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Featured Speakers



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Please note: A complimentary video playback of this eBook is now available on YouTube at this link.



Introduction



Adam Pick: Hi, everybody, my name's Adam Pick, and I'd like to welcome you to the webinar titled "Advances in Mitral Valve Therapy". If I have yet to meet you, I'm the patient that started <u>HeartValveSurgery.com</u> all the way back in 2006. The mission of our website is really simple: we want to educate and empower patients just like you. This webinar, which has had over 450 patient registrations from people in countries all over the world, was designed to support that mission.

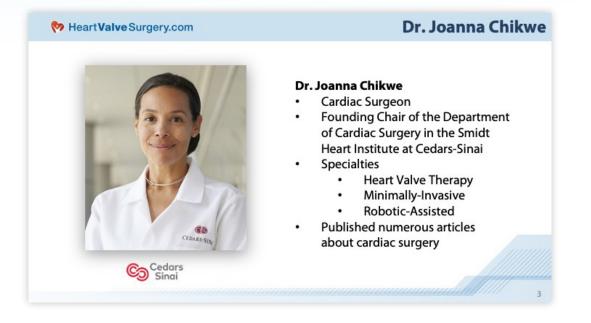
Throughout the webinar, you're going to be in what's known as "listen-only" mode, but I'd encourage you to submit your questions in the control panel that's up on the screen, and I'll explain why as we look at the agenda for today.





I'm going to introduce the featured speakers. We're going to talk about, in a very interactive way, mitral valve disease and mitral valve treatment. We're going to get into a lot of question and answers, so please submit your questions. Then, at the end of the webinar, I'm going to ask you to complete a very quick five-question survey.

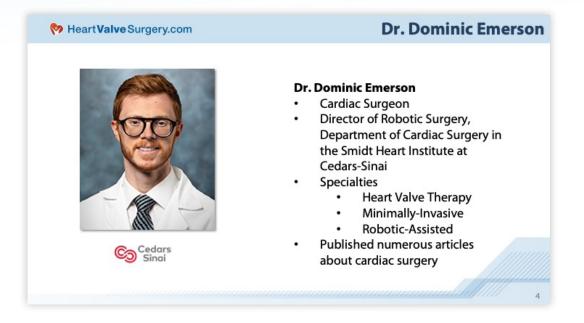




Today, we're joined by <u>Dr. Joanna Chikwe</u>. She is a cardiac surgeon, yes, but she is not just the chair; she's the founding chair of the department of cardiac surgery in the Smith-Heart Institute at Cedars Sinai. Her specialties are heart valve therapy. She also is very skilled at minimally-invasive techniques that often use robot-assisted approaches. She's published numerous articles about cardiac surgery and the last I checked, Dr. Chikwe, I think you're up over 125 contributions in peer-reviewed journals like The New England Journal of Medicine. Dr. Chikwe, you and I have known each other for a long time. Thanks so much for being with us today.

Dr. Chikwe: Adam, thanks so much for having us and thank you to the HeartValveSurgery.com community.





Adam Pick: Yeah, and so now let's talk about and introduce <u>Dr. Dominic</u> <u>Emerson</u>, who yes, he's a cardiac surgeon. But, he is also the director of robotic surgery, the department of cardiac surgery, in the Smith-Heart Institute at Cedars Sinai. His specialties are heart valve therapy, minimally invasive and robot-assisted techniques in which he and Dr. Chikwe often team up to perform those procedures. Similarly to Dr. Chikwe, he's published a lot of articles about cardiac surgery. Dr. Emerson, thanks for being with us today.

Dr. Emerson: Thanks for having me. It's a pleasure to be here.



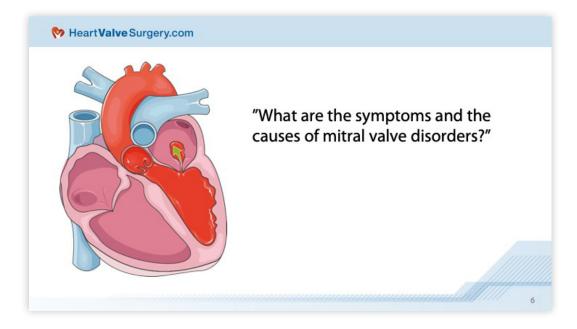
Cedars-Sinai Patient Success Stories



Adam Pick: I could go on and on about the accolades and the achievements of Dr. Chikwe and Dr. Emerson. What I would like to do, though, because we only have a short amount of time, is show you this: these are the smiling faces of patients from the HeartValveSurgery.com community who have come to Cedars Sinai. They're not just surviving mitral valve disease and heart valve disease. They're thriving, whether it's Josh, Jerry, Layla, Patricia, Steven and Rich. With that being said, I'd like to turn controls over the webinar to Dr. Chikwe.



Mitral Valve Symptoms



Dr. Chikwe: So here's the first one: what are the symptoms and causes of mitral valve disorders? I think there's a huge range of symptoms, but one of the most common ways that patients come to us is a doctor's just put a stethoscope on their chest and heard a murmur. The patients themselves feel absolutely fine, just going about their normal, day-to-day without any problems at all. We call that asymptomatic and yet, if you've got a severe leak, even though you feel fine, it's usually better to get it treated if that leak is due to a floppy mitral valve.

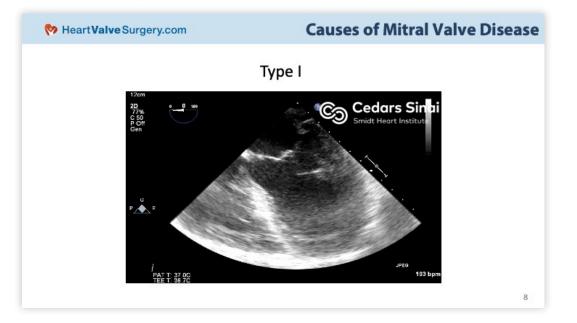




The things that people feel when they do feel symptoms can be fatigue; that's extraordinarily common. People can feel breathless or winded and have to stop when they're climbing a flight of stairs or just walking a block. Occasionally, people get chest pain. Often times, a crushing central chest pain. It comes at odd times. Sometimes, you can even put a finger on it. It's odd chest pain, and sometimes dizziness and palpitations, that can be quite common with mitral valve disorders.



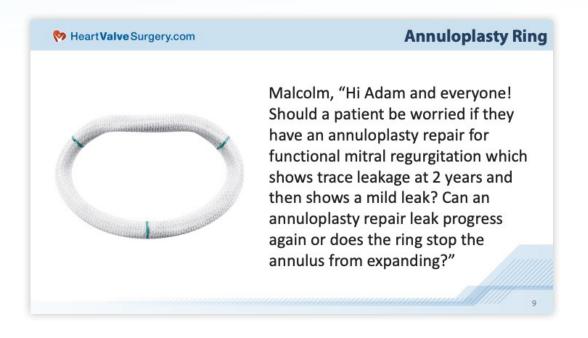
Causes of Mitral Valve Disease



Dr. Chikwe: There are two different kinds of mitral valve disease. I'm going to show you this one first. This one is called functional. Here the leaflets of the mitral valve are completely normal. You can see that there's a big gap between them. That's why the valve leaks. It's because the annulus, which is the support of the valve, is stretched. We treat that by putting a ring – that's that white thing that's sewn in around the valve – that brings the annulus back to a normal size. That holds water.

When we open the valve, you can see that water is coming out under pressure. All of that nice, white tissue below the purple line is the tissue that will meet and keep that valve from leaking. That's the echo afterwards; there's no leak. That's a very common type of mitral valve regurgitation. But, it's not as easy to get a good long-term result with this because all that that ring has done is treated the problem at the top of the valve; it hasn't treated the problem that caused the valve to stretch in the first place.



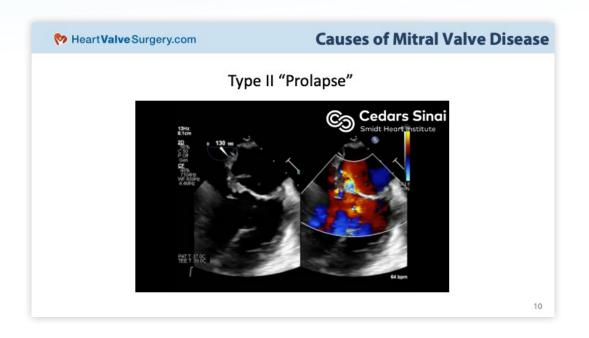


So the next type of mitral valve disease... And this answers this question by Malcolm which is should a patient be worried if they have an annuloplasty repair? He's seen progression; it's gone from trace leakage, which is a very small amount at two years, and now it's mild, which is a little bit more.

His question is, "Can an annuloplasty repair leak progress again, or does the ring stop the annulus from expanding?"

The answer is if the ring is correctly placed, it will stop the annulus from expanding, but as we've just mentioned, the things that cause the valve to leak are parts of the heart that's behind the annulus and the annulus hasn't corrected that. Sometimes in patients where the heart muscle isn't working normally, that can progress. My hope would be that the mild leak isn't going to get a lot worse, but those repairs can progress from moderate and even severe mitral regurgitation with time.





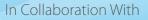
This is very different. This is Type II mitral regurgitation or prolapse. Here the problem is this floppy leaflet. If you're squeamish, it's time to look away and I'll tell you when you can look back. This is a mitral valve operation. This is done robotically, which is how we do almost all of our mitral valve repairs at Cedars. Here, the problem is all of those cords are broken.

You can see that there's a lot of little floppy bits that aren't attached to anything, and that's why this valve leaks. The way that we repair that is one option is to reconstruct those cords with artificial cords. A nicer option is just to take out that segment, where the cords are broken, in a triangle. You can see that's a triangle of tissue that's being taken out. Then, we're going to join together the nice normal bits of the valve either side of that, and we're using a suture that's finer than a human hair to join these back together so the whole valve and all of the cords are yours.

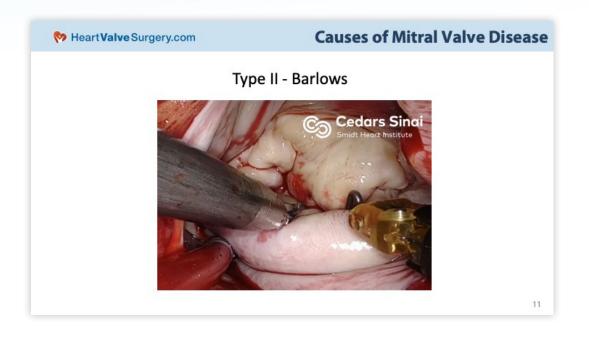


You're keeping all your own natural valve tissue. It just doesn't leak because everything is supported by a nice normal cord. This is an operation – we did one very similar to this this morning; did several earlier this week that is incredibly low risk.

In the United States, the chances of dying or having a stroke as a result of this kind of surgery is less than 3 in 1,000, a third of one percent for the vast majority of people. That's super low risk. The great thing is this treats the problem. That's a ring going in, and now we're testing the valve with saline to see that it holds and it's water-tight. We've essentially, unlike the first kind of functional regurgitation, we've corrected the problem that's there, the leak. The heart muscle is normal, and you see there's no mitral regurgitation.



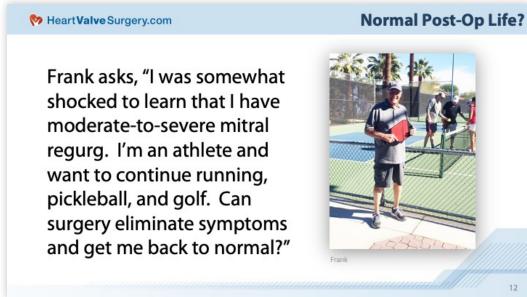




This is Barlow's disease. This is prolapse, but you can see that this is a really different kind of level of prolapse here. There's almost no normal segments in the valve. This is one that many surgeons find really challenging to repair. I really would recommend for those patients that have been told they've got a severe leak due to Barlow's disease, you really do need to find a specialist mitral surgeon. I think you really get a sense that there's a lot going on in this valve. It woud be a complicated repair.



Patient Question: Return to Normal Life After Surgery



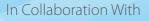
Dr. Chikwe: Let's pause there and answer some questions. Dr. Emerson, I'm wondering, what would you tell a patient like Frank who's shocked to learn that he has moderate-to-severe mitral regurgitation. He's an athlete; he wants to continue running, pickleball, and golf. Can surgery eliminate his symptoms and get him back to normal?

Dr. Emerson: I think one of the most important things about somebody who presents with a typically normal active lifestyle is that you really want to make sure that we are intervening before their function is really bad and before the heart is starting to feel the strain of that valve leaking. I think we're going to talk about this a little bit later as well, but when you have a diagnosis of severe mitral regurgitation, it's not something to put off. You can cause damage to the heart that can be hard to completely recover from, in terms of the function of the heart.

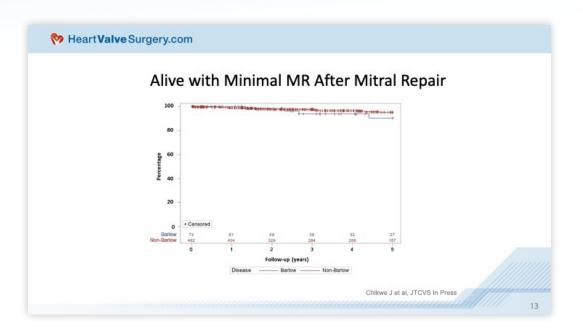


We have plenty of patients that come in who are looking for a return to their normal activities. I literally just came from clinic now seeing a patient who wants to go back to his extremely labor-intense work as a construction worker. The expectation will be that he will be able to get back to that, obviously after the recovery period of surgery and all the healing that has to go on. For the most part, our patients are able to get back to their normal quality of life pretty quickly.

The ultimate goal is that we want people to, once they've healed up, to be walking down the street and nobody would know that you had anything ever done. And, that you'll be able to do all the things that you normally love to do and the activities that you love to do.





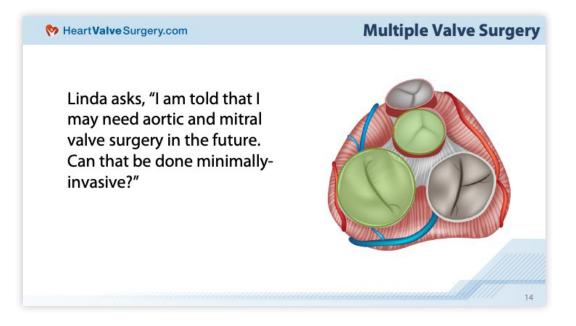


Dr. Chikwe: This is a really important way of answering some of the questions about, "If I have a mitral valve repair, how long will it last?" This is a study that we did based on patients at Cedars-Sinai, more than 1,000 that we have operated on. Here, you can see a graph that shows on the vertical axis the chances of being alive after a mitral valve repair at one, two, three, four and five years.

You can see that it's over 95%. So, fantastic survival after mitral valve repair. We looked at two kinds of patients. In red, are most patients with a single bit of prolapsing valve, that's what most patients. In blue, it's those Barlow's patients, that valve that we showed you before, which was super floppy. Essentially, they both do really, really well after surgery.



Minimally-Invasive Mitral & Aortic Valve Surgery



Dr. Chikwe: Linda asks, "I'm told that I may need aortic and mitral valve surgery in the future. Can that be done minimally invasively?" Dr. Emerson, what would you offer Linda if she wanted a minimally-invasive aortic and mitral valve operation?



Dr. Emerson: It depends a little bit on the exact pathology that somebody has. For the most part, we are doing most mitral and aortic valve procedures that need to be done concurrently through a slightly more invasive operation.

We can still manage most of these – even though we're not necessarily doing it through the side using the robot. Most of these can be done through a small incision in the front of the chest. Those are actually very, very well tolerated and people bounce back a lot faster than you would assume. The typical course for those individuals who we do them through the front, through the sternotomy, is that we expect them to be up and walking around within 24 hours after surgery in the ICU.

Out of the ICU in about a day on the floor and most of those patients are home about post-op, day five. Obviously, there's a little bit of variability here, everybody's a little different, but those people also have a really, really good path forward after surgery.



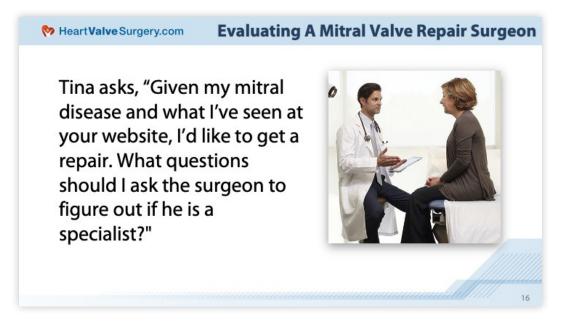
Minimally Invasive Mitral Incision



Dr. Chikwe: This is the kind of incision that we aim for. Robotic mitral surgery allows you to have an almost invisible incision for most patients. It's more difficult to achieve that in a double valve, aortic and mitral valve setting, but certainly that's our routine for mitral valve surgery.



Finding A Mitral Valve Surgeon



Dr. Chikwe: Tina asks, "Given my mitral disease and what I've seen at your website, I'd like to get a repair. What questions should I ask the surgeon to figure out if he or she is a specialist?"

Dr. Emerson: So, how much shopping should you do. Don't feel bad about looking around. I find it interesting that we never think twice about going to three different car dealerships to look at the car you want to buy. But, then we're hesitant to ask different opinions about our health, which I think is the wrong way to go about it. Both Dr. Chikwe and I are more than happy to be the second or third or fourth opinion for somebody to help them come to the right decision and to feel comfortable with their care.

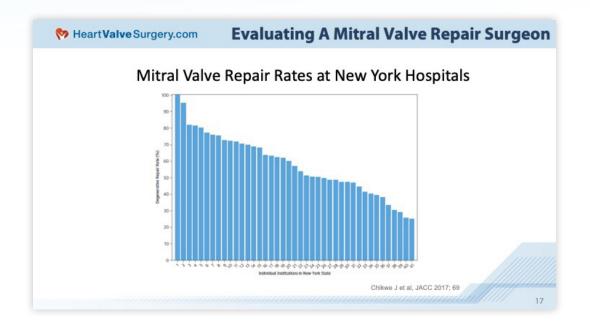


I think that when you're evaluating your surgeon, there's a few things that are very, very important. One is your rapport with the individual and how you feel about the center that you're at. You want to be at a place where you're going to feel comfortable. The key elements for your surgeon are that they do the procedure a lot, whatever operation that is, especially something like mitral valve repair, which is extremely specialized.

Good questions to ask them are, "How many of these operations are you, at this center, doing a year?", "What are your repair rates?" and "What are the approaches that you're comfortable doing?"

You want to be at a place that's very comfortable doing this and does this day in and day out. You want to hear that their repairs rates are in the high 90% for most of these valves; that's the kind of numbers you want to see.

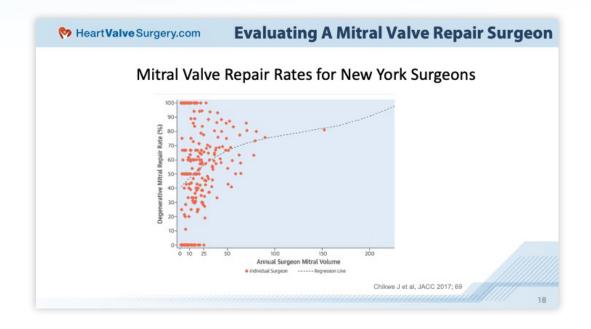




Dr. Chikwe: This is a slide that shows the chances of you going into any hospital in New York state – each blue line represents a hospital – with a floppy mitral valve and getting a mitral valve repair rather than a replacement. Remember, we all know that mitral valve repair should be possible in about 99% of people with a floppy mitral valve. It's really what is better for people in the short- and long-term and yet look at this variation. It goes from about one hospital on the far left that can get a mitral valve repair done for you 100% of the time, almost, to hospitals down there on the right side, where they're achieving that less than 50% of the time.

That's an extraordinary variation.

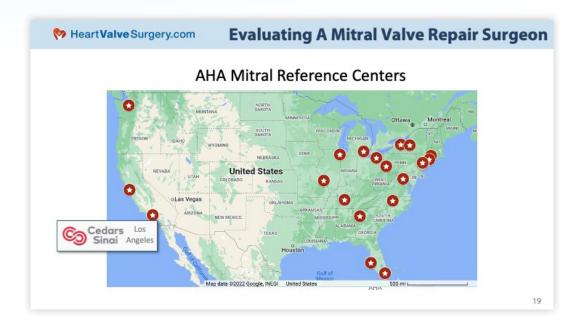




If you go to the next slide, you'll see why there's this variation. Each red dot here represents an individual surgeon in New York state, and this is recent data, and it's very much similar to the data around the country. Again, you can see this enormous variation between surgeons there at the top who can repair the mitral valve about 100% of the time, or even 90% of the time and surgeons at the bottom who rarely, or never, repair the valve. They replace it, even when it's a floppy valve.

One of the reasons we did this study was to see if busy surgeons were more likely to repair valves successfully and they are, but it's not the only solution. There's one surgeon out there who's pretty busy doing 150 operations a year, still only repairing that valve about 70% of the time. What you want to do is find somebody who's up at that 90 to 100%.





It's traditionally been really hard to do that, but the American Heart Association has done a wonderful thing, which is identified a group of about 25 to 30 reference centers. We all have to send our data to the American Heart Association team and they, essentially, look to see how many of the patients that we evaluated we were able to repair successfully. They're not just looking at what we report, they're looking at our echos. That allows you to identify a center that's hopefully near you, where you could get the best chance of getting a good mitral valve repair. Look at that gap in the middle of the country. Unfortunately, that does mean that a lot of people may need to think about traveling for their surgery, to maximize their chance of a great repair.





If you get even more specific and talk about robotic mitral valve repair, there's a very small number of centers that have vast experience in this. I would say, Cedars-Sinai is one of the centers that's been doing this a really long time, since about 2006 and other great centers are shown there. I always tell patients when they're calling from the east coast, there are good centers near you, but again, this is something you often need to travel for.

Adam Pick: Dr. Chikwe, maybe we could just press pause because I'm guessing patients are wondering – some folks are newly diagnosed, so they're hearing a lot of terms: sternotomy, minimally invasive, robotic. When it comes to mitral valve repair, obviously there's a lot of benefits to that. I'm curious to know, you and Dr. Emerson spend a lot of time using the robot. What is it for you as a physician that you've elected to go down the path of using the robot where other folks doing repair are not?



Dr. Chikwe: Well, Dr. Emerson, as one of the most experienced robotic mitral surgeons in the country, what is it that switched you on to the robot?

Dr. Emerson: Actually, I was literally just having this conversation with a patient just before this webinar. The thing I tell people, and our trainees as well, is that it's not just the gimmicky nature of the robot. It's not that it's just cool to say that I do robotic surgery. There are some really dramatic differences between robotic cardiac surgery for the mitral valve and open procedures. It's not saying that a standard approach with the sternotomy is in any way a bad way to do it. It's totally fine and sometimes the appropriate, absolute way to do it.

With the robot, you have the ability to use smaller incisions, which means that you're manipulating the tissue less, you're putting less stress on the body, you're not having to open the chest as wide, like you would for a sternotomy. I think that makes pain and recovery better for individuals.

For me, as a surgeon, probably the most important part of using a robot is I'm just, I think, better at doing it with a robot, to be perfectly honest, than I am at doing it open. That's because I see in a way that I can't possibly see open. The robot uses a three-dimensional camera that is in ultra-high definition that's zoomed in. When we're doing it open, the mitral valve itself is like that. It's about that size in total and so when I'm open, I'm looking at a structure that's that big and it's down here a little bit. When I do it with a robot because of the camera and the way it looks, the valve itself looks like it's this big in front of me.



You saw on the videos how big and detailed the valve looks and that's exactly what it looks like to me when I'm on the robot. That, with the increased dexterity of the robot, gives me or Dr. Chikwe or anybody using that technology, a different platform that we can use that will get us to being able to do, technically, things that we would potentially not be able to do otherwise. I think that that's the real benefit of that.

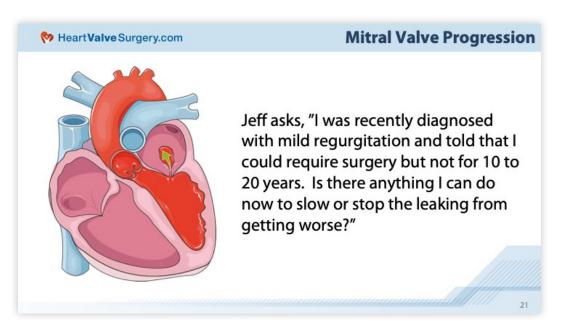
Our repair rates with the robot are in the very high 90s - close to 100% range. I don't know if 100% of that would have been achievable in a standard open approach. That's the reason that I absolutely love using the robot for this and I think it's the preferred way, I really do.

Dr. Chikwe: I have to say, I'm a robotic surgeon and that's how I'd want the operation if I needed it. A beautiful, elegant operation. It allows you to be super cosmetic, fast recovery without compromising the quality of the surgery.

Dr. Emerson: Absolutely!



Mitral Valve Disease Progression



Dr. Chikwe: Jeff asks, "I was recently diagnosed with mild regurgitation and told that I could require surgery but not for 10 to 20 years. Is there anything I can do now to slow or stop the leaking from getting worse?" I think that's a really tough thing to tell somebody who's got mild mitral regurgitation. My bias would be, unless your valve looks very abnormal, I think the likelihood is you would never need surgery.

Unfortunately, there's not a lot you can do to change the natural history of things, other than maybe avoid anything that raises your blood pressure dramatically for long and regular periods of time. The one activity we typically tell people to avoid is heavy weightlifting.

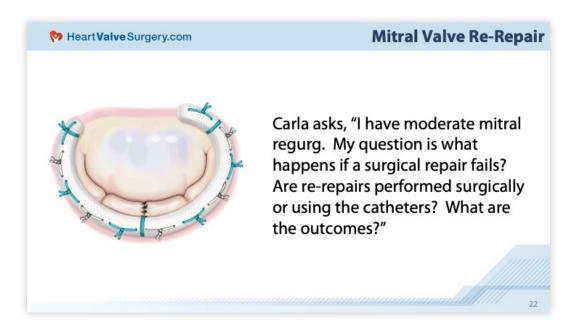




So, bench pressing 100, 200 pounds on a routine basis, but other than that, good pressure control, work out regularly. No, I think there's not much that you can do to stop that progressing, but just be confident it may never progress.



Mitral Valve Surgery Failure

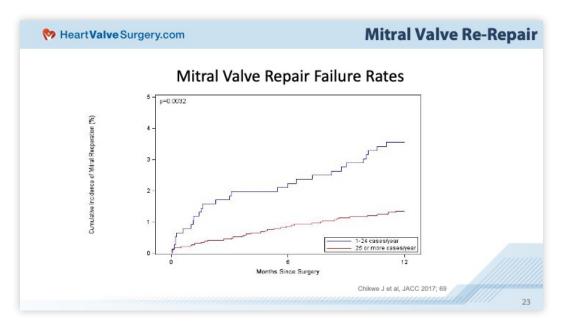


Dr. Chikwe: Carla asks, "I have moderate mitral regurgitation. My question is, "What happens if a surgical repair fails? Are re-repairs performed surgically or using catheters? What are the outcomes?" This is a great question and it's really important. First of all, if you have moderate mitral regurgitation, it is very unlikely that you would need or be offered surgery or any procedure.

We really only work on the mitral valve surgically if it's severe regurgitation. That's really important. Occasionally, people will describe that it is moderately severe, but you need the word "severe" to be thinking about surgery.



Mitral Valve Repair Failure Rates



Dr. Chikwe: Surgical repairs are the best thing that we have but I tell every patient that I see in the office, nothing is 100% guaranteed in this world and about 1% of repairs will fail each year or two. A handful of people, 10 years after surgery, may have a leak that's moderate to severe and may need the valve being treated. Typically, re-repairs have been done but they're tricky. Only about 30% or 40% of patients who get leaks after repairs are successfully re-repaired and that is absolutely something you would do at a center of excellence. They're very hard to re-repair well. Most patients who have failed surgical repair will get a replacement.

Very few patients are appropriate for catheter treatment. Catheter treatment means you have a puncture via a vein or an artery in your leg and that's the way up to your heart, without having surgery.



Very few of these failures can be treated with a clip or a similar device. The outcomes are variable, which is why the majority of people with a failed repair frequently end up with a replacement. A lot of what we're talking about today is trying to avoid that situation. It's trying to choose a surgeon and the timing of your surgery so that your valve repair is good to start with and hopefully, lasts you a lifetime.

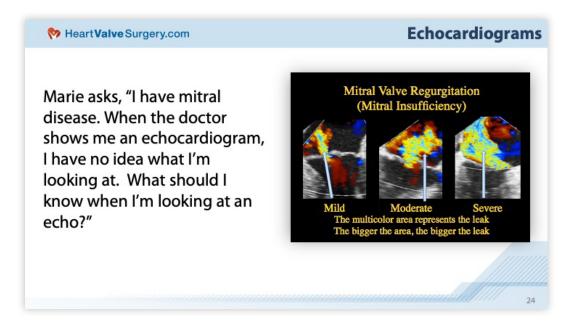
This gives you an idea of what mitral valve failure rates are after a repair in New York state. Again, this is research that we did and we look at surgeons – in red there, you can see the surgeons who see a mitral valve at least twice a month and in blue there, you can see surgeons who see the mitral valve less than twice a month.

What you're seeing there is the rate at which their repairs fail in percentages. At one year, 12 months, 1% of repairs have failed in the busier surgeons' hands, compared to nearly 3% of repairs failing in the less frequent mitral valve surgeons' hands. Again that's underlining this importance of making sure your repair is done by somebody who spends a lot of time looking at mitral valve repairs. It also underlines the fact that, even in experienced hands, with the best results, these can fail, but it's a low rate of failure.





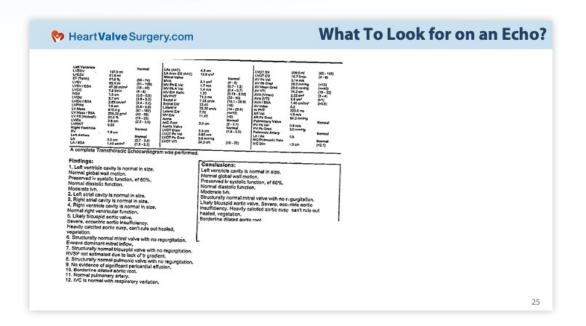
Echocardiograms: What Should Patients Know?



Dr. Chikwe: Marie asks, "I have mitral disease. When the doctor shows me an echocardiogram, I have no idea what I'm looking at. What should I know when I'm looking at an echo?"







Dr. Emerson: I think it's okay to not know what you're looking at. A good consultation should involve, if you have questions about that sort of thing, going through that with you and showing you what you need to understand about it. The big things that you're going to look for in the echo, as a patient, are – some of it's actually just a report and that will help you – it'll probably say to you whether it's mild, moderate or severe-type regurgitation. With regard to the moving parts and the color and all that, the colors that you see on the echo is just turbulence and flow of blood. Some of that is normal, some of that we expect to see as it goes through the valve.



Heart Valve Su	irgery.com	ı			Wh	at To Look for on an Echo?
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Most of the time, what they're pointing out and they're looking at in those echoes that they're showing you, is the regurgitant blood, the blood going in the wrong direction. The valve is just a one-way door, that's all it is. What you want is that when the heart squeezes, the blood all goes in the forward direction towards the aortic valve and out the heart.



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Dr. Chikwe: One rule of thumb that I use is before surgery, you only need to think hard about your echo if something says "severe". Pretty much everything else is not going to require you to need surgery or a procedure. It's all within acceptable limits. Look for "severe" on the report and that's the thing to ask your cardiologist about in more detail. Where it says "normal", that's all good. After surgery, what we really want to see is things that say, no mitral regurgitation, no tricuspid regurgitation or trace. Trace means very, very, very little. That again is something that suggests that your valve repair should last you a long time.

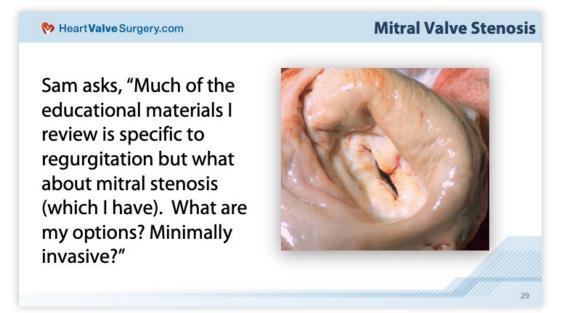


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Mitral Valve Stenosis



Dr. Chikwe: Sam asks, "Much of the educational materials I review is specific to regurgitation but what about mitral stenosis (which I have). What are my options? Minimally invasive?"

Absolutely yes to minimally invasive. The main difference is that mitral stenosis is really hard to repair in a way that lasts and artificial valves tend to be a better option. You can have a minimally invasive operation with a very small incision but the likelihood is, if you're having surgery, you're going to have a valve replacement. You're basically choosing between an animal valve, which doesn't need a blood thinner, but you will have to replace it if it wears out in eight to ten years, which is what they tend to so, versus a mechanical valve, which won't wear out but will require you to take a blood thinner for life.

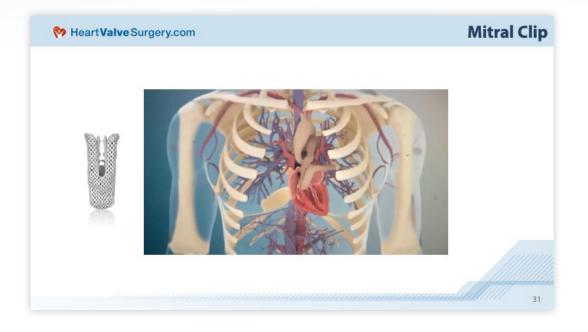


The Future of Mitral Valve Therapy



Dr. Chikwe: "How will mitral valve procedures transform during the next ten years?" Well, this is a great lead into one of the options that don't involve surgery for patients with regurgitation and stenosis. Hopefully there are some exciting answers.





So, here's a MitraClip. This is a tiny little device that is transcatheter. So it's a clip that those arms open and close and by transcatheter, I mean it can be introduced into your heart via a puncture of a blood vessel in your groin. This means it's much less invasive than even minimally invasive surgery. The catheter goes across the right chamber of the heart, through the wall separating it from the left chamber, so it actually makes a little hole in your heart. Then, a device is threaded across that wire and dips into the valve. Here you can see the mitral valve opening and closing.

The job of this clip is going to be to catch the two leaflets at exactly the point where it can reduce the leak between those leaflets. This is a real art form, and it's taken cardiologists a fair while to get very adept at this. This treatment is delivered by cardiologists and by some surgeons. It works a little bit like a technique that was designed by a surgeon where the leaflets are just sewn together.



Here you can see the clip being deployed, bringing the leaflets together, and then we assess the leak. If there – this has changed the valve from having one opening into two openings, as you can see there. The midpoint of the valve is kind of clipped together. If there's still a leak, as is shown in this animation, you can redeploy the clip until you're happier with the position.

To answer the questions in the chat that were asking, "If the leak could go disappearing off or could the clip go disappearing off?". This clip is designed to cause scarring of the leaflets, and that scarring essentially glues the clip to the leaflets. So, it's not going to go flying off. That's really important for a few reasons, not just because it reduces the chance of the clip flying off, but because that scarring can cause problems if that repair, that clip, doesn't work well. I think you can get a sense from that video that if that repair fails and you have a severe leak after you have your valve clipped, it's quite difficult to repair that surgically. You've scarred the leaflets. You're not going to get such a perfect result. The clip is really good for certain patients, and we all talk about which patients are great candidates for a clip on the next slide.





This is the surgical theatre and Dr. Emerson, I don't know if you want to talk about this. Some people are curious how the robot works.

Dr. Emerson: Yeah, so this is actually me doing some lectures on the robotic technique and the devices. You can see here that big area there. That's the mannequin that we use with all the little black dots on it. The robot is the thing with the arms that's going into it, that white part. The robot itself has four arms, and we control them.





People often ask is the robot doing the operation autonomously without us, our input, and that's not how it works. We sit at a station that has the 3D camera. We look through it, and we control the arms completely. The robot doesn't actually do any part of the operation without our input. It's just a tool that we use to be able to do those things in a minimally invasive approach.

Dr. Chikwe: I think this is a great illustration of the precision that the robot gives you. Again, these sutures are finer than a human hair, and that needle is about 3 millimeters long. It looks huge under magnification, but it's actually almost microscopic. I think that the robot really enhances the precision of what you can do through a tiny little hole.



		Mitral Repair
	PRIMARY	REPAIR-MR
Sponsor	NIH	Abbott
Population	All-comers>65 years	Moderate risk (>75 or risk factors)
Design	Randomized	Randomized
Treatment	TEER vs. Repair	MitraClip vs. Repair
Primary endpoint	3-6 year death, reintervention, heart failure hospitalization, <u>></u> 2+ MR	 A) 2-year death, stroke, heart failure hospitalization, dialysis b) 2-year <2+MR without replacement or reintervention
Patients	450 - 650	500

Clinical Trials for Mitral Valve Disease

Dr. Chikwe: Right now, the mitral clip, which is what a lot of people are interested in because it is essentially avoiding the need for any surgical incision. Because we in the United States have not been doing it for much longer than a decade, we don't have long-term outcome data.

We don't know for patients that might live 30, 40 years whether it's the good long-term option. Your insurance won't cover it, and your cardiologists probably won't offer you that option. One way to access the clip if you have prolapse and you are very interested in the clip, as well as a surgical repair, is through a trial. Currently there are two trials, two studies, looking at this device, comparing it to

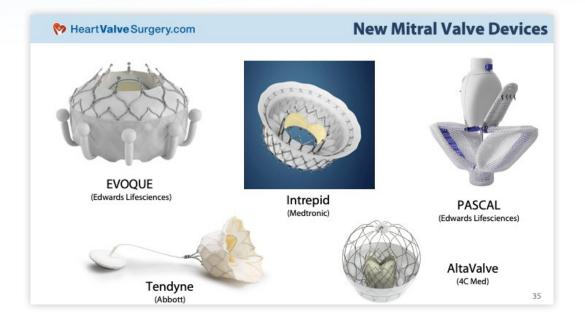


surgery. The trial on the right is a trial of moderate risk patients, so that's being – the clip is being offered to patients that are aged over 75 or younger with some medical risk factors that make them higher risk surgical candidates. Then, at Cedars, we're running a trial which offers the clip to any patient over the age of 65 with mitral valve prolapse if they qualify.

We're comparing the clip with surgery. To be really clear, although you will be allowed to have the clip, the decision as to whether you get the clip is made by the study. You're randomized to either the clip or surgery.

Those are the two very exciting trials that really should tell us a lot more about which patients are most suitable for a surgical approach or the MitraClip or PASCAL, which is another device which is a little bit like the clip for mitral valve prolapse.



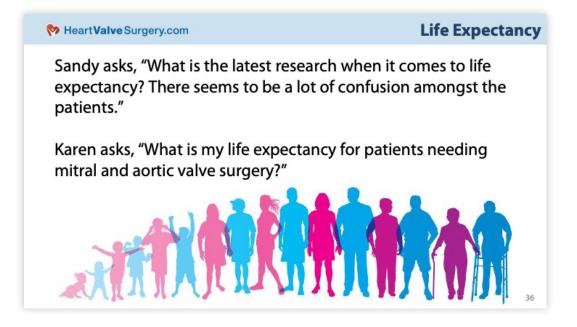


Dr. Chikwe: Now, here are a number of devices which can be introduced into a patient just like the clip that you saw in that video, and PASCAL, which is another clip, which has recently come into practice in the US there shown on the right.

EVOQUE is a mitral valve replacement, along with a couple of the other devices that you can see. The reason I picked out EVOQUE is because Dr. Makkar at Cedars-Sinai is the principal investigator of the trial that is exploring the use of this device to treat mitral valve regurgitation with a valve replacement done through a catheter, and that's a trial that's currently recruiting that he is leading. These are all really investigational devices but one or two of these, for sure, apart from PASCAL – one or two of those replacements will probably emerge as a great option for patients in the future.

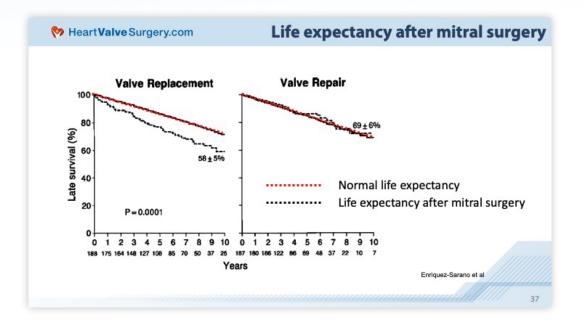


Questions and Answers:



Adam Pick: Great. We have about 20 minutes to get into some great patient questions. Let's not waste any time. The first one – and I think I probably get a question about this once every three days – is all about life expectancy. Sandy asks, "What's the latest research when it comes to life expectancy? There seems to be a lot of confusion amongst the patients." Karen tags onto that. She says, "What is my life expectancy for patients needing mitral and aortic valve surgery?" I know Dr. Chikwe, you sent over some slides that hopefully can address Sandy and Karen's questions, right?





Dr. Chikwe: Sure thing. The reason there's confusion amongst patients is there's confusion amongst doctors and surgeons. Here's one thing that we do know: if you have a floppy mitral valve with a severe leak and you do nothing, your life expectancy is much, much, much lower than normal, which is why we want to fix it.

The reason that we get very excited about fixing it with a mitral valve repair and not using an artificial valve is this study. Now, this is an old study but it's really important where hundreds of patients with floppy mitral valves were followed The dotted red line is normal life expectancy. That's what a person with a similar



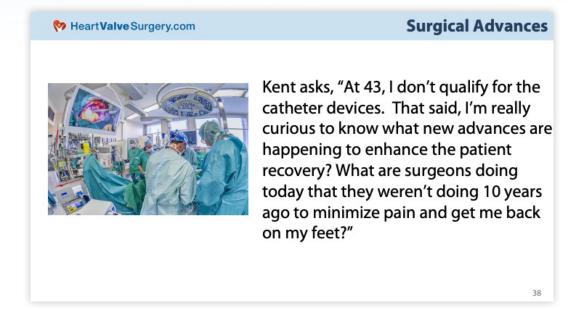
age could expect in the United States. As you can see, if you had a mitral valve repair there on the right, your life expectancy was the same as normal life expectancy of a person without any mitral valve regurgitation. That's what we want, normal life expectancy.

On the left, you can see that if you had a valve replacement for your leaky mitral valve that your life expectancy was lower, only 58% of people alive at 10 years, which was lower than the normal population and lower than if you'd had a valve repair That's why valve repair is so important for people with mitral valve prolapse.

I think that the question about aortic valve disease is a little different but again, that's a disease where we either want to try to repair the valve or replace it with a biological option that's as close to a normal human valve as possible. Really, I expect we could do an entire separate webinar on whether the Ross procedure can restore normal life expectancy and what the value is of repairing valves and sparing the valves when you've got aortic disease.



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Dr. Chikwe: So, here was question about how to minimize pain control after mitral surgery. Dr. Emerson, I'm curious. What do you tell patients when they're trying to decide between regular mitral valve repair and maybe one done robotically through the side?





Dr. Emerson: It's one of the most common questions that we get for patients. I mean, everybody is concerned about their pain, and I think rightfully so. Pain is so variable between individuals. It's hard for me, or any of us, to 100% predict what your individual pain will be like. We try to, as much as possible, to use a multi-modal therapy, meaning doing different things between blocks, oral and IV pain medication to try to achieve the best pain control that we can have with the knowledge that we'll never make your pain zero but that we will try to get it to a point where you're – it's completely tolerable.

The difference between the open, more traditional approach to the sternotomy coming through the front here, and using a minimally invasive approach when we come through the side is that the pain, I think, in the longer term, meaning



days out, is going to be better with this smaller incision but the immediate pain I think is actually kind of similar in – between the two approaches The way that we address pain for the minimally invasive approach is, as you can see on this slide here, is using nerve blocks. What a nerve block is it's directed medication that's a local anesthetic that will block the nerves that cover that area of the chest and make that area numb so you don't feel much of the pain there. We do those and can redo them during your hospital course to try to make your pain better. That's one of our prime message after a minimally invasive approach.

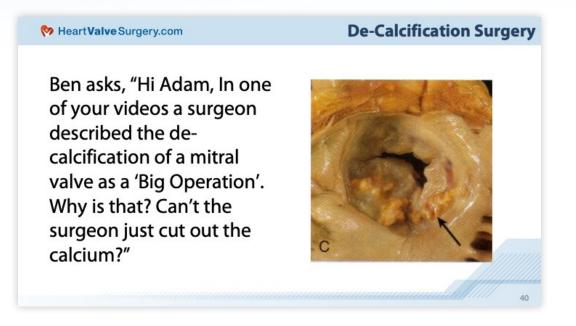
Adam Pick: Just a question, as a patient, when I had my surgery, I can tell you I came out of the hospital. I was on a lot of medication I ended up, unfortunately, getting addicted to Vicodin for a period of time. It wasn't fun. I really want to commend Cedars, the societies that have come together to really approach this issue in a big way for patients. I've got to ask, Dr. Chikwe and Dr. Emerson, are your patients – are they leaving the hospital without any opioids at all, or is that still something we're hoping to get to in the future.

Dr. Chikwe: I would say in my experience, most of my patients leave the hospital without opioids, and certainly when they come back to the office, it's almost the second or so question I ask, "Are you off – are you taking any narcotics?" I can't remember one this year that was still taking narcotics.

Adam Pick: Wow, that is fantastic. Great job.



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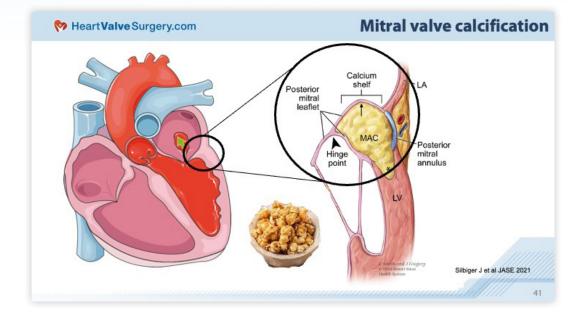


Dr. Chikwe: Ha! Here was a question about calcification Why is it such a big deal? I'm going to give this one to Dom. You've got some popcorn there.

Dr. Emerson: Yeah, I see that. So mitral annular calcification, which you're going to hear us say MAC, what you see on the center of that slide, M-A-C, and that's just because it's easier, is a phenomena where the area – the hinge point of the valve, which if you think the valve as a door, is just where the door hinge would be, that area can become very stiff and calcified. That becomes quite problematic for repair.

It's something that if you have, I would very strongly encourage that you go seek





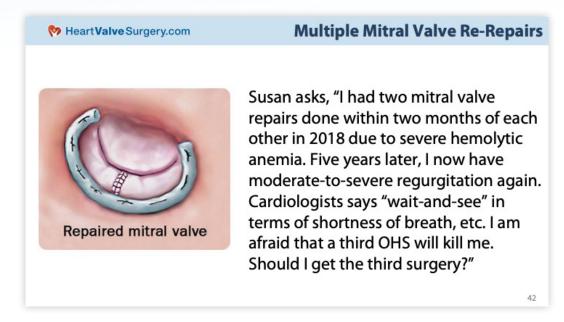
care at a center that is really specifically geared to handling it, meaning a mitral valve center of excellence. It can increase the complexity and the challenges of any kind of repair and can actually increase the complexity and challenges if you need a replacement as well. Most of those – most patients with MAC are going to be patients that are going to be traditionally steered towards more of a replacement. I don't think that that's necessarily the answer that has to happen. We certainly have repaired a lot of valves with some degree of MAC and it's very much a individual call and something that we would have to look at from patient to patient. It is something that certainly should be seen at the center that is really geared towards good mitral valve care.





Dr. Chikwe: The challenge with MAC is that it's really difficult to treat safely and well from a surgical standpoint. There are not a lot of transcatheter options for it, either. There's a ton of work being done right now because everybody sees this as a really important area. We would love to be offered – able to offer a much safer way of tackling this.

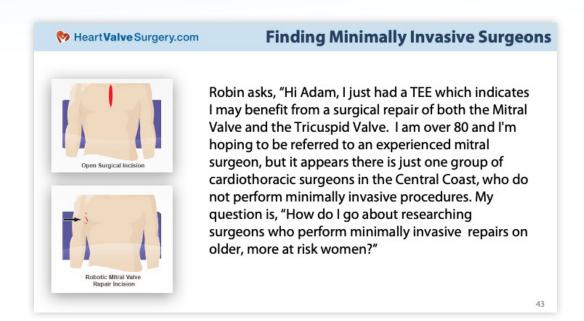




Adam Pick: This is all about not just a re-repair, a re-re-repair, and Susan is very concerned. She had a repair, then she had another one due to severe hemolitic anemia Now she's in watchful waiting because she had moderate to severe regurgitation again, and she just asks, "I am afraid that a third open heart surgery will kill me. Should I get the third surgery?"

Dr. Chikwe: So it's really difficult to give a helpful answer without knowing your story in a lot more detail because your general fitness and medical problems are really key to understanding the risks of third-time surgery. What I would say is that an experienced center, you should do really well if you don't have a lot of other major medical problems. Third time mitral surgery is challenging but in the right hands, this is something that you should absolutely get through. The chances are that the third-time surgery will be a replacement, not a re-re-repair.





Adam Pick: This is – when it comes to patient advocacy - I think this is just a great question from Robin. She has been diagnosed with – I need a mitral and tricuspid valve surgery. She's over 80. She lives in central California and when she went to research surgeons, Dr. Chikwe and Dr. Emerson, she didn't find anybody that performed a minimally invasive procedure. Robin asks, "My question is how do I go about researching surgeons who perform minimally invasive repairs on older, more at-risk women?"

Dr. Chikwe: I would say about 10% of our patients – and Dr. Emerson, correct me if you're wrong – certainly over the age of probably 78, 79, 80, and at least half of those are women, so that's something that we have fairly deep experience in and I think uniquely, we are very liberal in who we choose to do robotic surgery. Many centers will screen you out based on age or other issues that come with age whereas a robotic approach, we found in our hands, is safe across the board with very few exceptions.



We'd evaluate you very carefully, but I don't see – it's challenging to get that kind of surgery locally. It may be something you have to commit to traveling for.

Dr. Emerson: I think we – 80 isn't 80 isn't 80 just like if you're 60, it's not the same as every other 60. I think we try to evaluate individuals really not just on your chronologic age but on your biologic age. If you're somebody who's 80 who's walking three miles a day and is otherwise in great shape, never been to a hospital, you're probably going to do actually extremely well following mitral valve repair. I think that you're absolutely right, Dr. Chikwe. I think at least 10% of our patients are in that age group who we do mitral – minimally invasive mitral valve repair on.

Adam Pick: Thanks for these points, Dr. Chikwe and Dr. Emerson. I love that 80 isn't 80 isn't 80. What I say to a lot of patients is heart surgery is – it's not a haircut. You've heard this throughout the discussion today. Take the time to find the right surgeon, to do the right research to find the right center that has a lot of experience so that you can find a way to stay on that normal life expectancy.





Let's get to Nupur's question. Because we're starting to go short on time here, I'm going to get to – and you've addressed some of these, but what happens when the MitraClip fails? Does having a mitral clip rule out future repair? This is interesting. I have a bad anterior leaflet and possibly a flail segment. Does that mean the mitral clip is less likely to work?

Dr. Chikwe: There are a lot of questions and quite a lot of concerns behind the questions here. Perhaps the most important one to answer is a question that wasn't really asked. A 56-year-old woman who doesn't have a lot of other major medical problems is safest with surgery because as I said earlier, surgery in the US is super, super low risk. We have a 0.3, that's a third of one percent, mortality in the US when we do this operation. Right now, mitral clip has about a 1 to 2% mortality in the US at treating mitral valve disease. That's partly because mitral clip patients are a lot older, but that does really – and frailer and often sicker, but it does really underline the safety of surgery. The chances are 99.9% chance of doing really well in surgery.



What happens if the mitral clip fails? It can cause a severe leak that's very difficult to repair. In the US, 95% of patients with a failed mitral clip that need surgery end up having a valve replacement, not a repair At Cedars, that's about 50%, but it's really hard to get those repairs to be great and durable.

Does having a MitraClip rule out future repair? It doesn't, but it reduces your chances of having a good future repair. As a patient with a bad anterior leaflet and possibly a flail segment, you're less ideal for a mitral clip. The clips work really well in patients that just have a little bit of prolapse in the middle of the posterior leaflet and not so ideal for other kinds of morphology. It can be done, and it can be done well, but for the majority of patients right now, surgery is a very safe and very reliable, very durable option.

Adam Pick: Nupur, I hope those comments from Dr. Chikwe help dispel some of the fear that it says you're going through, or I think I read in one of your earlier emails. If you'd like to email me your phone number, I'll call you and we can talk this out and do whatever we can to help you get to – come to terms with all the great points that Dr. Chikwe just made.





Adam Pick: Here comes, I would have to say, one of the biggest questions that we get here at HeartValveSurgery.com. Pamela asks it. It's probably come up already several times. What is the durability of mitral valve surgery?

Dr. Chikwe: Hey, Dr. Emerson, what do you tell patients? What did you tell your patient today?

Dr. Emerson: Yeah, so if you divide it into repair or replacement, so replacement, what you see on top there, what you're looking at, just to orient you, is on the left side there, that's a mechanical valve. It's made out of metal and will not, in general, fail over time. I tell patients the valve's going to outlive you. It's just going to keep doing its thing forever. On the right there is a biologic valve or bioprosthetic valve. The difference for a patient after surgery of those valves is

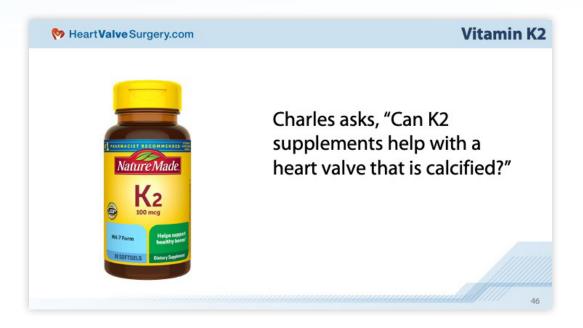


on the left, you have to take a blood thinner with a mechanical valve – a blood thinner the rest of your life. A lot of people on blood thinners – a lot of people tolerate it very well, but there's that – that's a consideration going forward.

On the right, the bioprosthetic valve, you don't have to take a blood thinner, but they don't last forever. When we say they don't last forever, that's a little bit of a variable answer depending on the individual, how old they are, that sort of thing. In general, if you get 10 to 15 years out of it, that's about the most that you get out of those valves. In the mitral position, the majority of those vales that fail are going to require you to have another operation. That's the consideration between those two valves. The repair – when we're able to repair the valve, that durability – we always tell people yes, we hope that this is the only operation you ever have in your entire life, but as Dr. Chikwe showed you with those earlier slides, there is some failure rate with those over time. It's a little variable depending on the kind of pathology you have, but that 1% per year, plus or minus, is a pretty reasonable expectation for that.



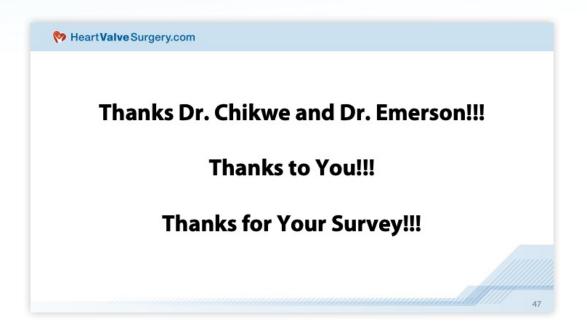
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Adam Pick: Great, and we're going to get another common question. Charles asks, "Can K2 supplements help with a heart valve that is calcified?"

Dr. Chikwe: Nope. I wish they could and people have tried many different things but unfortunately, a valve that is calcified, there is really nothing to make that calcium go away or nothing to slow it progressing.





Adam Pick: Great. Well, thanks so much. On that note, we are coming to the top of the hour. I'd appreciate it if you don't hang up just yet. I'd like to take a quick minute and thank you, Dr. Chikwe, and you, Dr. Emerson, for getting on the line today, taking time away from your practice, and educating us all about some of the latest and greatest advances in mitral valve therapy. I also need to thank all the fantastic people in our community that are on the line right now with us, spending time, getting educated, getting empowered, asking the tough questions, so that you are on your journey to a healthy heart. In advance, as we wind up today, I just want to thank you for taking just a minute here and answering five quick questions that are going to be coming up onto your screen in a minute. Thanks, everybody, for being with us and thank you, Dr. Chikwe and Dr. Emerson.

Dr. Chikwe: Thank you so much. Really appreciate it.

Dr. Emerson: Thank you.



Patient Resources

Since 2006, <u>HeartValveSurgery.com</u> 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.

- <u>Adam's Free Patient eBooks</u> Download 10+ free eBooks about heart valve dis-ease and treatment options for aortic, mitral, pulmonary and tricuspid valves.
- <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.
- <u>Adam's Heart Valve Blog</u> 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.

