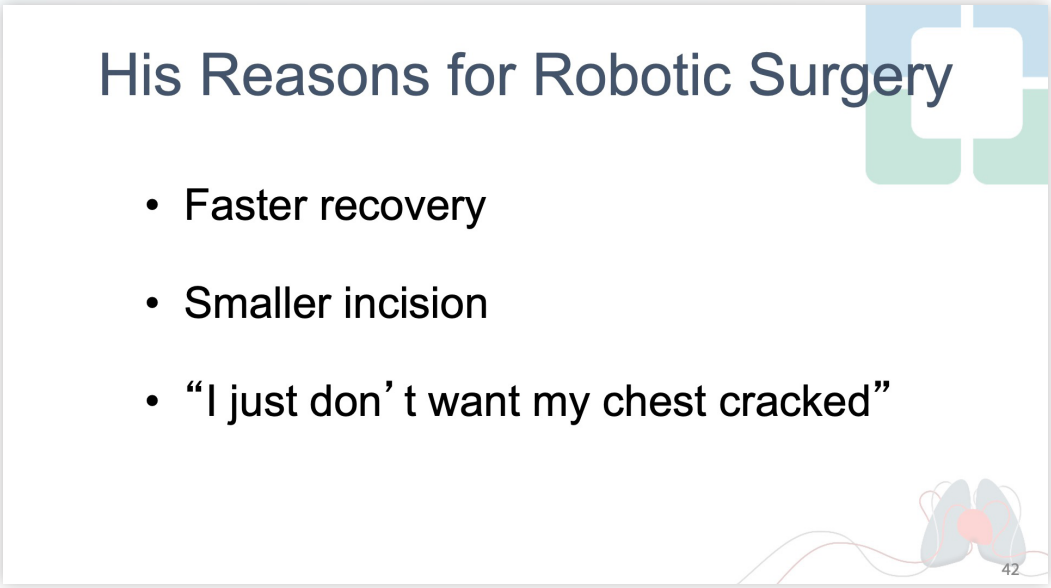
Dr. Marc Gillinov: Now we'll move on to question number three. You want to know, "Can you sneak in there with the robot and get my valve fixed because I don't want to look like I had heart surgery and I want a quicker recovery?"

The answer requires a lot of discussion. In this patient's case, the answer was yes.

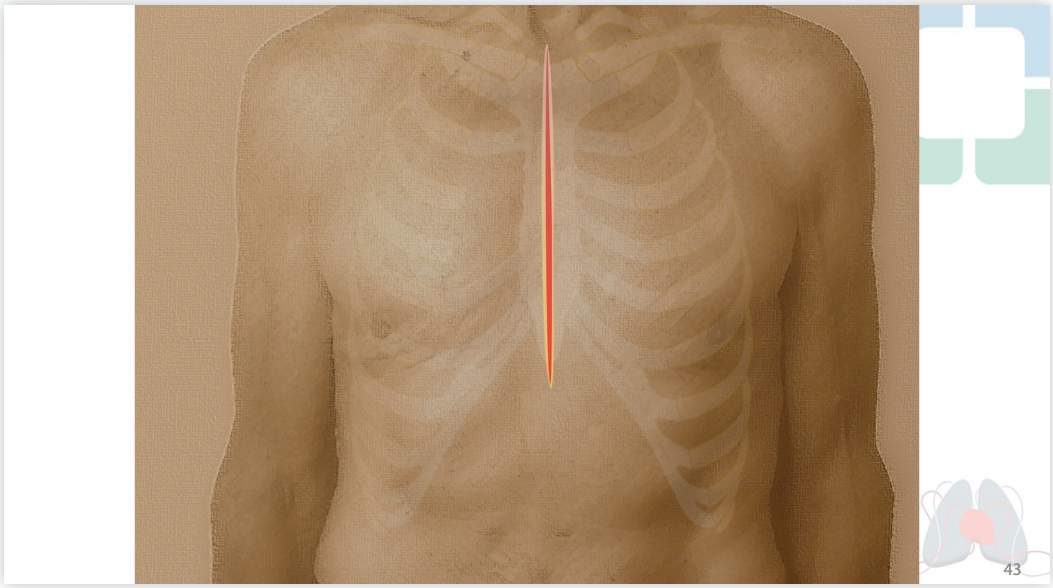


There are many ways to get to the mitral valve. They're seen here starting at the top left, a complete sternotomy which works great. Bill Clinton, David Letterman, Arnold Schwarzenegger, many many people, millions of people have had a sternotomy and this heals very well. To the right of that going clockwise would be a partial sternotomy. That's another way to get through the valve. You still cut some of the bone. Then in the bottom left, many people, surgeons will do an anterolateral thoracotomy which is less invasive or the least invasive.

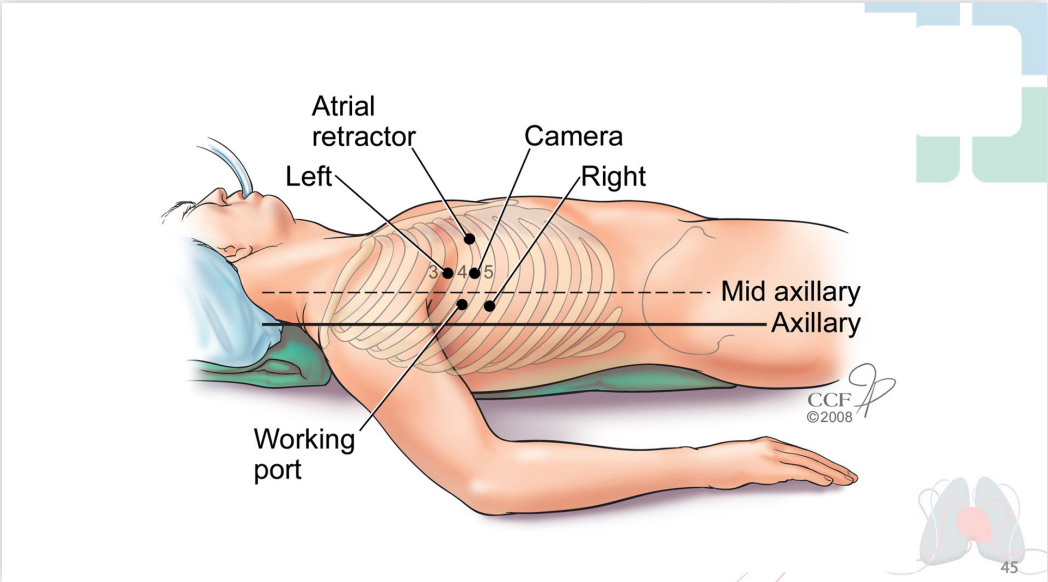
Bottom right is a robotic approach, which you see those three circles. Those are little ports that we make which are about one centimeter long and we put instruments through that are a little bit thicker than a big pen. Then there is an incision which is marked by this red line on the right side of the chest or to your left right there. That incision usually is quite small, maybe an inch or two inches. This is our least invasive approach to the valve.



Why did he want robotic surgery? Faster recovery, smaller incision, and this just general statement we hear a lot, "I don't want my chest cracked."

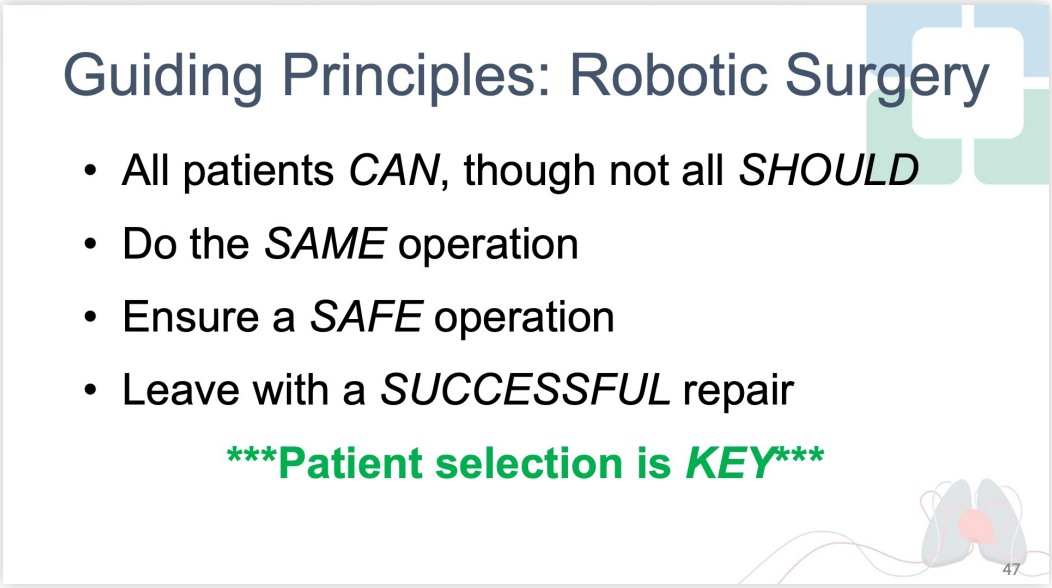


What he's talking about is a sternotomy incision, which is the most commonly used incision for heart surgery. Again, it heals well, but next his gut instinct was, I don't want a cracked chest. Unless you have to do that to save my life, I'd like something on the right side with the robot.



Here is a schematic illustration of what robotic surgery looks like. It's actually ironically a collection of incisions. Each incision is small and heals quickly. That's robotic surgery.

While people recognize your heart is more on the left side of the chest than on the right, the approach to the mitral valve with the robot is from the right side because that enables us to look at the left atrium, which is where the mitral valve lives.

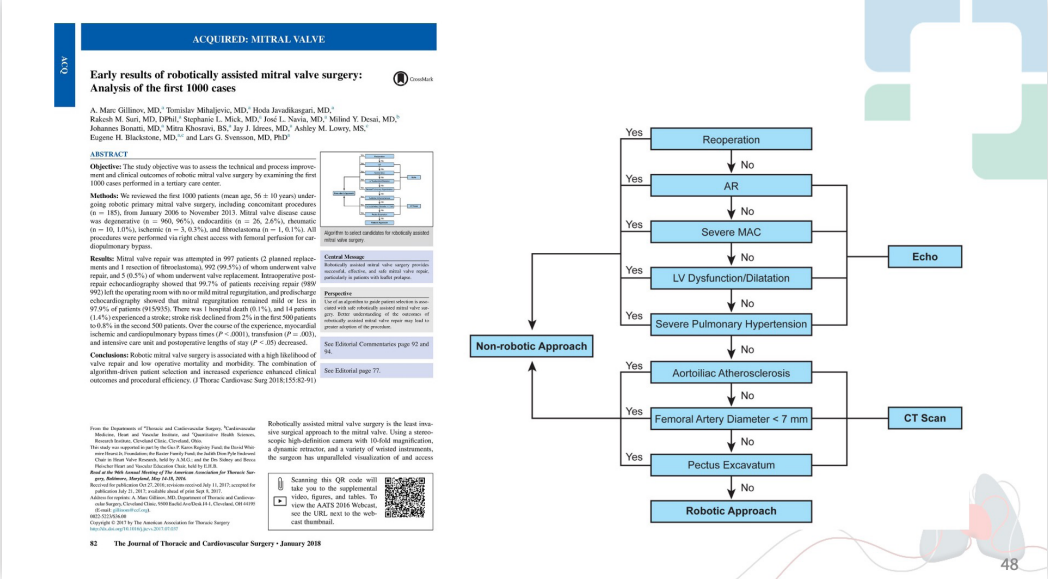


The question for robotic surgery isn't can a surgeon do it, it's when should the surgeon do it? This is a slide that really states our guiding principles for robotic surgery.

First of all, as I said, all patients can have it though not all should have it. In order to do robotic surgery well we've got to be able to look at the patient and look in the mirror and say we're doing the same operation with the same safety and we're going to have a successful repair.

That means we've got to choose the patients wisely and well. As we've become more experienced at the Cleveland Clinic, we've done more than 2,400 cases, we've extended our criteria because we can do it relatively quickly now but the robot is just a surgical tool. It's a super advanced amazing tool. Like any tool, you've got a tool chest.

You open it up, you've got to decide which tool is the best for the project at hand; in this case the project being fixed, your mitral valve.



ACQUIRED: MITRAL VALVE

Early results of robotically assisted mitral valve surgery: Analysis of the first 1000 cases

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ABSTRACT

Objective: The study objective was to assess the technical and process improvement and clinical outcomes of robotic mitral valve surgery by examining the first 1000 cases performed in a tertiary care center.

Methods: We reviewed the first 1000 patients (mean age, 56 ± 10 years) undergoing robotic primary mitral valve surgery, including concomitant procedures (n = 185), from January 2006 to November 2013. Mitral valve disease cause was degenerative (n = 960, 96%), endocarditis (n = 26, 2.6%), rheumatic (n = 10, 1.0%), ischemic (n = 3, 0.3%), and fibroelastoma (n = 1, 0.1%). All procedures were performed via right chest access with femoral perfusion for cardiopulmonary bypass.

Results: Mitral valve repair was attempted in 997 patients (2 planned replacements and 1 resection of fibroelastoma), 992 (99.5%) of whom underwent valve repair, and 5 (0.5%) of whom underwent valve replacement. Intraoperative post-repair echocardiography showed that 99.7% of patients receiving repair (989/992) left the operating room with no or mild mitral regurgitation, and predischarge echocardiography showed that mitral regurgitation remained mild or less in 97.9% of patients (915/935). There was 1 hospital death (0.1%), and 14 patients (1.4%) experienced a stroke; stroke risk declined from 2% in the first 500 patients to 0.8% in the second 500 patients. Over the course of the experience, myocardial ischemic and cardiopulmonary bypass times ($P < .0001$), transfusion ($P = .003$), and intensive care unit and postoperative lengths of stay ($P < .05$) decreased.

Conclusions: Robotic mitral valve surgery is associated with a high likelihood of valve repair and low operative mortality and morbidity. The combination of algorithm-driven patient selection and increased experience enhanced clinical outcomes and procedural efficiency. (J Thorac Cardiovasc Surg 2018;155:82-91)

Algorithm to select candidates for robotically assisted mitral valve surgery.

Central Message

Robotically assisted mitral valve surgery provides successful, effective, and safe mitral valve repair, particularly in patients with leaflet prolapse.

Perspective

Use of an algorithm to guide patient selection is associated with safe robotically assisted mitral valve surgery. Better understanding of the outcomes of robotically assisted mitral valve repair may lead to greater adoption of the procedure.

See Editorial Commentaries page 92 and 94.

See Editorial page 77.

From the Departments of "Thoracic and Cardiovascular Surgery, [b]Cardiovascular Medicine, Heart and Vascular Institute, and [c]Quantitative Health Sciences, Research Institute, Cleveland Clinic, Cleveland, Ohio.

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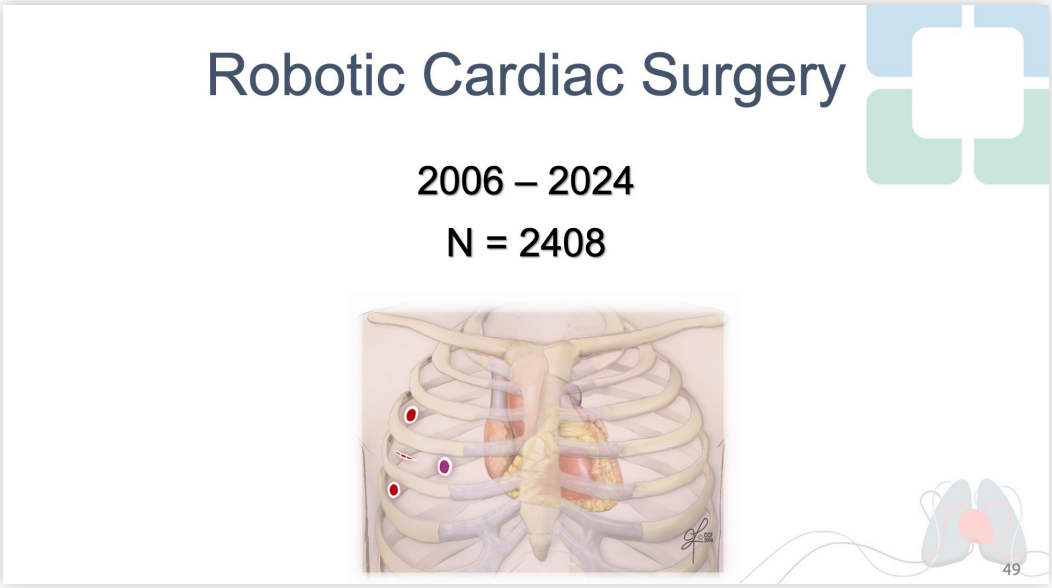
Robotically assisted mitral valve surgery is the least invasive surgical approach to the mitral valve. Using a stereoscopic high-definition camera with 10-fold magnification, a dynamic retractor, and a variety of wristed instruments, the surgeon has unparalleled visualization of and access

Scanning this QR code will take you to the supplemental video, figures, and tables. To view the AATS 2016 Webcast, see the URL next to the webcast thumbnail.

I'm going to show this in bigger print, so don't string your eyes.

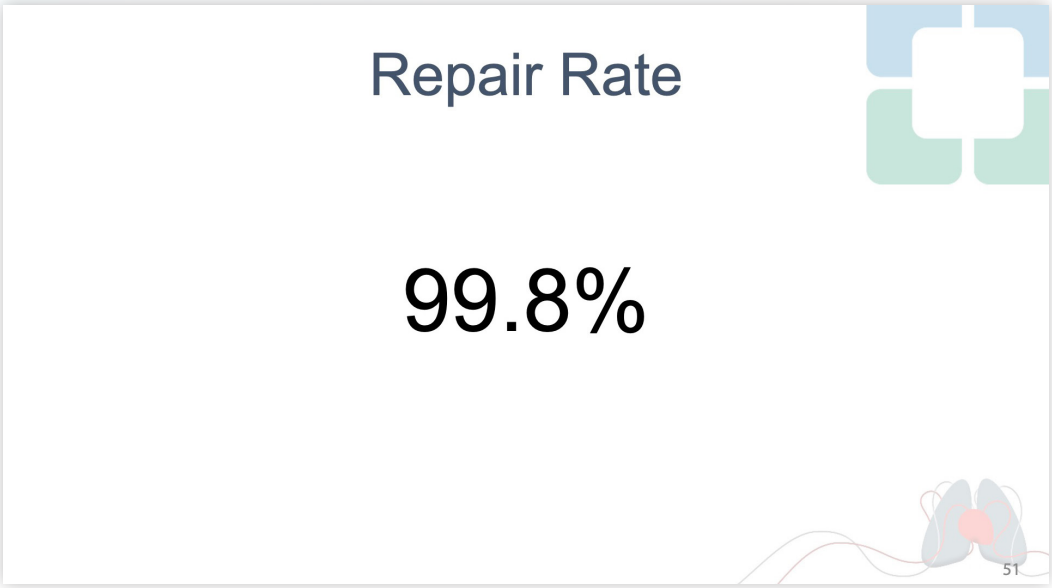
After our first thousand robotic cases, which is about seven, eight, nine years ago, we determined how we judge or screen who is the best candidate for robotic surgery versus non robotic surgery.



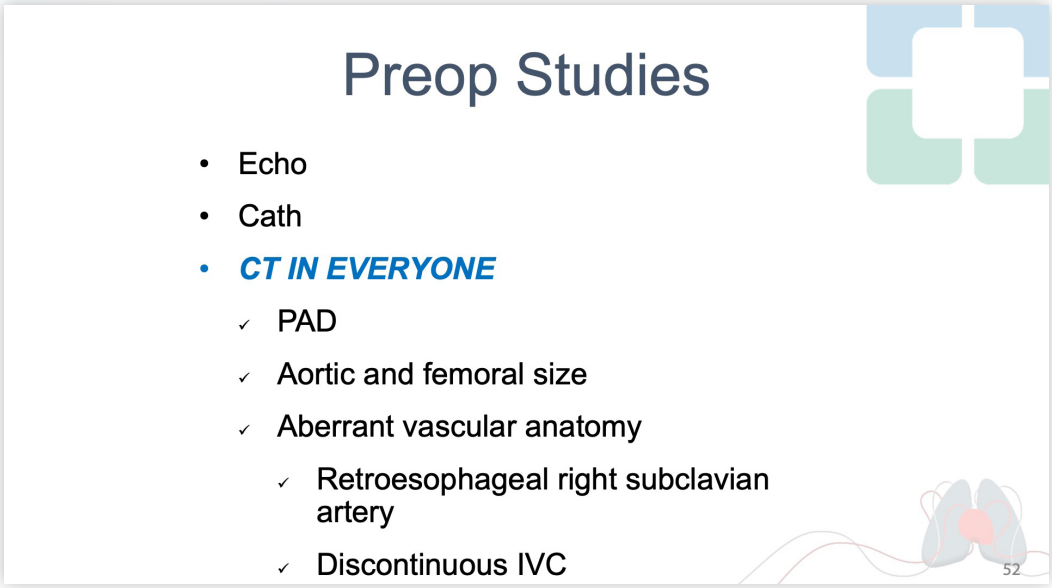
These are our data most currently. Actually as of today we're 2,418 robotic cases because we did two Monday, two Tuesday, one Wednesday, one Thursday, and a couple last week.

These are what we have been able to achieve by careful selection and application and expertise. We always do this as a team. Right now my partner, Dr. Tarek Malas and I do the robotic cases together.

First of all, what's the risk? Under one in 2000, so the chance of getting through surgery is greater than 1,999 out of 2,000.

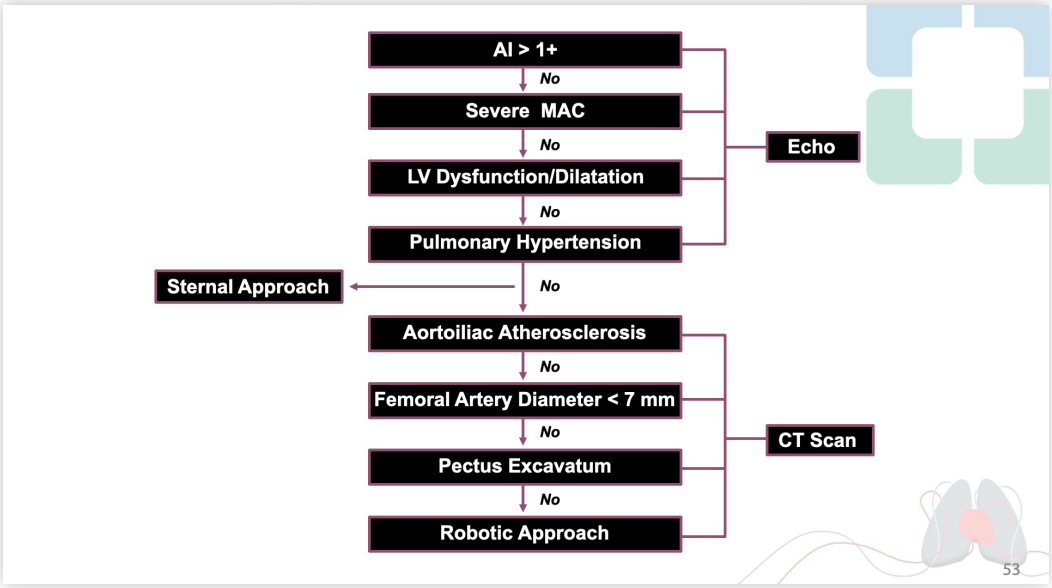


Our repair rate with the robot is 99.8%, meaning that we know how to repair the valve with the robot and we know which maneuvers are suitable for the robot.



A lot of this depends on the preoperative studies. Today, I was reviewing a chart where the patient had had an echo to look at the valves, a cardiac cath to make sure that there are no blockages in the arteries, but this patient had not yet had a CT scan, or a CAT scan, of the chest, abdomen, and pelvis, which we need as a roadmap to tell us if robotic surgery is safe.

This patient had had an echo and a cath and had been told you are good for robotic surgery, that's what we're going to do. She sent me her records and we got back to right away and said, please send the CT scan. She said, well I don't have one of those. I said, well don't have any semblance of robotic surgery until you have a CT scan because that's how we determine how to get where we're going. That is our roadmap.

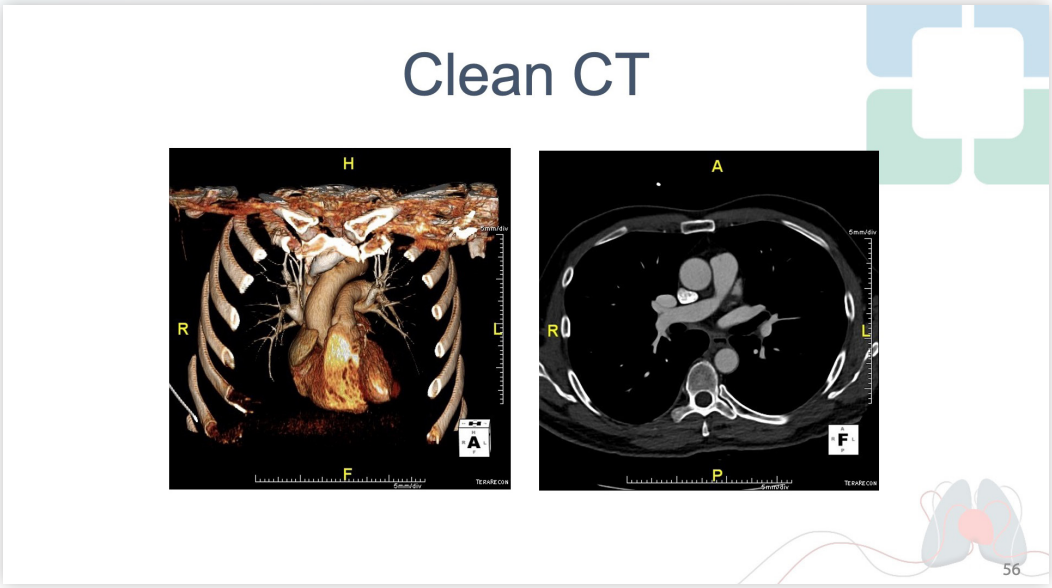


Here's how our preoperative testing boils down. Before surgery, we need an echo and a CT scan in addition to the cardiac catheterization. If certain criteria are met, we get through this algorithm, we are able to do it robotically. If there is a leak to the aortic valve which may need treatment or will complicate surgery, you don't want robotic surgery. If there's a lot of calcium in your valve, an open approach is probably best and certain heart conditions are best treated with an open approach. Those are determined by echo. The CT scan is equally important. When we do robotic surgery, we generally hook up the heart lung machine by putting a tube in the artery and vein to your leg. We send the blood from the heart lung machine into the artery in your leg, which means we're sending the blood backward. As we're all sitting here now, our hearts are pumping and sending blood from our chest toward our toes. With robotic surgery, we reverse the flow of blood. What that means is if there is some plaque or blockage in the arteries to your leg or in the arteries in the abdomen, a piece of that could get broken loose by the reverse flow of blood and that would potentially cause a stroke. That's the main reason to get a CAT scan, to avoid strokes because stroke is amongst the most devastating complications. I'm pleased to say in our experience it's very rare, but I think that's because we plan ahead.

Adam Pick: Dr. Gillinov, I've heard you lecture and talk about safety, safety, safety, robotics, mitral valve surgery. It's fascinating to see this algorithm that your team has put together and the constraints around doing robotic mitral valve surgery. I'm curious to know, you talked about stroke and risk, how does atrial fibrillation play into a situation for a patient with mitral valve disease because I think the data is about 35% of patients with mitral valve disease may have some form of AFib and I know you want to prevent strokes? Can you manage both robotically?

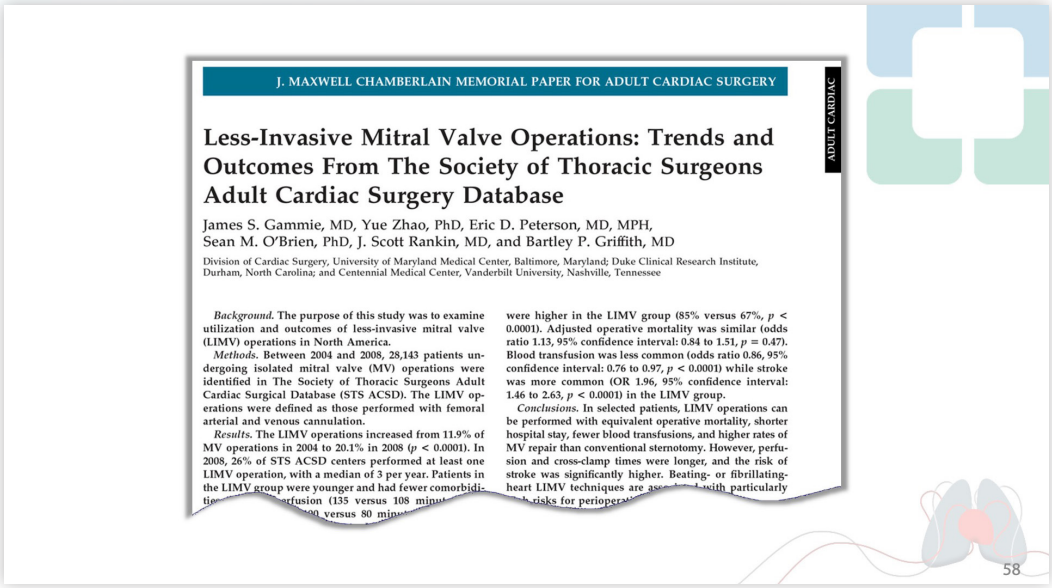
Dr. Marc Gillinov: Yes, you can. Yesterday in the morning I did a robotic procedure on a patient with a history of atrial fibrillation and we did a Maze procedure with the robot. The thing is though, in my opinion, we don't do quite as complete an ablation of AFib or maze procedure with the robot as we do through a sternotomy. The reason for that is that the tools we use to do the AFib procedure, the maze procedure are designed to be used primarily through a sternotomy.

That said, I feel like we can do a pretty good job with the robot to treat both the AFib and the mitral valve. The other factor that goes into that is robotic surgery, if it's early in the surgeon's experience, definitely takes longer and you don't want to have someone on the heart lung machine for an excessive period of time. In our first thousand cases, we did not treat AFib with the robot very often because we said look, just dealing with the mitral valve with the robot is going to take a while. At this point the times are equal to an open procedure. What does that mean? It means that short answer to your question is yes, we can do a good job with AFib with the robot now, but that's after a lot of experience.



Dr. Marc Gillinov: The main point here was going to be get that CT scan. If your surgeon says we can do it through the right chest or do it robotically, that's wonderful, but make sure you've had a CT scan and I'll show you why.

Above is the the kind of CT scan we're looking at and we're looking for. To your left is a three dimensional reconstruction. You can see the ribs are cut away and you're looking at an actual person's heart, which is just amazing. To your right is a slice of that scan. This would be if a patient's laying on his or her back and the top is the front of the patient, the bottom is the back, outlined in whiter bones so that rectangle at the top that's outlined in white, that's the sternum, and then at the very back is the spine. Then the middle is the heart and the circle at the top is the aorta, and you want to see that's very clean. There's no plaque in there.



J. MAXWELL CHAMBERLAIN MEMORIAL PAPER FOR ADULT CARDIAC SURGERY

ADULT CARDIAC

Less-Invasive Mitral Valve Operations: Trends and Outcomes From The Society of Thoracic Surgeons Adult Cardiac Surgery Database

James S. Gammie, MD, Yue Zhao, PhD, Eric D. Peterson, MD, MPH, Sean M. O'Brien, PhD, J. Scott Rankin, MD, and Bartley P. Griffith, MD

Division of Cardiac Surgery, University of Maryland Medical Center, Baltimore, Maryland; Duke Clinical Research Institute, Durham, North Carolina; and Centennial Medical Center, Vanderbilt University, Nashville, Tennessee

Background. The purpose of this study was to examine utilization and outcomes of less-invasive mitral valve (LIMV) operations in North America.

Methods. Between 2004 and 2008, 28,143 patients undergoing isolated mitral valve (MV) operations were identified in The Society of Thoracic Surgeons Adult Cardiac Surgical Database (STS ACSD). The LIMV operations were defined as those performed with femoral arterial and venous cannulation.

Results. The LIMV operations increased from 11.9% of MV operations in 2004 to 20.1% in 2008 ($p < 0.0001$). In 2008, 26% of STS ACSD centers performed at least one LIMV operation, with a median of 3 per year. Patients in the LIMV group were younger and had fewer comorbidi-

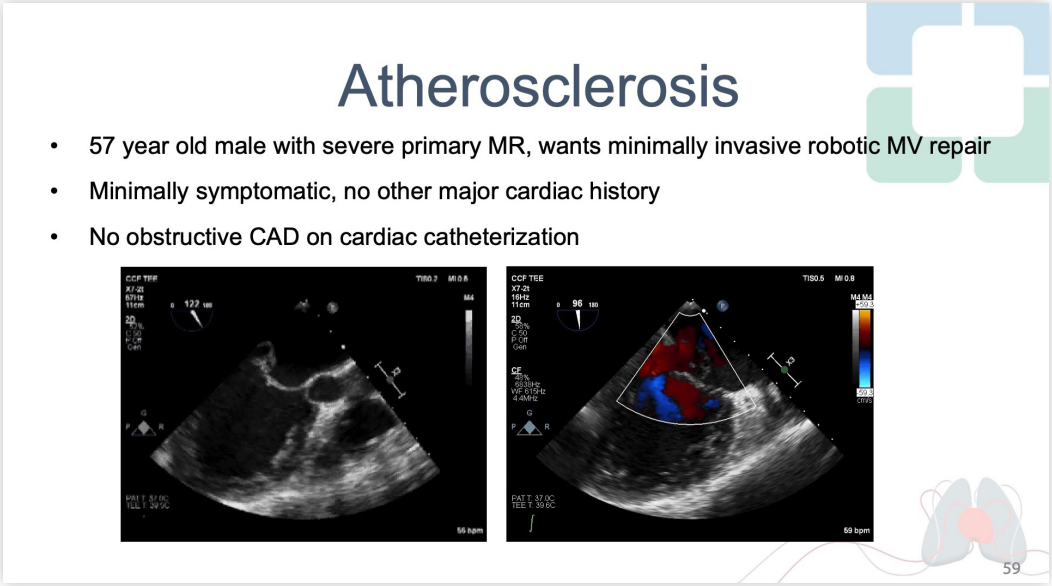
were higher in the LIMV group (85% versus 67%, $p < 0.0001$). Adjusted operative mortality was similar (odds ratio 1.13, 95% confidence interval: 0.84 to 1.51, $p = 0.47$). Blood transfusion was less common (odds ratio 0.86, 95% confidence interval: 0.76 to 0.97, $p < 0.0001$) while stroke was more common (OR 1.96, 95% confidence interval: 1.46 to 2.63, $p < 0.0001$) in the LIMV group.

Conclusions. In selected patients, LIMV operations can be performed with equivalent operative mortality, shorter hospital stay, fewer blood transfusions, and higher rates of MV repair than conventional sternotomy. However, perfusion and cross-clamp times were longer, and the risk of stroke was significantly higher. Beating- or fibrillating-heart LIMV techniques are

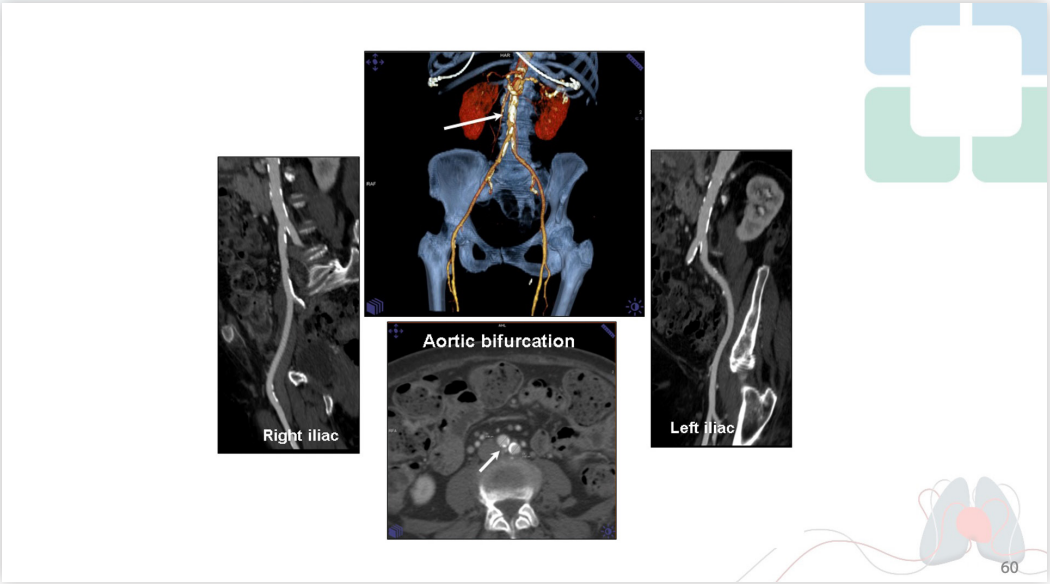
58

In contrast, some people will have atherosclerosis or plaque or blockages. This was a paper that got a lot of publicity and a lot of quotations in cardiac surgery and it suggested that if you have an operation where the heart lung machine is attached to the leg, you were more likely to get a stroke. This was without scanning people and scanning people is key.

Patient Case Study: Mitral Patient with Atherosclerosis

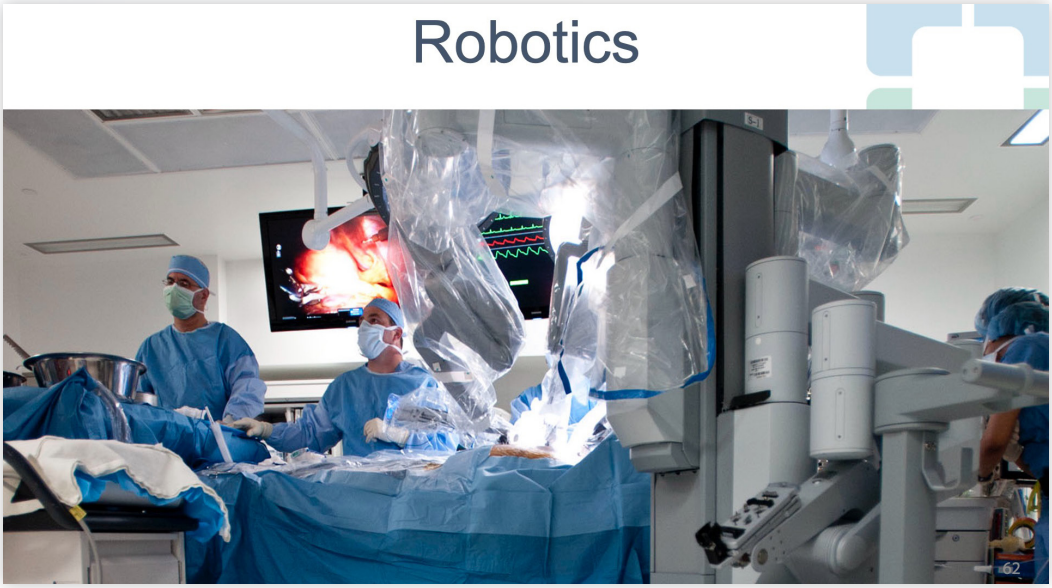


Dr. Marc Gillinov: I'll show you why scanning is key. Here's another patient case. 57-year-old man has severe mitral regurgitation. Primary mitral regurgitation means that it's called by prolapse. If you look at the bottom, two echos. To the left, you see toward the left part of the screen, that thing flapping in the breeze, that's the posterior leaflet which isn't meeting its friend the anterior leaflet. To your right, again you see this mosaic of color. That's the leak. With this echo, he came and said, I want the robotic approach. I want you to hook up the heart lung machine to my leg. His cardiac catheterization, look at the arteries on his heart, suggested his arteries look pretty darn good. Maybe it's possible but let's get a CT scan and see.



Here's his CT scan and to the left, the white stuff you see that's in the artery, that's calcified plaque. In the middle where there's blue and red, the red is the kidney on both of the portions of the middle figure. That white stuff or the arrow points, that is all plaque.

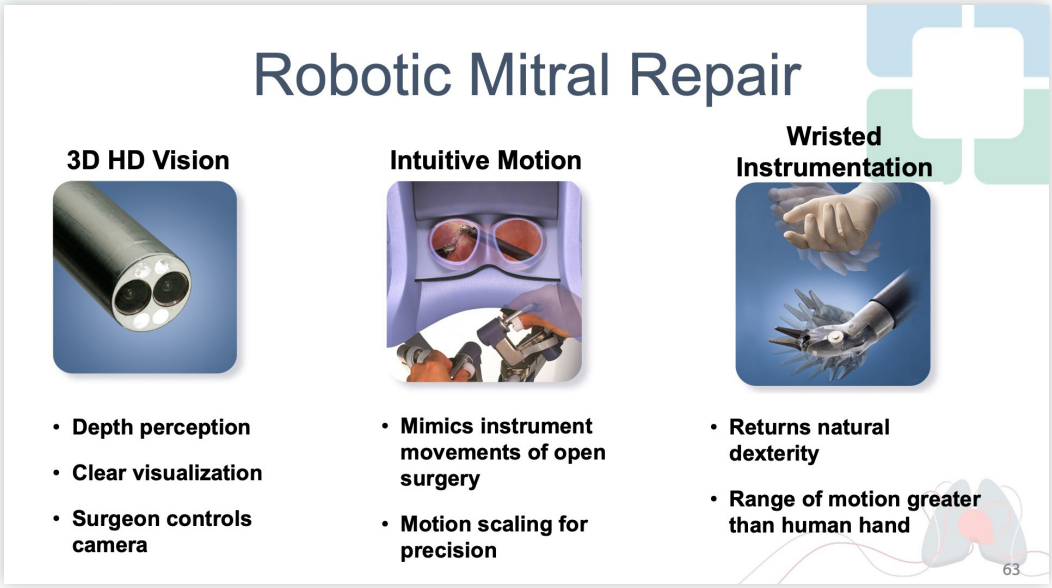
Even though this person felt fine, he's got this white appearing calcified plaque and to do robotic surgery on him without looking would be an absolute disaster. He would've a stroke almost for sure. He fixed his valve with a traditional operation and he did very well.



What's good about the robot? Why do we do it?

It's complicated. It's not something that a surgeon can dally in. You've got to be with a team that does this every day. Here you see the surgical robot with these arms which are encased in sterile plastic and you see the people at the table side.

There's a patient under all that looking at the screen where the robotic image is displayed.



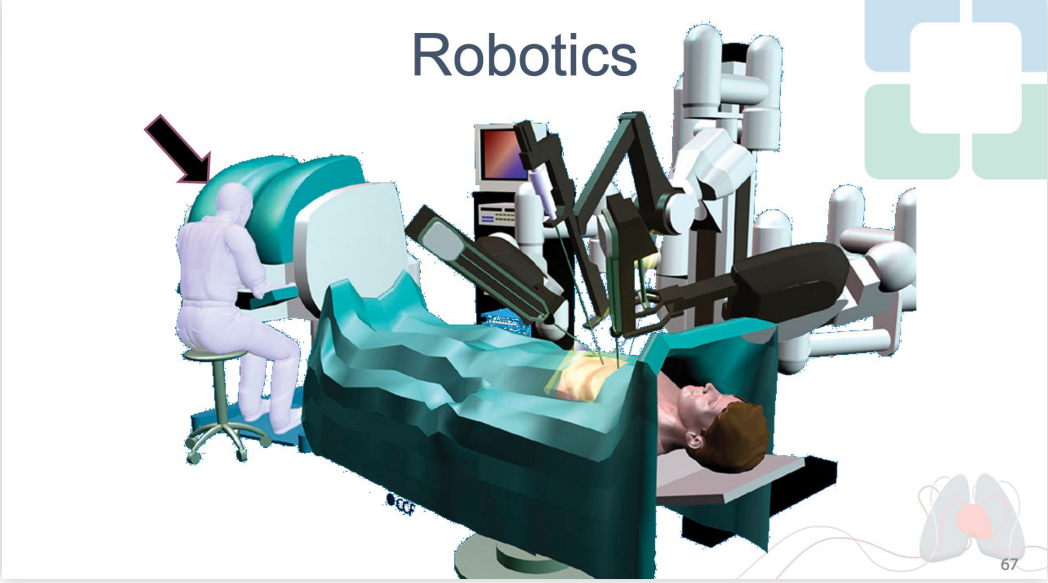
What's really good about the robot is the visualization. We have three dimensional high definition vision.

I remember I was at a sports bar type place having a dinner with my wife and we were watching on the television the Olympics about three weeks ago and we were watching gymnastics and she said, "Wow, that television has great resolution. We should get one of those."

I said, "The resolution is nowhere near what I see every day in the operating room with the robot." The resolution is absolutely spectacular and we see in three dimensions, because if you look at that frame to the left, that's the camera but there are two cameras on it; one for your left eye, one for your right eye, which means the surgeon has stereoscopic vision. Having two eyes is what gives us 3D depth perception.

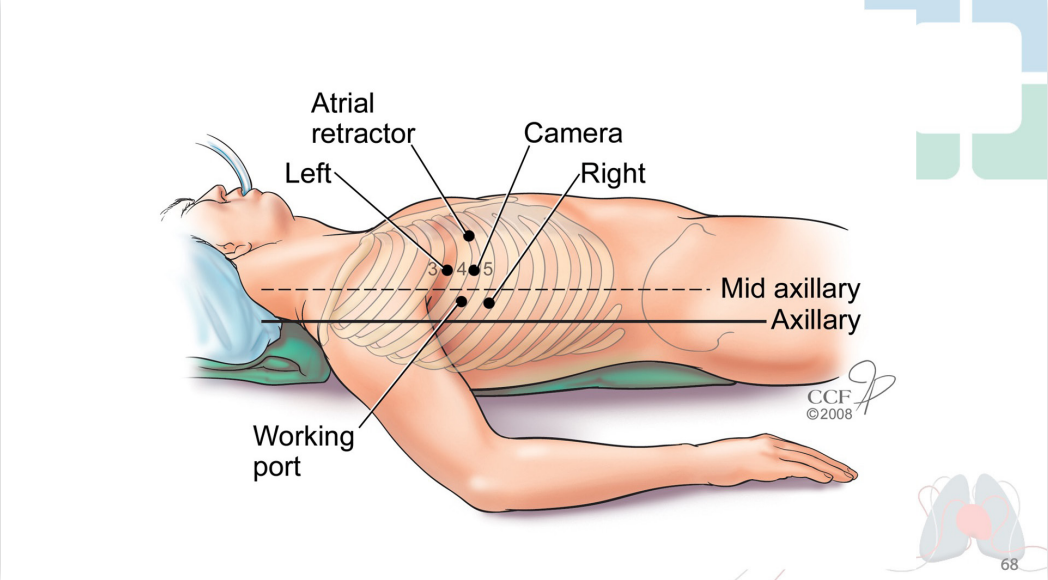
Now, it's not just me or here you see me standing there. I'm the guy, not so tall guy with the glasses.

It takes this whole team of specialists to know how the robot works, how to do it, and to get you an excellent repair with extraordinary safety.

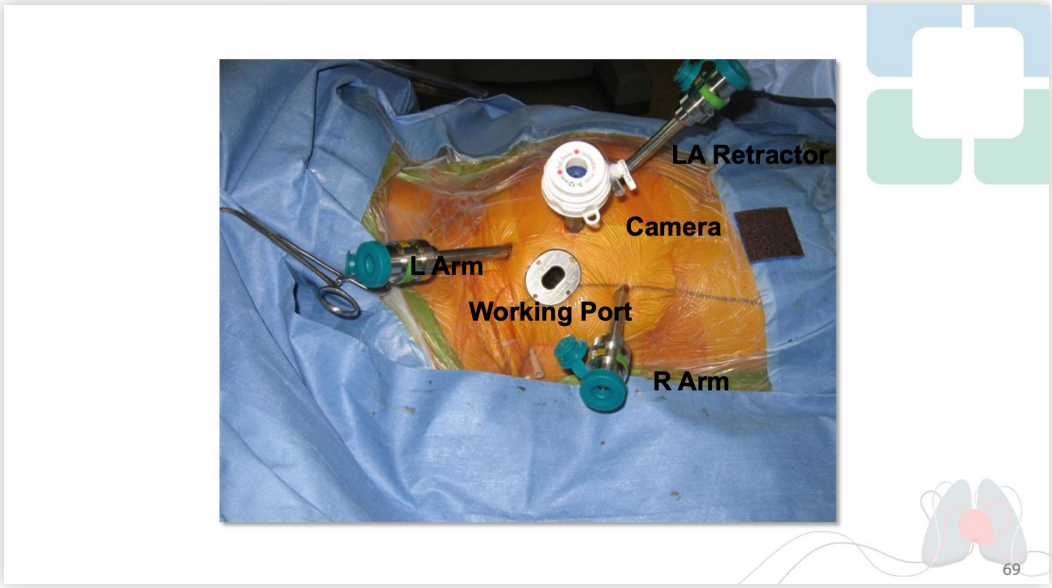


The operation itself is very, very cool. It's just amazing. We have visitors from across the country and around the world come to see robotic surgery and I think it encourages them to get into the field.

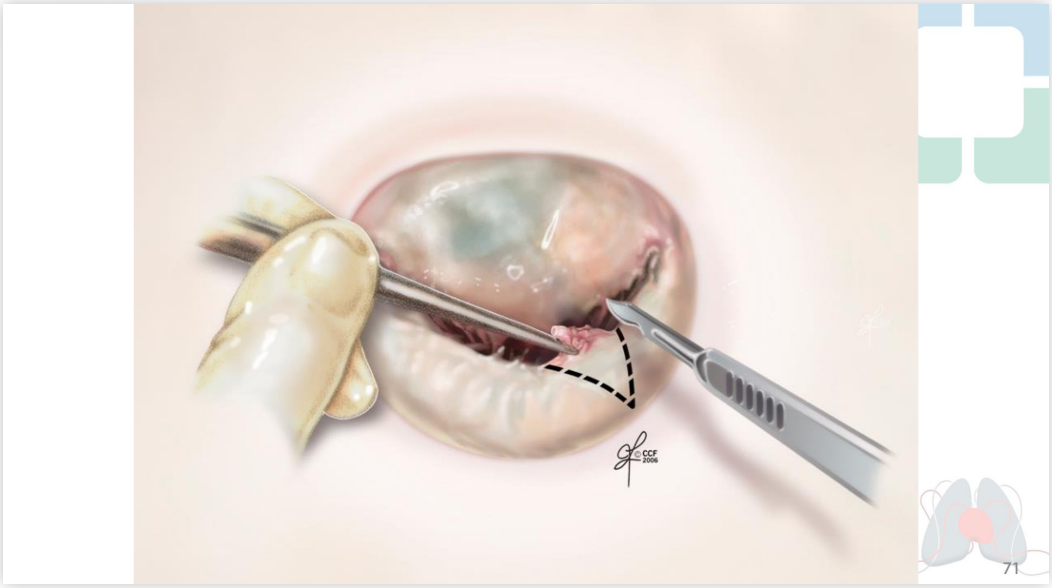
The surgeon is in the room. The black arrow points to a surgeon and the patient would be over here just a few feet away. There have been a couple of transatlantic robotic operations where the surgeon is in New York and the patient is in Paris. I think I'd rather be a little bit closer to you if you're having heart surgery, so let's just do it all in one room.



Again, because the instruments are phenomenal and the camera's visualization is so perfect, we don't need to have our hands or our eyes in your chest. We can do it through these ports or small incisions.



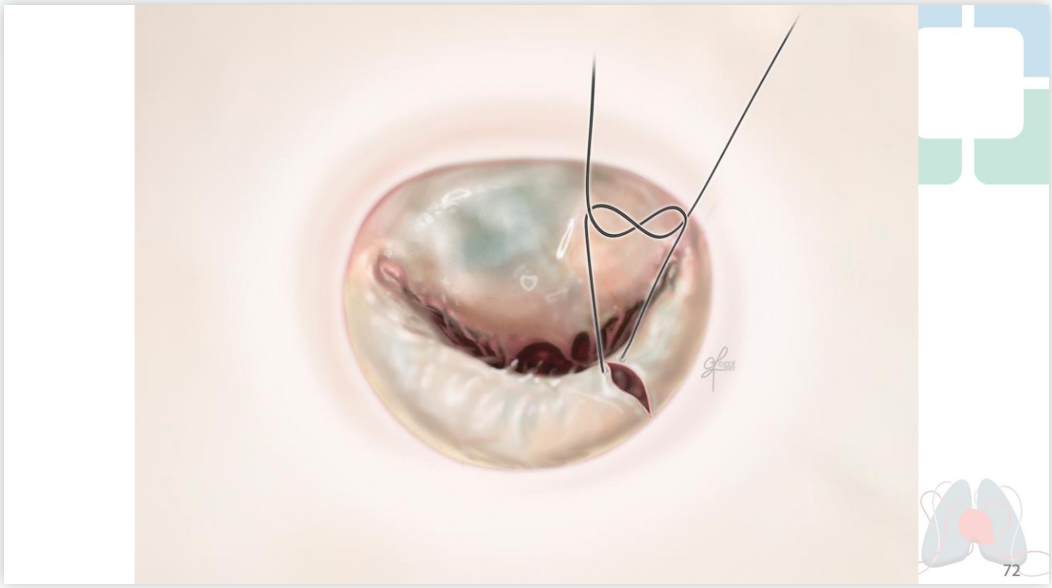
Here's what it looks like in real life. This is a patient, the head would be to your left, the feet to the right, and as I mentioned, you've got a collection of incisions but a collection of small incisions, none of them through bones. Each one of these ports attaches to the robot and enables us to have perfect control from the console.



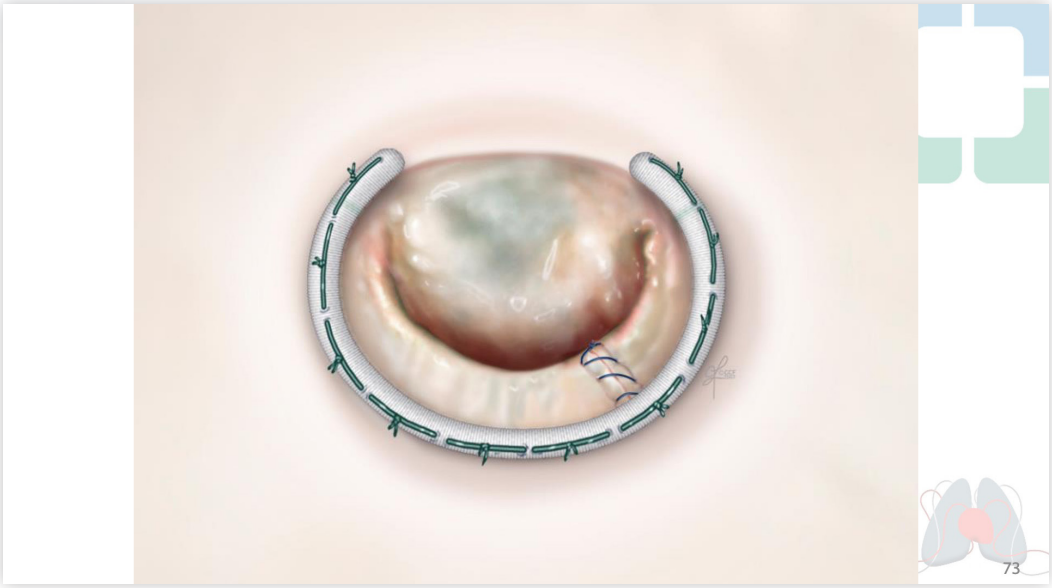
What we do for our 52-year-old triathlete patient? How did we get him back in the game?

We did what's called a triangular resection. Here you see a mitral valve and the anterior leaflet is the bigger part at the top. The posterior leaflet is at the bottom. You see the surgeon is holding up a bad piece of the valve, a piece where there was a ruptured cord. A ruptured cord would be like someone's floating down on a parachute and one of the struts to the parachute breaks. Same thing happens to the valve.

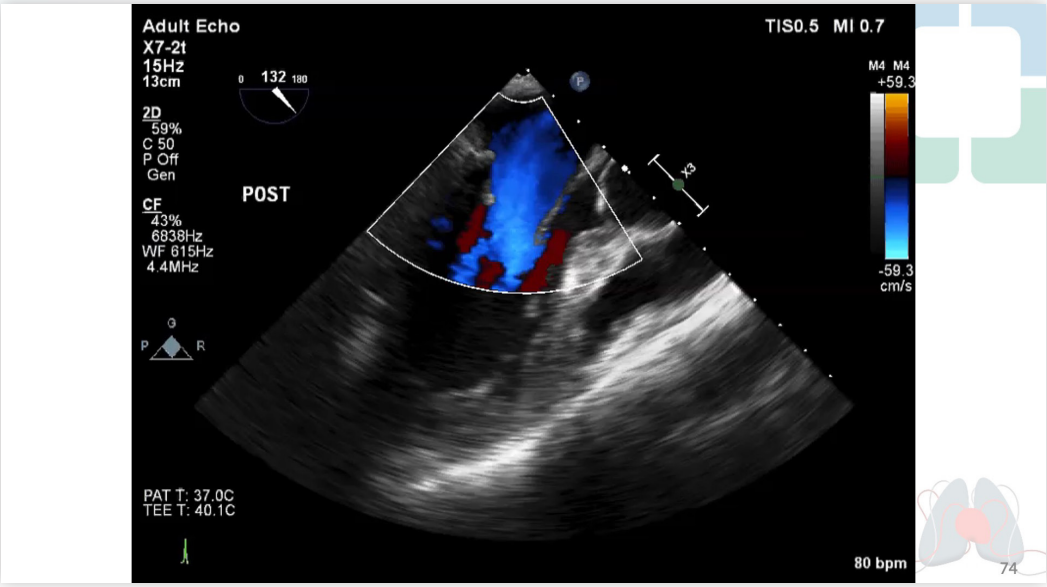
The valve flails just like the parachute canopy would. Here what we did is very simple. We cut out a pie shaped piece, triangular resection.



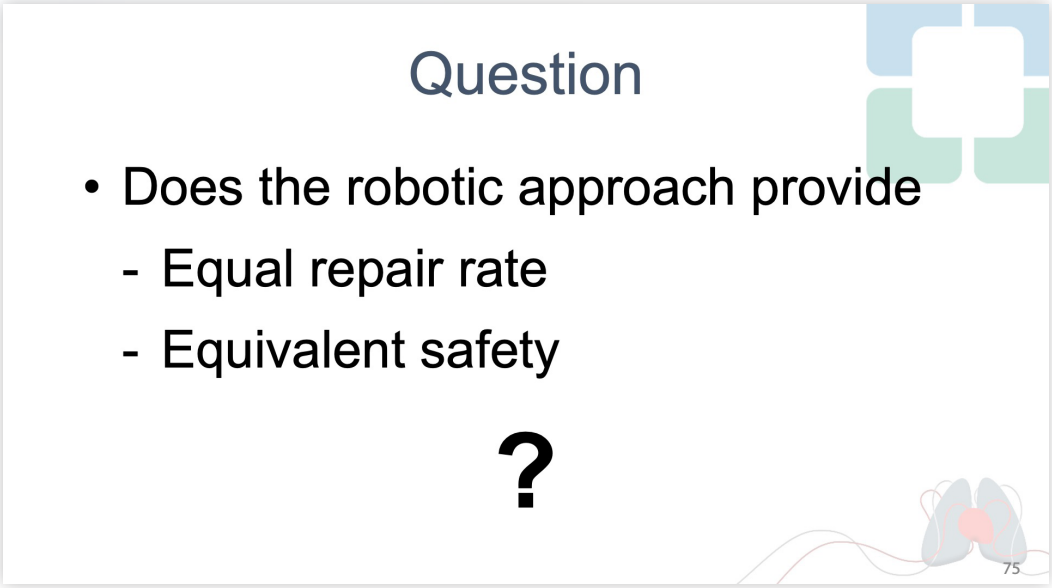
Then we sew that together. The valve tissue is like skin, it's got a flexibility to it, a bit elastic. We can just close that little defect we created up, so normal valve to normal valve.



Then we put this ring around it, which we discussed a little bit earlier before the webinar started; this white ring with sutures in it, holding it in place. It's called an Annuloplasty and you can think of it as being like a washer. It compresses the valve a little bit, brings it to normal shape and size. This one is a U-shaped or C-shaped band. It could also be complete. Each of them works just fine.



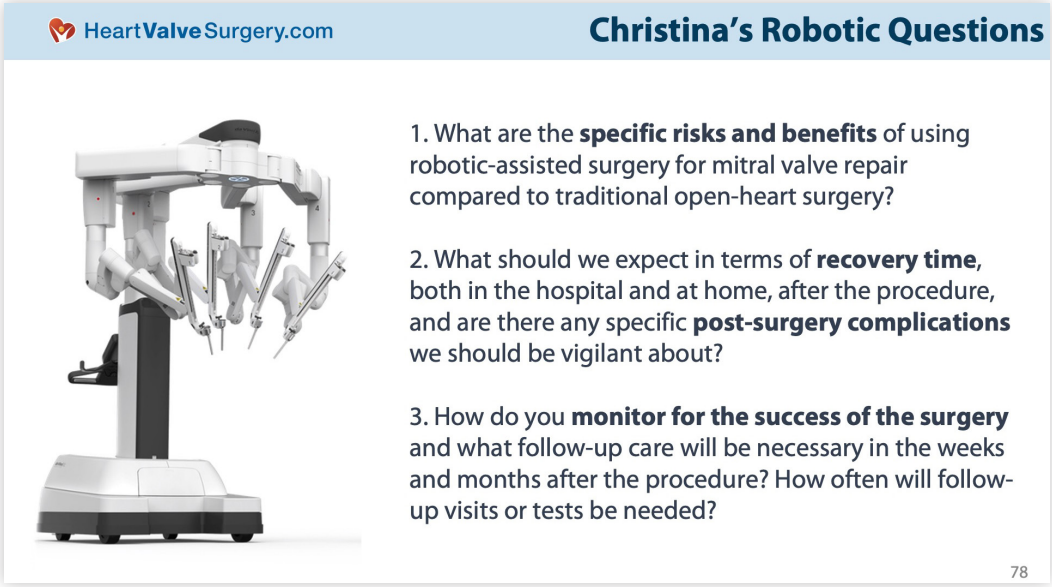
This is now the echo in the operating room, actually at the operating room after surgery. What you see is the anterior leaflet of the mitral valve, which is the thing that's going down and up and down and up is meeting the posterior leaflet, which is like a door stop and we don't see anything flapping around and we don't see any color, any leak going backward, meaning this valve now works, which is what happens when you do a posterior leaflet resection.



In summary, when we're talking about the robotic approach, ask the surgeon and the surgeon should ask himself or herself in this case, in this person, does the robotic approach provide an equally repair rate? Meaning I'm not giving up anything. I can do the same operation with the robot on your valve and I can do it with equivalent safety, meaning we're not taking a chance. These are the questions to ask.

If the answer is yes, next slide, then the yes goes with get it done robotically. I think the robot is a phenomenal tool. We love it, but it's got to be used like any tool in your toolbox at the right time in the right place.

Questions and Answers



Adam Pick: Dr. Gillinov, thank you so much for the prepared remarks. Thank you for taking the time to put this together and sharing your insights about mitral valve surgery.

We have received a total of about 59 questions submitted. In addition to what you see on the webinar, my inbox is lighting up. Let's enter a "Rapid Q&A Session" specific to Q&A. We only have so much time, so let's try and get as much in as we can. This is coming from Christina. What should we expect in terms of recovery time, both in the hospital and at home? Are there any specific post-surgery complications we should be vigilant about?

Dr. Marc Gillinov: Great question. Recovery with the robot is quicker than with a sternotomy as you'd expect. Most people are in the hospital for about four days and everyone says, I feel surprisingly good, but I am a little bit sore. It's like you have a pulled muscle, but you can drive when you get home after robotic surgery. At about two to three weeks, let's say three weeks, people say I'm feeling like 95% of myself, so a pretty quick recovery. The most common postoperative complication of any heart surgery is atrial fibrillation, an irregular heartbeat, and it happens in about 40% to 50% of people who have mitral valve surgery but the key thing is it goes away usually before people go home. If you were home and you felt your heart going a little fast or skipped beats, not an emergency, not 911, but get an EKG.

Adam Pick: Great, and let's continue with Christina's question. How does the Cleveland Clinic monitor the success of a surgery? You've got patients coming to you from all over the country, all over the world, what type of metrics or observation do you use to say, hey, that was a successful patient?

Dr. Marc Gillinov: We're really, really dedicated and very compulsive about this. In the operating room, we do an echo at the end of the repair to make sure that we are happy with it.

Then we do another echo before you go home, which is generally within the first week. Then we offer follow up to the Cleveland Clinic and if not with us, with your cardiologist at home. You should get an echo at four to six weeks and then once a year, and please answer our surveys because we try to collect all the follow up we can because that's what makes us better.

I remember in the early 1990s we'd been employing a repair technique that looked great called cordal shortening, which we don't do it anymore and we don't do it anymore because we found over time when we got enough follow up people filled out our surveys and send us their echoes. It didn't last as long as other techniques. We really, really, really want to monitor everyone with echoes. Whether you get it at our place or you live in Florida or California, please send us your echos or echo reports.

Adam Pick: Dr. Gillinov, I've got to ask you, we started this conversation with your success stories from HeartValveSurgery.com. We saw the pictures of the patients from New York, Arkansas, Texas. How many of your patients are from are from Ohio and how many folks are coming to visit you or require some form of travel?

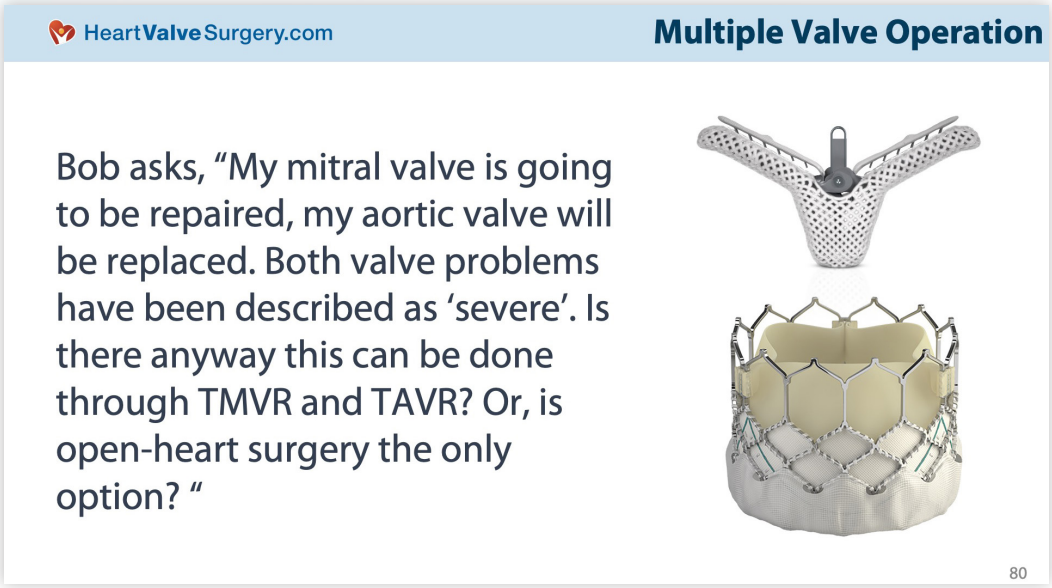
Dr. Marc Gillinov: I have that data. Overall, at Cleveland Clinic, we do about 5,300 open heart procedures a year, and about half of the people come from outside of Ohio. For mitral valve surgery specifically, it's more like 75% come from outside of Ohio. We've got everything very streamlined in terms of the travel. We have three hotels on campus. We send a car to get you at the airport, et cetera, because having surgery that is stressful enough and then traveling for it could add another layer and we want to make that as easy as possible for the more than 2,500 people who come each yea

Adam Pick: Here's a great question from Seth who asks, "I have mitral stenosis and I'm in the waiting room. Is there any update on mechanical valves that do not require Coumadin or have lower levels of Coumadin required?"

Dr. Marc Gillinov: Short answer is, "No update." At this time, if you have a mechanical mitral valve, we still want you on coumadin with an INR which stands for International Normalized Ratio (INR) in the range of three. There have been a couple of trials with specific types of valves trying to use a lower level of coumadin and they were not positive. It's got to be Coumadin and it's got to be at this level INR around three.

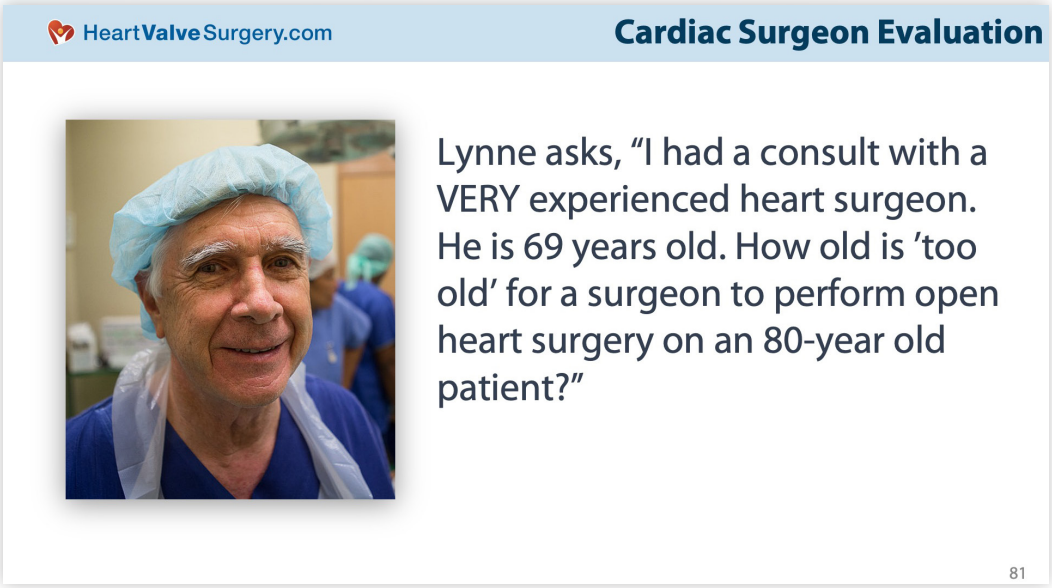
Adam Pick: If a patient is newly diagnosed, can you share what Coumadin, the drug does relative to the mechanical valve?

Dr. Marc Gillinov: Coumadin is also called Warfarin because we've got to have two names for everything in medicine to keep it interesting. The issue with this mechanical valve, you see the white part is the sewing ring. That's the part where we put stitches through your heart, then through that soft fluffy ring. It's about the consistency of a shoelace and the black part is the valve itself. That black material is carbon. It lasts forever. It's super smooth, highly polished, but if you put this valve into your bloodstream, the blood's reaction to manmade materials is to clot. If you put this in the bloodstream without anticoagulants without thinning the blood, blood clots will form on the valve, which will either interfere with the valve function or go through the circulation and cause strokes. Therefore, if you get this kind of valve, you get this kind of mechanical valve that lasts forever. The tradeoff is you need to be on an anticoagulant, Coumadin specifically.



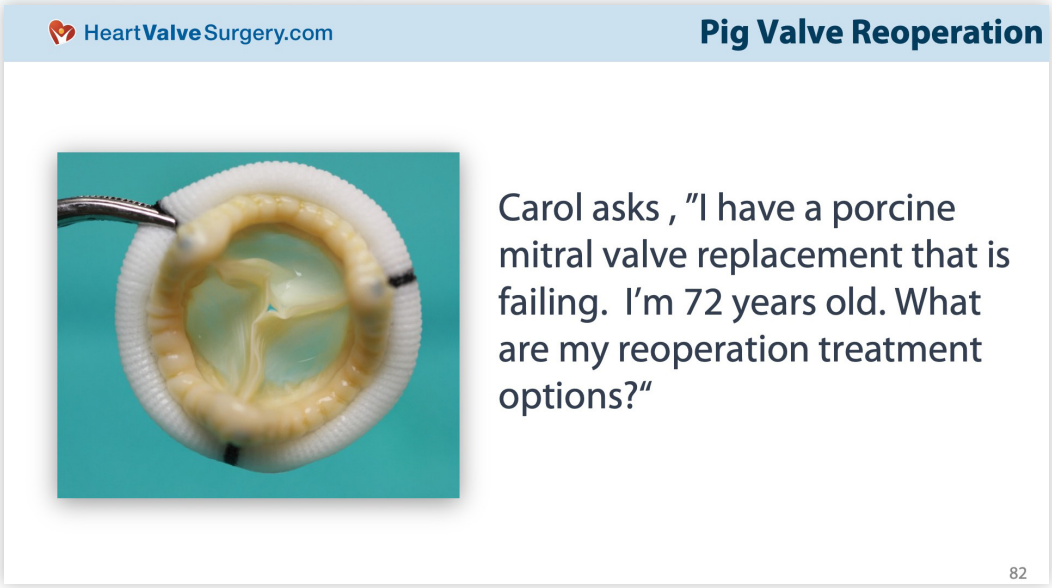
Adam Pick: Bob asks, “My mitral valve is going to be repaired, my aortic valve will be replaced. Both valve problems have been described as severe. Is there any way this can be done through TMVR (transcatheter mitral valve repair) and TAVR (transcatheter aortic valve replacement replacement) or is open heart surgery the only option?”

Dr. Marc Gillinov: It can be done in many cases without surgery, but the question is, “Is that the best option for you?” At the top, what you see is the MitraClip, which is something that is placed by a cardiologist through a stick in the femoral vein, meaning in the groin. Below that is a transcatheter aortic valve which can be placed to replace your native aortic valve. One of the things we don’t know is how long each one of these devices is going to work. Meaning if you are 40 or 50 or probably even 60 years old, these are taking a chance. They may or may not last. However, if you are 85 years old and you’re otherwise high risk for surgery, this may not be a bad idea to consider.



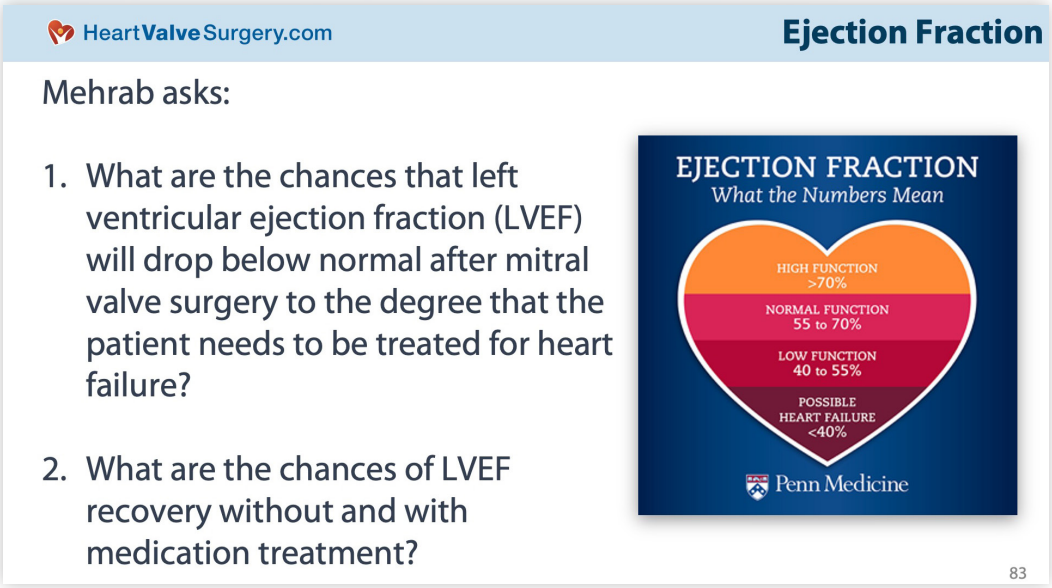
Adam Pick: Lynn's question, "I had a consult with a very experienced heart surgeon. He's 69 years old. How old is too old for a surgeon to perform open heart surgery on me? I'm 80 years old."

Dr. Marc Gillinov: We just did a study of this in the Cleveland Clinic. We have surgeons who have ranged from 33 years old up to now 80 years old. We found that thus far surgeons continue to get better with age. Of course there's a selection bias because some people who might've been 70 or 75 retired, but if you've got a 69-year-old surgeon and he or she looks lively and relatively youthful, then I think that is okay. I think surgeons are probably getting into their stride when they're in their 50s and 60s.



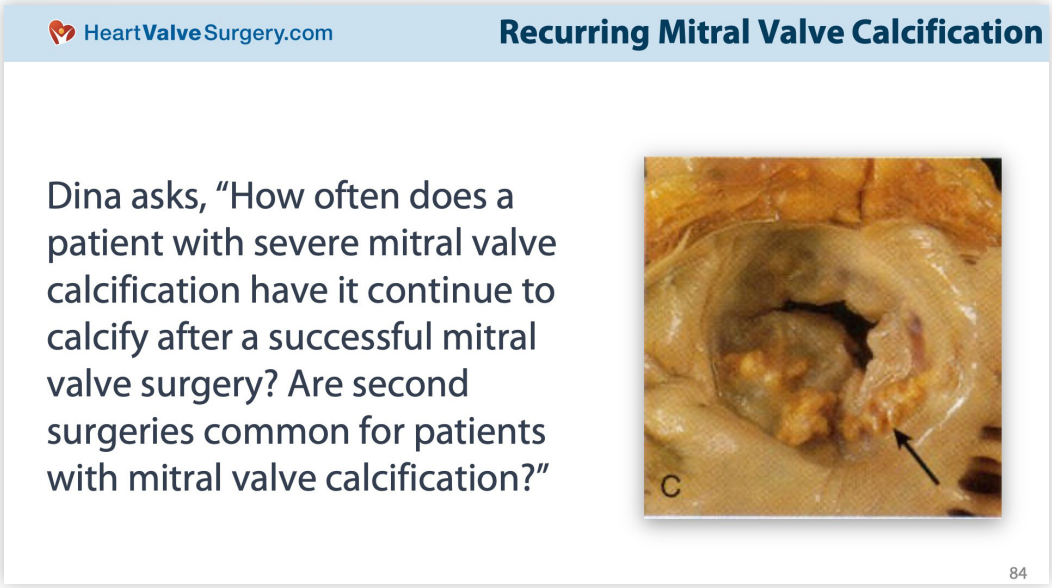
Adam Pick: We have this fascinating question from Carol who says, "I have a porcine mitral valve replacement that is failing. I'm 72. What are my re-operation treatment options?"

Dr. Marc Gillinov: The re-operation is extremely safe and the idea is take the old valve out, put a new one in, and you would likely go for another porcine valve or a biological valve. In again, selected instances because this is new, we might be able to do a nonsurgical valve in valve where we take a percutaneous aortic valve, meaning a TAVR valve, one designed to be placed through the vein or artery or leg and put it right in the middle of this valve when it's worn out so it goes in the middle of this white circle. It depends on the size of your valve and the veins in your leg and the anatomy, but if you've got a pretty good size, being a big valve in there might be able to get this done without surgery.



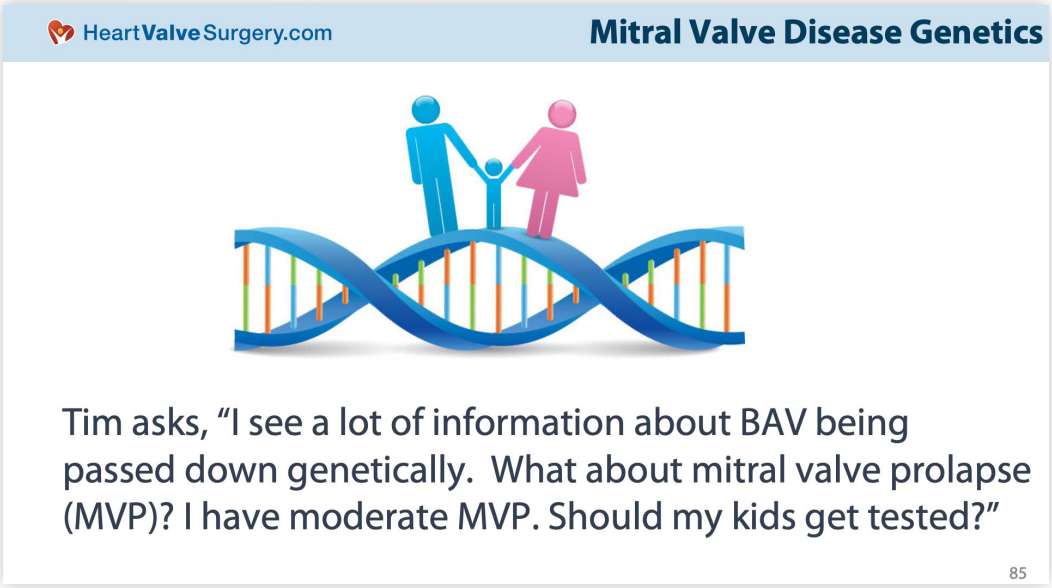
Adam Pick: Mehrab asks, "What are the chances that the left ventricular ejection fraction will drop below normal after mitral valve surgery to the degree that the patient needs to be treated for heart failure?" The follow up, Dr. Gillinov, is, "What are the chances that the ejection fraction can recover without or with medical treatment?"

Dr. Marc Gillinov: If somebody has waited until their heart has enlarged or their ejection fraction EF or rejection fraction has fallen, then we cannot predict if the heart will recover. Most people don't wind up needing to be treated for heart failure, but a normal ejection fraction in most people is 50 to 55. If your mitral valve is leaking a normal ejection fraction with a leaking mitral valve is 65. If somebody says you have a normal ejection fraction and severe mitral regurgitation and then they say your number is 55, that's not normal. That means you've already got some heart damage. In any case, probably about half of people recover with surgery and treatment and having the heart being enlarged or the ejection fraction down a little bit isn't a reason to avoid surgery. It means you need it now to prevent further damage.



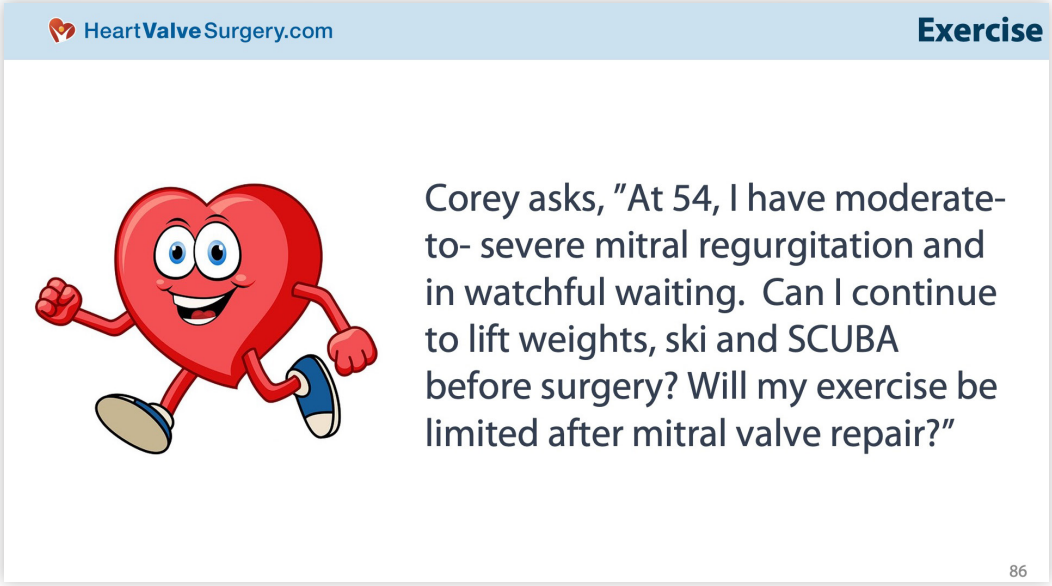
Adam Pick: Dina asks, "How often does a patient with severe mitral calcification have it continue to calcify after a successful mitral valve surgery? Are second surgeries common for patients with mitral valve calcification?"

Dr. Marc Gillinov: Short answer is almost never does the calcium come back to such an extent that the calcium cause reoperations. It's uncommon. The arrow down there is pointing to calcium around a heart valve. In cases like this, oftentimes you would have to replace the valve and a safe replacement can be achieved and the calcium does not come back and affect the replacement. If you've repaired the valve, you usually remove the calcium. Same thing does not come back.



Adam Pick: Tim asks, "I see a lot of information about BAV being passed down genetically. What about mitral valve prolapse (MVP)? I have moderate MVP should my kids get tested?"

Dr. Marc Gillinov: Your kids should not get tested. While mitral valve prolapse is almost certainly rooted in your genes, it's not a single gene such that it very rarely travels through families. If you've got much about prolapse, even if you've had surgery, you don't need to get tested. Unless you said, I've got it, my brother's got it, my dad's got it, my uncle's got it, then in your family it would be stronger, but almost always you do not need family testing.



Adam Pick: Corey asks, "I'm 54, I have moderate to severe mitral regurgitation, and in watchful waiting. Can I continue to lift weight, ski and scuba before surgery? Will my exercise be limited after mitral valve repair?"

Dr. Marc Gillinov: You can continue to do whatever you like. Nothing will affect your valve. Some old time doctors will say, "Don't lift weights and don't exercise." But, there's not a shred of data to support that.

Yes, stay active and provided your repair goes well, you should have no limitations after. This term moderate to severe always bothers me because it sounds like saying somebody is short to tall. You're one or the other. I would get some granularity on that. Do you have enough regurgitation that you should get it fixed now? If the answer is yes, get it fixed. If the answer is, it's more like moderate, get an echo every year.

Adam Pick: We still have another 50 questions to go. Unfortunately, we're not going to have time to get to them.

Dr. Gillinov, on behalf of our community, I want to extend a tremendous thank you to all the help that you've given our community in the past, the present and the future. I cannot thank you enough.

I also want to thank all the wonderful people on the call today. We appreciate coming together with you as a community to learn about how to manage our valvular disease and get the best possible outcomes.

HeartValveSurgery.com Resources for Patients

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 200 educational videos filmed by the HeartValveSurgery.com film crew.