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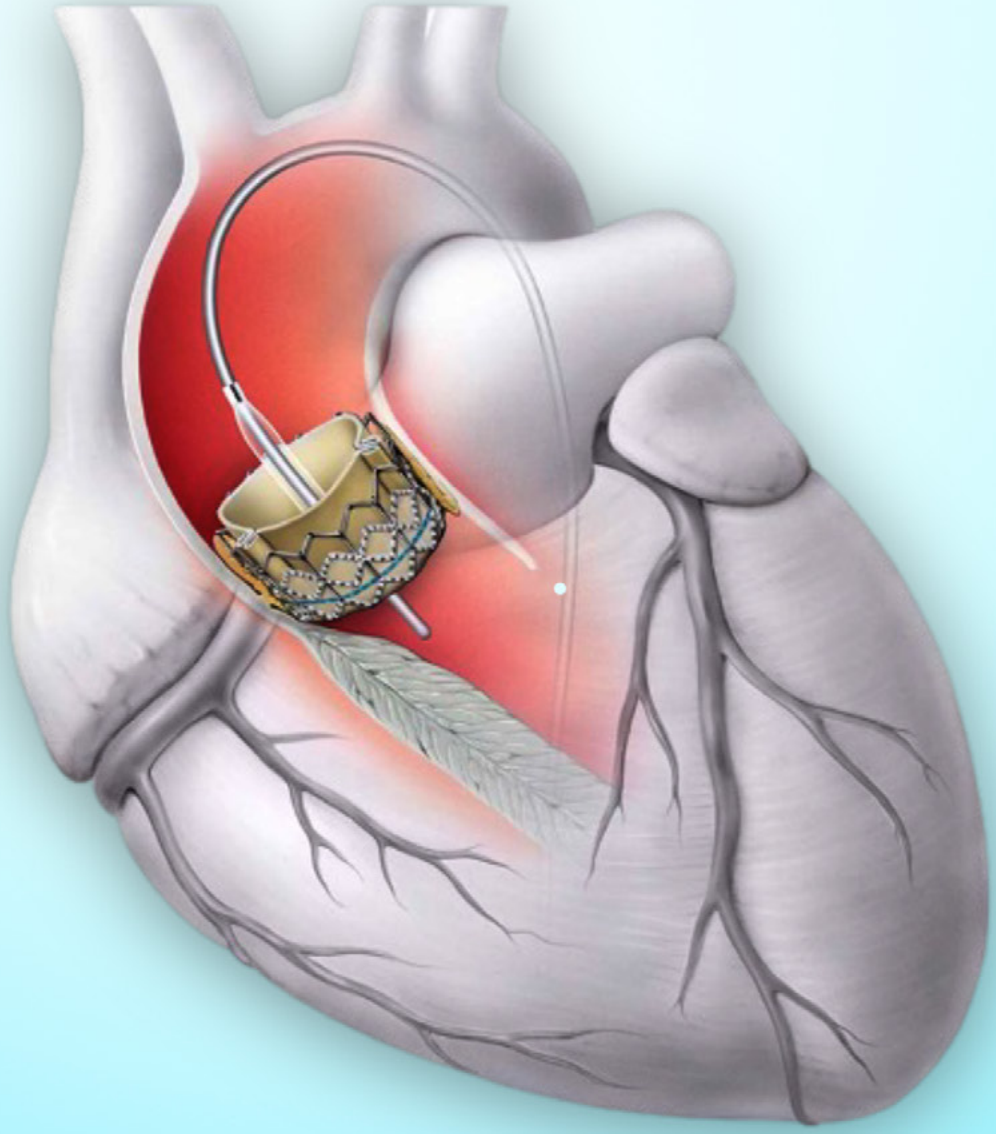
PRESENT & FUTURE

OF HEART VALVE SURGERY



MAYO CLINIC

HeartValveSurgery.com Named #1 Heart Website!

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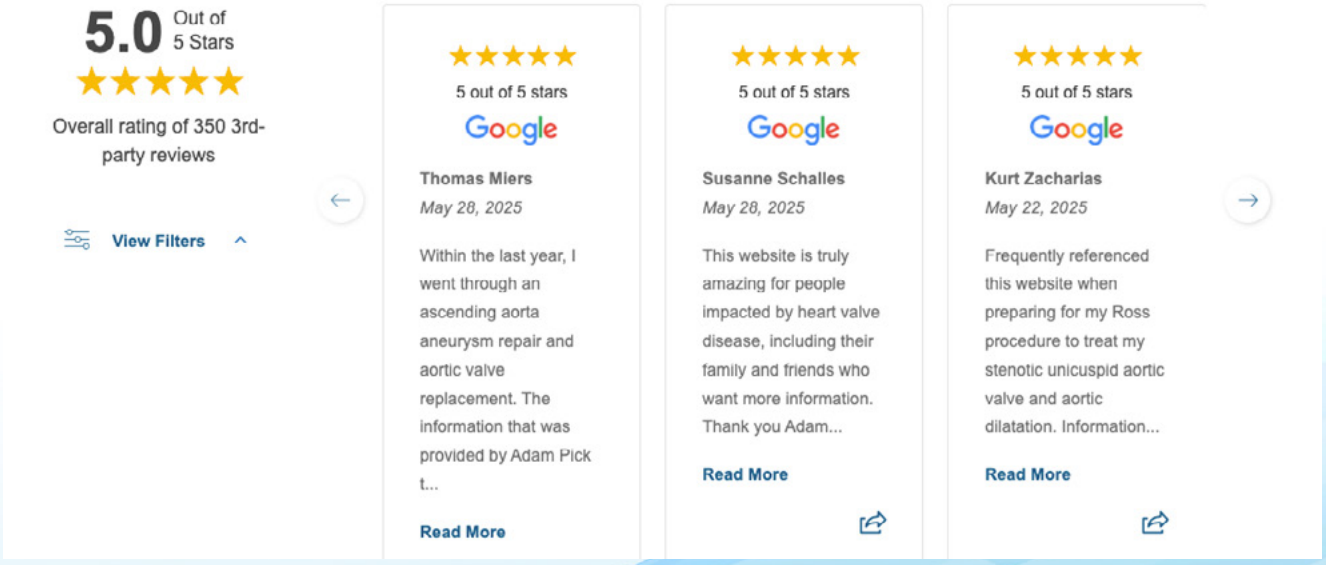

Featured Speakers

Dr. Jack Haney

Chair, Cardiothoracic Surgery
Mayo Clinic Florida (Jacksonville)
(904) 664-6338
Learn More.

Dr. Pyongsoo Yoon

Chair, Cardiovascular Surgery
Mayo Clinic Arizona (Scottsdale)
(480) 914-9748
Learn More.

Adam Pick

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

YouTube

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

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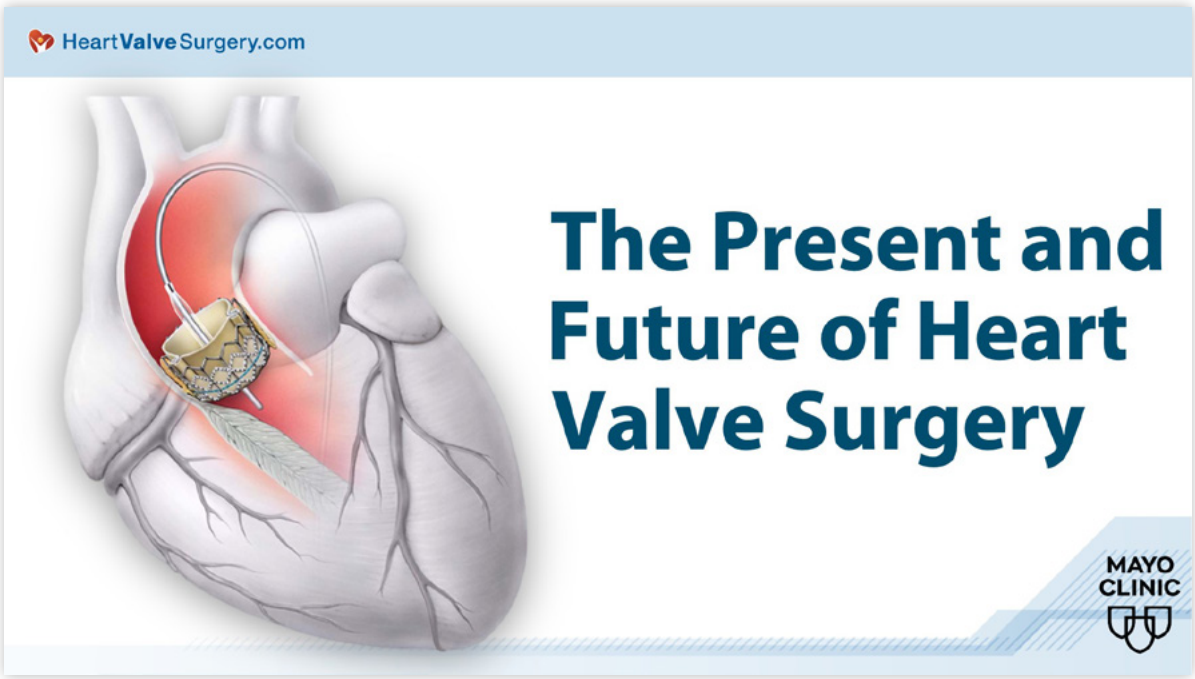
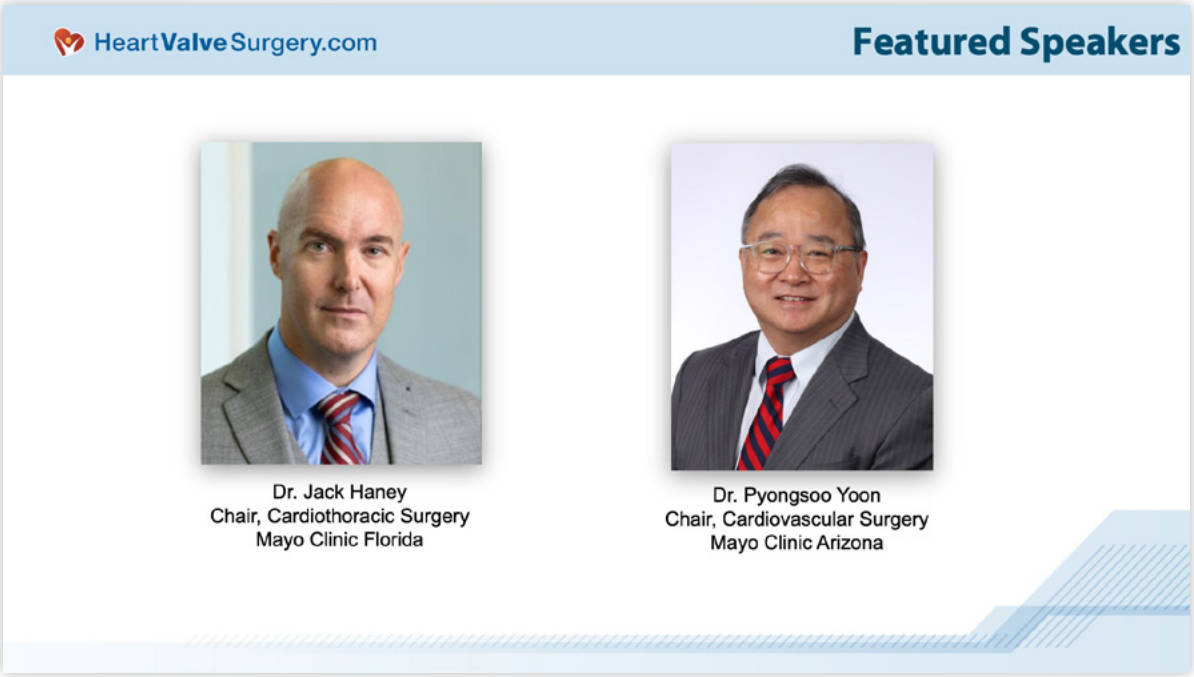


Adam Pick: Hi everybody, my name is Adam Pick. I would like to welcome you to the webinar titled, “The Present and Future of Heart Valve Surgery”. If I have yet to meet you, I’m the patient who started HeartValveSurgery.com nearly 20 years ago. The mission of our website is very simple, we want to educate and empower patients just like you.

This webinar, which has had over 700 registrations from patients in countries all over the world, was designed to support that mission. Now, throughout the webinar, you're going to be in what's known as "Listen Only" mode, but I encourage you to submit your questions on the control panel on your screen. I'll explain why when we look at the agenda for today. We've got a lot to get through today. We're going to introduce the featured speakers. We're going to talk about heart valve disease and traditional therapies. We're then going to shift gears and go into some valvular advances.

We're going to contextualize therapeutic approaches with patient case studies, then we're going to have a very exciting session about future interventional techniques. We're going to close the session with a Q&A back-and-forth between Dr. Haney and Dr. Yoon, and then I'm going to ask you to complete a very quick five-question survey.



As for our featured speakers, I am humbled and honored that they're taking time away from their very busy practice at the Mayo Clinic. Who are they? We have Dr. Jack Haney, who's a cardiac surgeon at the Mayo Clinic Florida. Dr. Haney, thanks for being with us today.

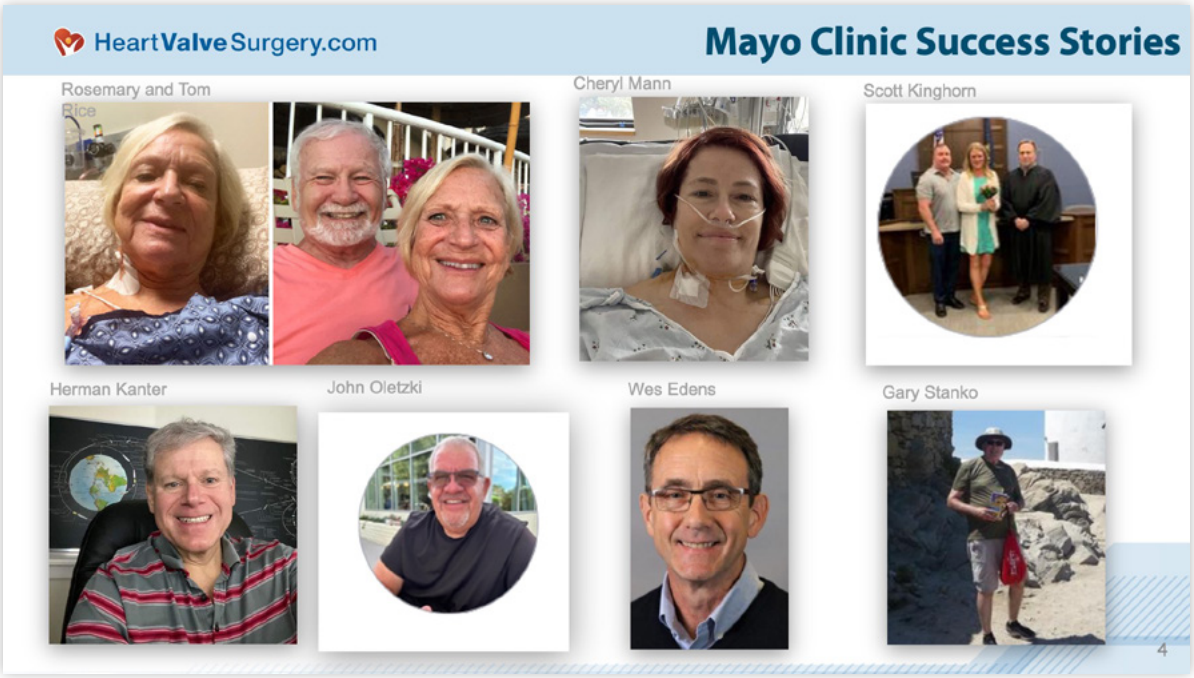
Dr. Haney: Thank you.

Adam Pick: We also have Dr. Pyongsoo Yoon, who is a cardiac surgeon at the Mayo Clinic-Arizona. Dr. Yoon, thanks for being here.

Dr. Yoon: Yeah, thank you.

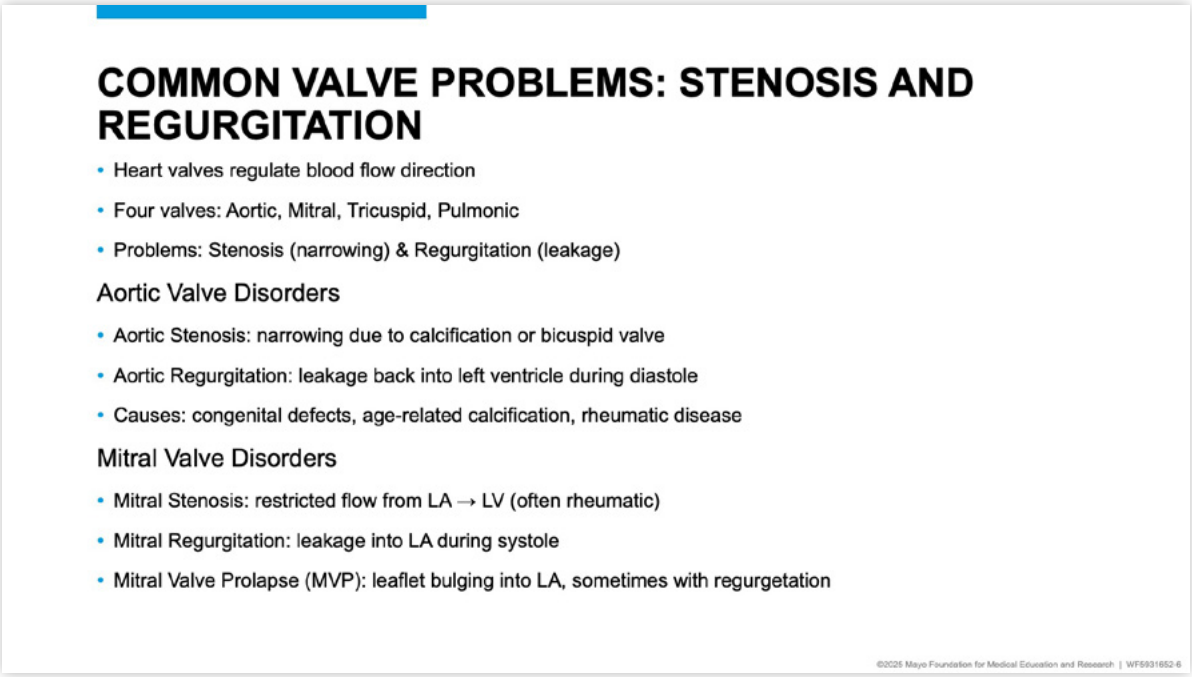
Adam Pick: I could go on-and-on about the accolades and the achievements of both Dr. Haney, who's at Mayo Clinic Florida in Jacksonville, and Dr. Yoon, who's at Mayo Clinic Arizona in Scottsdale, but our agenda is packed with information. This is the first time in heartvalvesurgery.com's webinar series that we don't just have one chair of cardiac surgery. We are very fortunate to have two chairs of cardiac surgery, being Dr. Haney and Dr. Yoon. Instead of going very deep into everything they've done over their careers, what I would like to do is show you this.

Mayo Clinic Patient Success Stories



Adam Pick: These are the smiling faces of patients from the heartvalvesurgery.com community who went to Mayo Clinic, whether it's Rosemary and Tom Rice, a married couple that both needed valve surgery, Cheryl Mann, Scott Kinghorn, Herman Cantor, John Oletzki, who I know Dr. Yoon just recently performed surgery on, Wes Edens or Gary Stanko. These are all folks who had extraordinary results by going to the Mayo Clinic. With that being said, I would like to kick off the webinar, and Dr. Yoon, I'm going to pass it over to you to get started with the present and future of heart valve surgery.

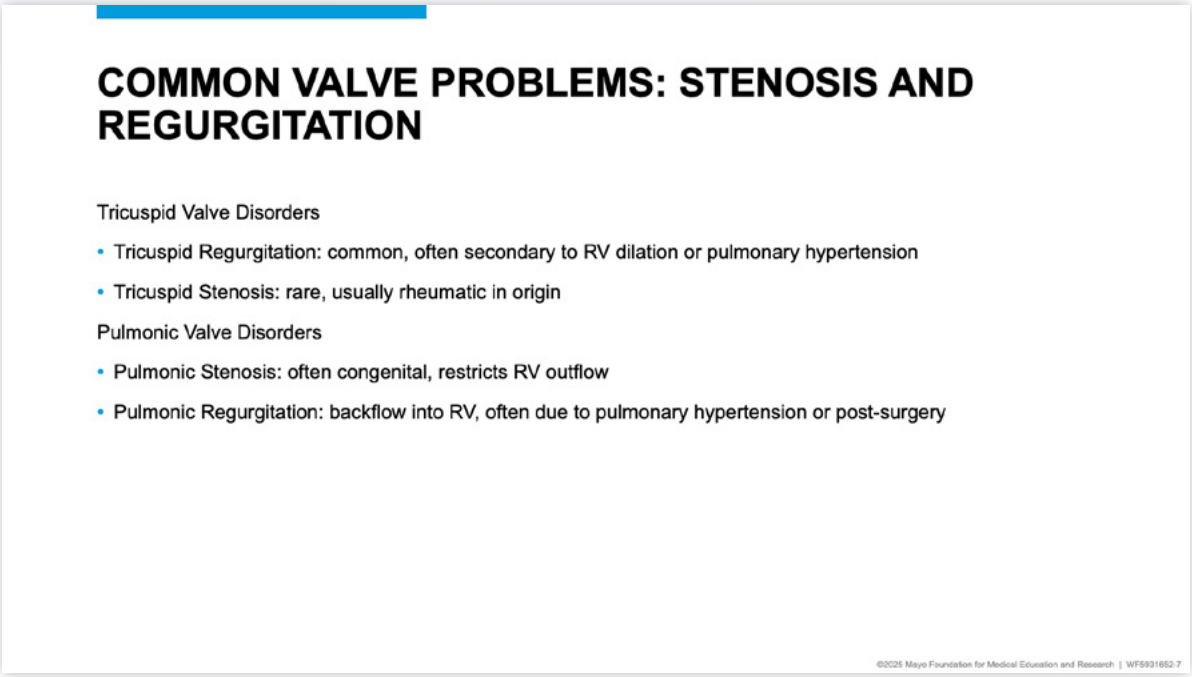
Heart Valve Disease: Stenosis and Regurgitation



Dr. Yoon: All right, good afternoon, everyone. I'm really excited to be here to meet all you guys and do this presentation. We're going to talk about today current status of cardiac valve surgery, as well as what's possible in the future. What common valve problems are there? Basically two types, stenosis and regurgitation. The heart valve is basically a structure within the heart itself that allows blood to flow one direction. It regulates blood flow direction. There are four valves, aortic, mitral, tricuspid, and pulmonic. Both aortic and mitral is on the left side of the heart, and tricuspid and pulmonic is on the right side of the heart. This can become stenotic or narrowed preventing forward blood flow and it can also become leaky valve or regurgitate and cause a backward flow.

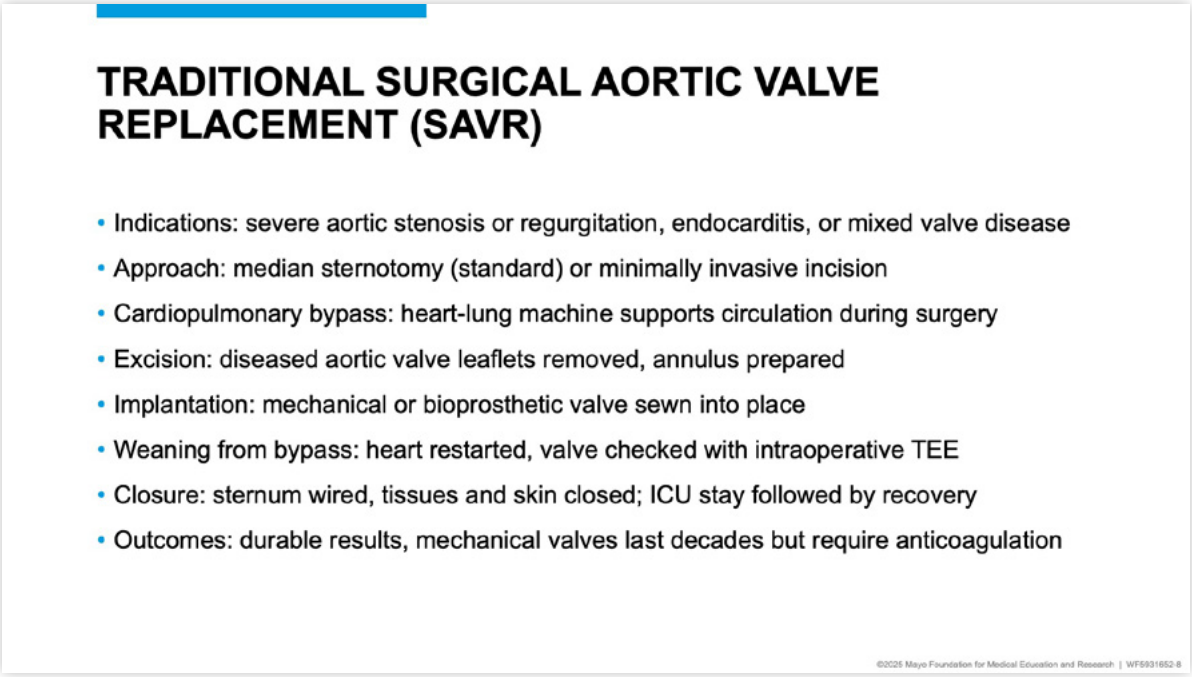
This is kind of simple plumbing. Okay, you want fluid to flow forward and you don't want it to back up. In aortic valve disorders particularly, this is probably the area that heart surgeons are more involved than other valves is the aortic valve. Traditionally, heart surgeons did have a monopoly in this area. Most common pathology is aortic stenosis. Again, that's the narrowing due to a lot of times the scarring of the valve tissues.

Normally, aortic valve has three flaps or three leaflets, and as you age, they can become scarred and degenerate and become calcified or bone like. You have a bicuspid valve, which means instead of three leaflets, you have two leaflets. It can affect 2% of general population, but not all bicuspid valves become diseased. Some of these patients will develop severe calcification and sometimes develop stenosis. You have aortic regurgitation, the leakage of the valve where the blood instead of flowing forward through the aorta, it can also back up into a ventricle, which is not a good thing. In the mitral valve disorders, again, you can have stenosis and regurgitation, and stenosis you're basically restricting blood flow from one chamber to the other chamber, from left atrium to left ventricle, and often these are rheumatic heart disease. Mitral regurgitation happens where the blood from ventricle is leaking backwards into the left atrium and causing symptoms. There's this condition called mitral valve prolapse. A lot of people have it, but it does not necessarily mean that it's going to become disease. A lot of people can have mitral valve prolapse without ever having a leakage, but when mitral valve prolapse gets severe enough and you have these leaflets or the chords get elongated or weak, then you can develop a regurgitation.



The other two valves in the right heart system, and there's a tricuspid valve. This just like the name, it's got three leaflets, three flaps. Surgeons often call this valve, the "forgotten valve", just because heart surgeons were not involved aggressively in managing these valve problems, because usually they're not lethal. They're symptomatic, but not lethal. Frequently, we left those valves alone. We'll talk about this valve a little bit more, but regurgitation is the most common problem and often is secondary to other things, like right ventricle stretching out or having too high pressure in pulmonary circulation. Rarely, you can have tricuspid stenosis, and these are rheumatic in origin. Pulmonic valve disorders; this usually occurs in babies. It's usually congenital problems, and it restricts the RV outflow, and basically you're having backflow into the right ventricle. Often this can be due to pulmonary hypertension or as a complication of surgery.

Traditional Surgical Aortic Valve Replacement

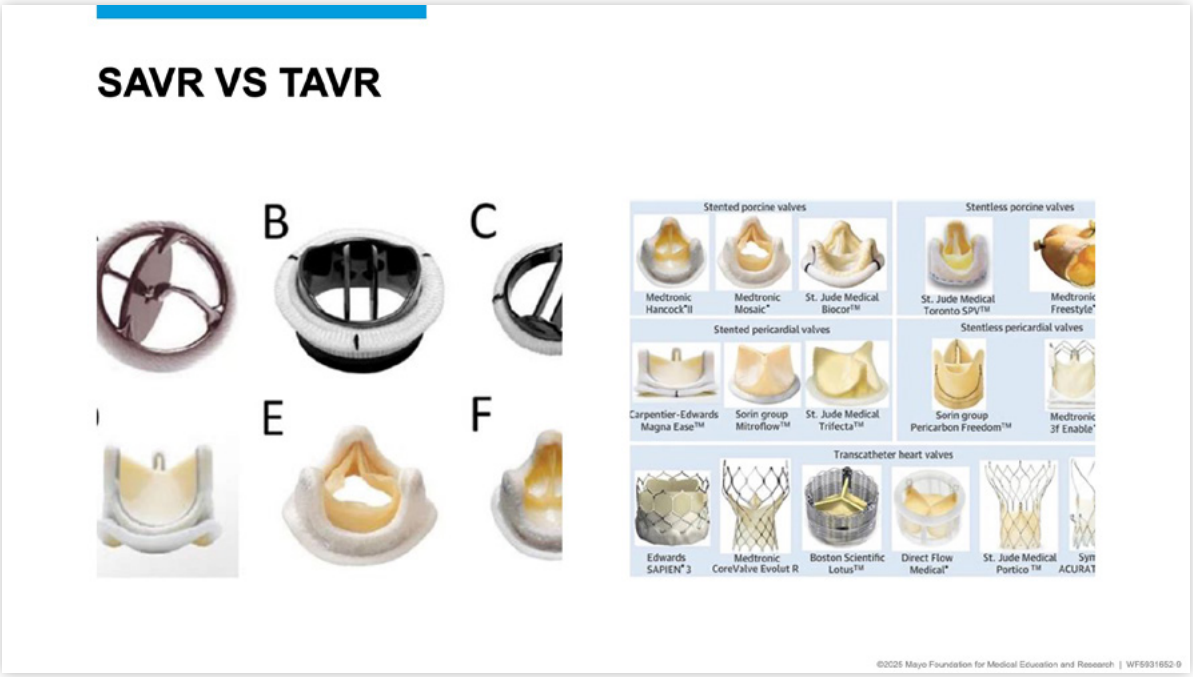


Dr. Yoon: Traditional surgical aortic valve replacement, we used to just call it "AVR" or aortic valve replacement. Since the advent of percutaneous valve, now we have to differentiate it, and we call it SAVR (Surgical Aortic Valve Replacement). The reason for doing the aortic valve replacement is usually severe aortic stenosis or severe aortic regurgitation, and sometimes the infection, endocarditis, or you can have mixed valve disease. Traditional approach was median sternotomy, where you cut from here to here, right through the sternum and opening and doing the surgery. Even today, that's the most common approach to heart surgery, and then sometimes you can also do minimally invasive incision, and there's variations of that. We all use a heart

lung machine to do the surgery because we have to stop the heart, and once we stop the heart, we open the aorta, cut out the aortic valve leaflets and clean the annulus. The annulus is basically the door frame of the aortic valve, and those are usually very calcified and we've got to clean all that calcium off. We basically suture in the new valve. It can be mechanical or bioprosthetic, or tissue valve, and we'll talk about that a little further later.

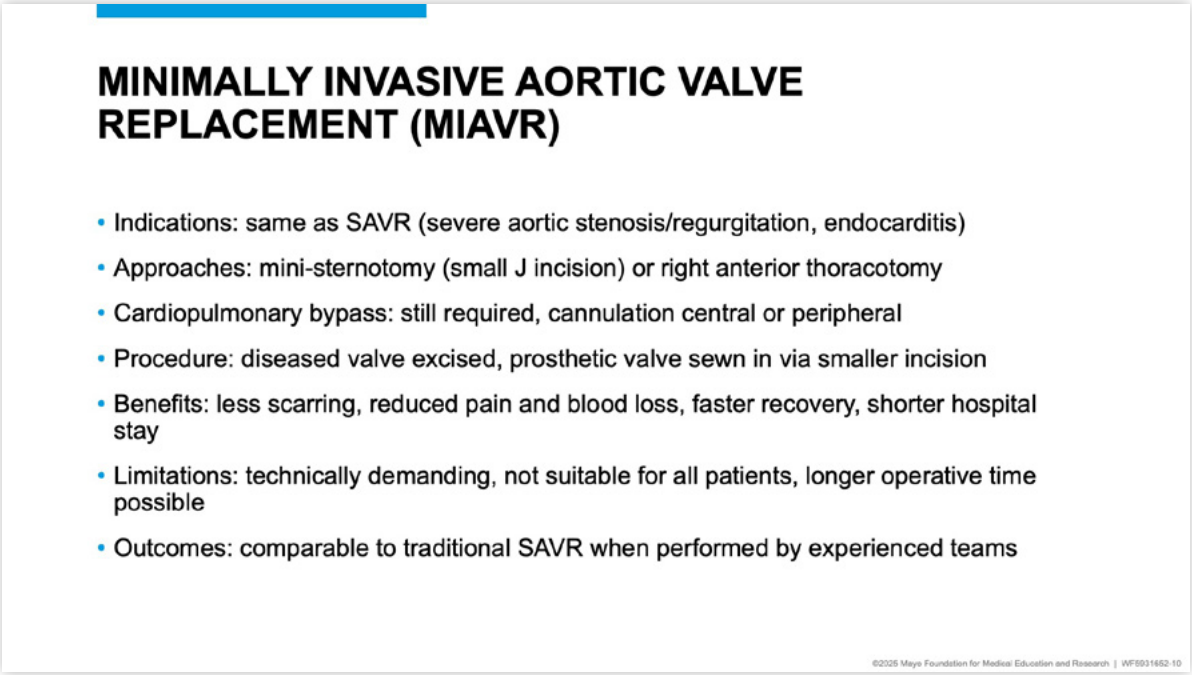
Once the valve is in, we close the aorta, and then we gradually turn down the heart lung machine. The heart is awoken and it starts doing its work and gradually takes over. We then turn off the heart lung machine, disconnect the heart lung machine from the heart, and basically your surgery is done. We close the chest - mostly with the sternal wires and sometimes with additional titanium plates. This patient will go to the ICU and recover usually overnight, and then be in the hospital anywhere between three to five days, and then go home and recover within first two to five weeks, and then they're back to society. Now, this surgical aortic valve replacement, traditionally and even now more so had excellent outcomes, the durable results. Mechanical valve can last decades, but it does require a blood thinner called Coumadin, which is anticoagulation. In fact, I have a friend who had surgery at age 12 with mechanical valve and he's 58, and his valve is still great and has not required any reoperation or any complications from bleeding.

SAVR vs. Transcatheter Aortic Valve Replacement (TAVR)



Dr. Yoon: These are the pictures of the aortic valves on the left side. On the top, those are mechanical valves. On the bottom, those are tissue valves. Tissue valve can be made from the pericardium or the sac around the cow's heart or the pig valve itself. Also, tissue valves can also come from human or homografts. If you look at the right side of the screen, you have on the top all of the surgical tissue valves at the bottom, you'll have a percutaneous or TAVR or tissue valves encased in nitinol cages.

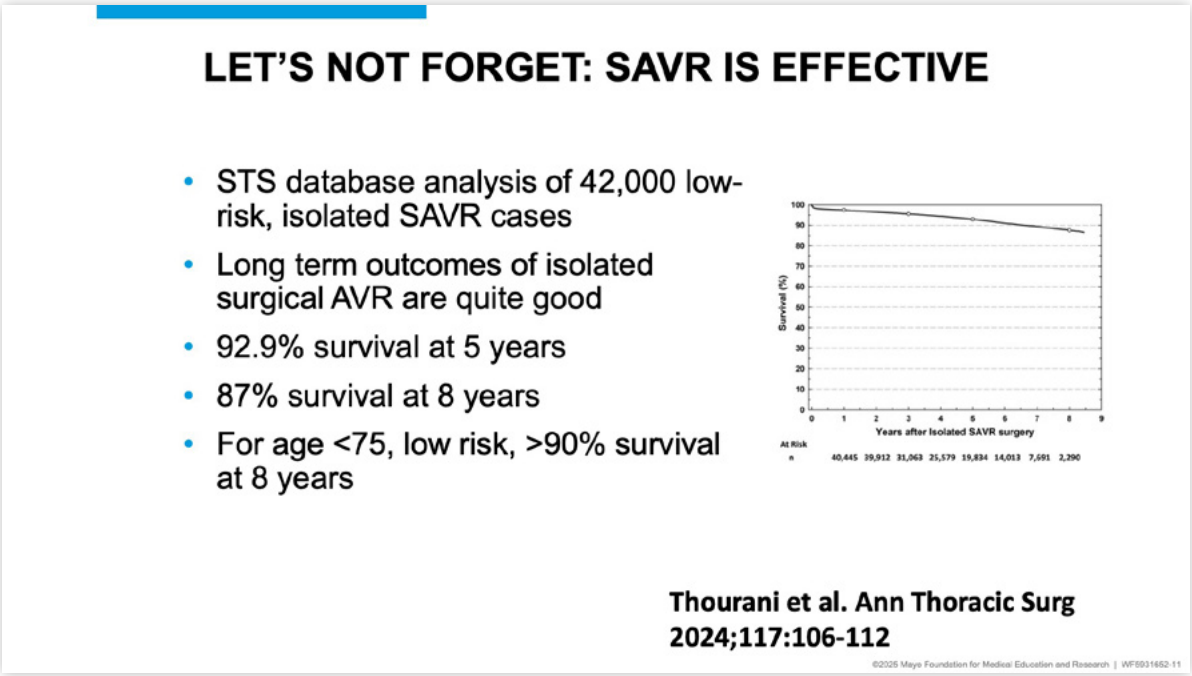
Minimally-Invasive Aortic Valve Replacement



Dr. Yoon: There's also a minimally invasive approach. Probably the correct term would be less invasive or smaller-incision approach. Indication is same as a standard aortic valve replacement. Approach can vary depending on the surgeon. It can be mini sternotomy or small, like half or one third of the sternotomy at the top. It can be small, right anterior thoracotomy approach. One of my friends actually does a full sternotomy, but through a small chest incision that's equivalent to mini sternotomy incision. There's a variety of ways you can do this. Rest of the surgery, you do it exactly same thing; use a heart lung machine, stop the heart, open the aorta, take the valve out, put the new valve in. The benefits; smaller scar; reduced pain, maybe; and blood loss, less blood loss. Yes, due to the fact that the incision is smaller; faster recovery, maybe, plus minus; shorter hospital stay, definitely since minimal invasive

surgeons are very interested in getting patient up and going and work very hard and discharging patient early. The limitation is, it can be technically demanding and it's not suitable for all patients and it can take longer operative time, and sometimes you can get into mishap. But outcomes are comparable to traditional surgical aortic valve replacement when performed by, very important term, experienced teams. It has to be something that you just decide to do one day. This is something that people have worked on for years to perfect it.

Let's Not Forget: SAVR Effectiveness



Dr. Yoon: This is a slide that I borrowed from Dr. Haney. He says, let's not forget, surgical aortic valve replacement is effective. The Society of Thoracic Surgeons (STS)database analyzed 42,000 low risk isolated surgical aortic valve replacement patients. When you look at long-term outcomes on patients who had aortic valve replacement, only 93% survival at five years, 80% survival at eight years. In fact, people that are aged, less than 75, this will include people even 73, 74, if your risk is fairly low, other comorbidities are not that high, then you have greater than 90% survival at eight years. Even surgical aortic valve replacement is an excellent outcome.

Adam Pick: Dr. Yoon, before we go on to Dr. Haney's piece, a question that I have for you is, given the effectiveness of surgical aortic valve replacement being conducted by sternotomy or minimally invasive, is there some advantage for the patients on the line where they want to pursue in terms of outcomes. Does one approach perform better over the longer term than the other?

Dr. Yoon: You mean within the surgical SAVR and you mean less invasive?

Adam Pick: Yes.

Dr. Yoon: No, the outcomes have been equivalent. Especially in the experienced hands of less invasive surgeons, the outcome of surgical valve replacement is equivalent to a standard sternotomy incision. Standard sternotomy incision is also making headways. Instead of just closing with sternal wires, they're placing titanium plates. In fact, rather than waiting for five weeks to drive, a lot of these patients are driving two weeks after surgery.

Dr. Haney: We also should remember that the minimally invasive approach, when we compare the outcomes and we say they're equivalent, we're talking about non-randomized data. These are patients who are deemed candidates for minimally invasive surgery, so not everyone should be a candidate from minimal invasive surgery. The question really is, "Can we get away with a smaller incision in this patient?" Frequently we can, but sometimes we can't, and they're both heart surgery. I think, Dr. Yoon, made a great point. It's all heart surgery on the inside, and the real question is, where do you want to take your risk? Where do you want to take your uncertainty? Is this a patient whose anatomy is suitable? So, we can take a minimal risk that we have a little less view and we can still think we deliver the same operation? Or, is this someone who needs a bigger incision?

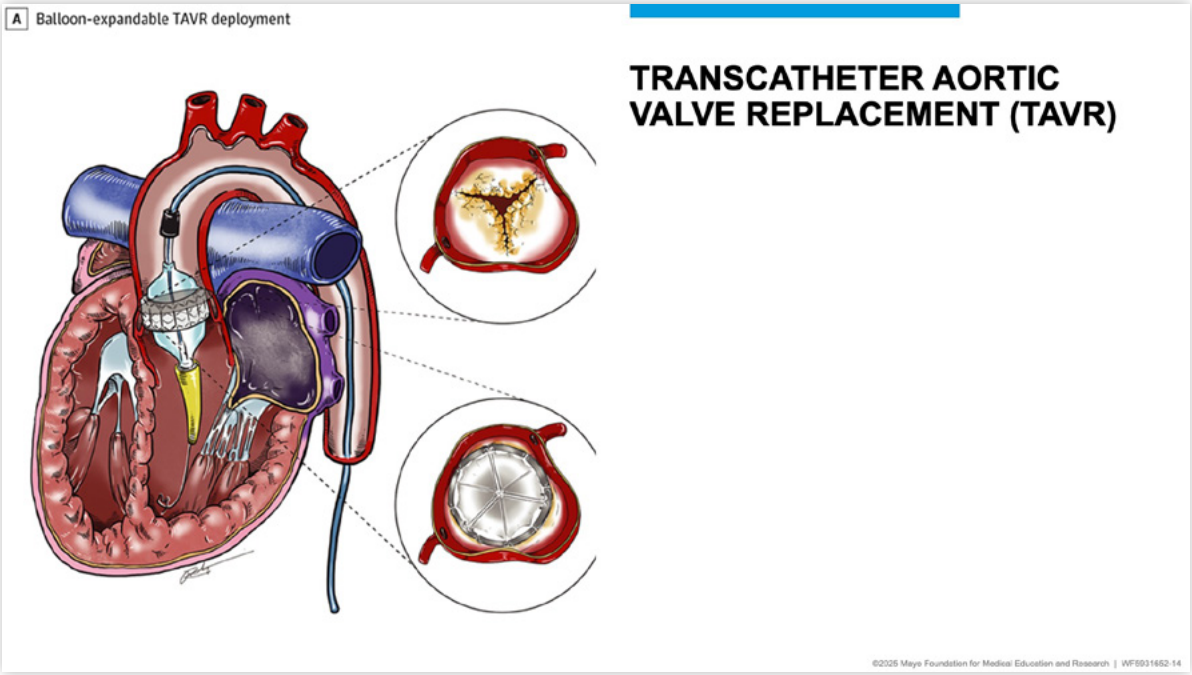
Future of Valve Interventions

Dr. Haney: So, when we're talking about minimally invasive surgery, really the, and I think Dr. Yoon put it well, the less invasive surgical incisions, whether that's a variety of thoracotomies using the robot, et cetera, that's all still heart surgery. What is truly minimally invasive and a big difference from our "on pump" aortic valve replacements is transcatheter aortic valve surgery, where we don't actually stop the heart, where we access the vessels, mostly through the groin, sometimes through even the carotids in the neck, and then we put a valve that's rolled up like an umbrella up through the native valve. We don't cut out or remove the scarred valve, but we put this thing up like an umbrella, and then we open it up and expand it usually with a balloon and pop it open, and it

presses the diseased valve leaflets to the sides, and that hardened tissue holds this stent frame in place so the valve is suspended there and holding by radial force, holding itself in place, and has little leaflets that move. That has become the minimally invasive intervention for aortic valve replacement.

One of the keys here is that it's really currently indicated not for regurgitating valves, because it requires enough thickened hardened tissue around the sides for it to stay in the aortic position. There was a time when we started doing this on very older or infirmed patients who were not candidates for surgery, and that's continued to change as we've seen that it's been successful. We used to not do it for patients who had bicuspid valves, which a number of people on this webinar probably have. We've now discovered you can do it with bicuspid valve patients, although it is slightly more complicated with slightly higher risks because of the asymmetric anatomy. The bottom line is transcatheter valves are here to stay.

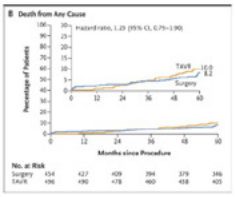
TAVR Deployment, Effectiveness & Guidelines

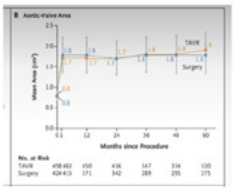


Dr. Haney: This is a demonstration of how TAVR is done. It's put across the aortic valve as we saw, and then it with a balloon expansion blasts open and pushes open the disease tissue and holds itself in place. This is an effective thing, even for low risk patients. This has been studied in a randomized fashion. Again, as transcatheter aortic valve replacement has become more and more adopted, we've continued to show both longer term durability that these valves last and they work well. Also in lower risk patients, it's still safe. This is no longer the procedure for the patient who can't get an operation.

TAVR IS EFFECTIVE- EVEN IN LOW-RISK PATIENTS

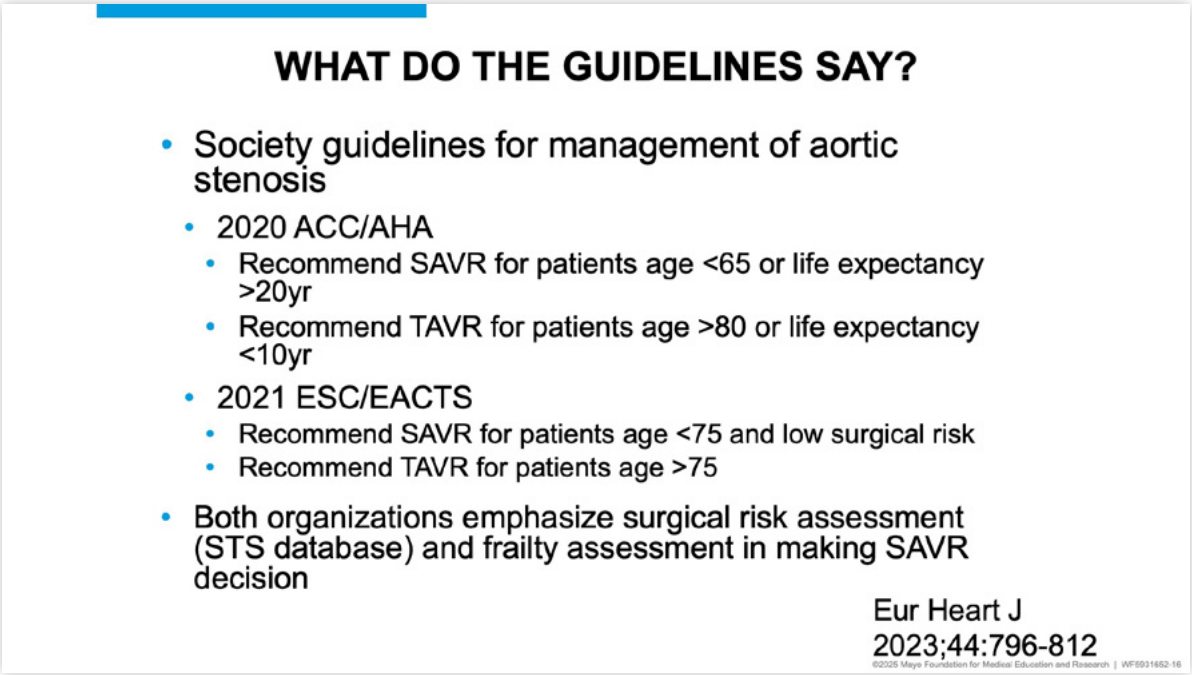
- PARTNER 3 trial shows safe short and intermediate-term results for **low-risk** patients
- TAVR durability results now hold by echo and clinical performance at 5 years
- Little doubt PARTNER 3 data will hold and TAVR will be as durable as a surgical bioprosthetic, maybe even better (certainly lower gradients)





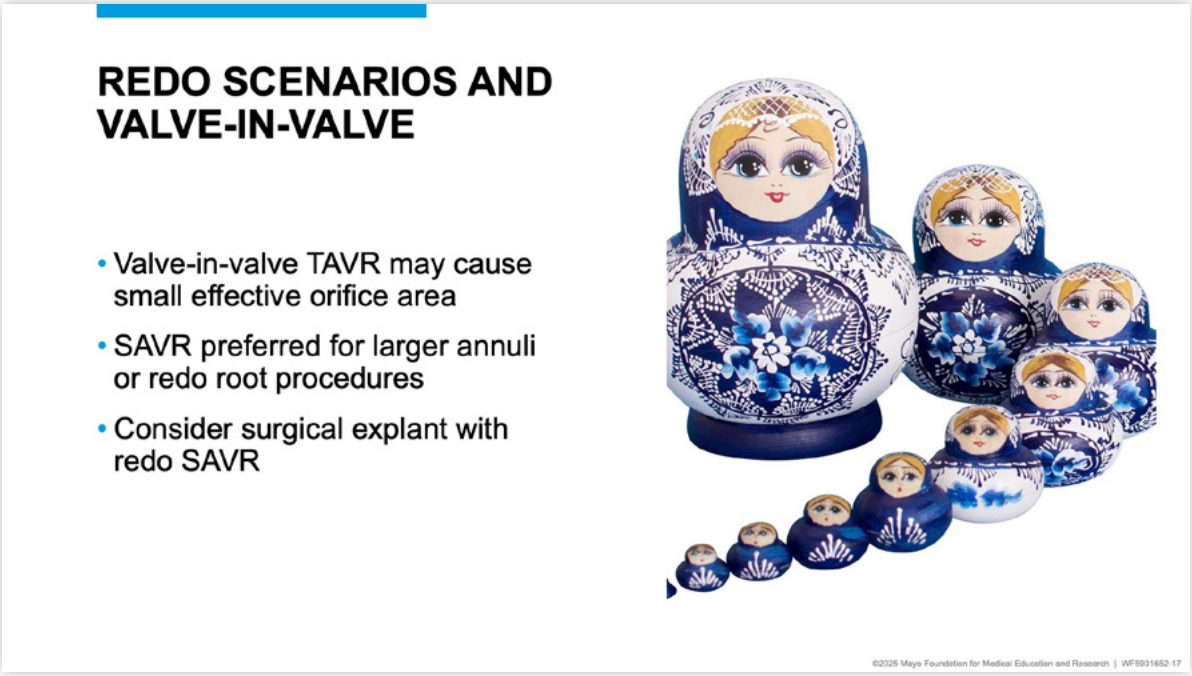
Mack et al. N Engl J Med 2023;389:1949-1960

Now, we still have guidelines written by doctors and surgeons who are making recommendations of things, and still it is notable that the recommendations are for patients who are younger, who have a longer lifespan ahead of them. In general, surgical aortic valve replacement is still recommended for younger patients, whereas TAVR is recommended for older patients.



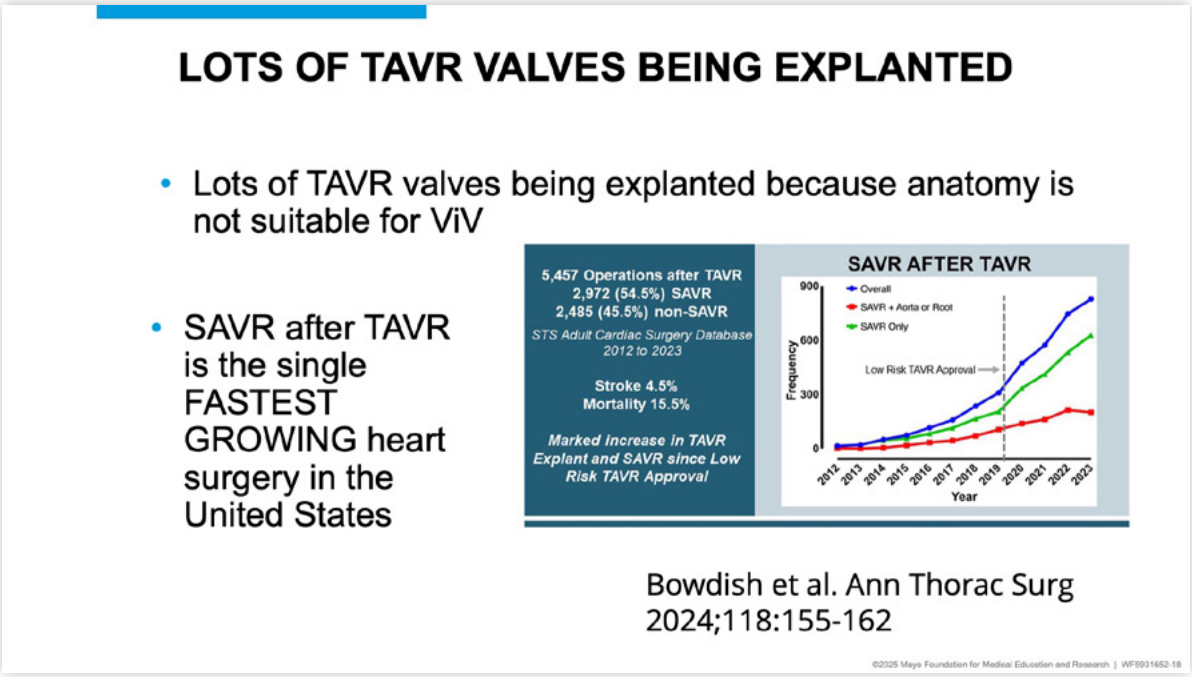
One of the reasons is that we have to think about this and there's another slide coming up describing it as a “Chess Match”. We have to think about patients through the lifetime of their valve pathology. Our goal here and often is thinking about the patient. How can we manage your aortic valve disease to the end of your natural life in as few steps as possible, with as few interventions, certainly as few surgical interventions as possible? It used to be the case then that we would do a heart surgery and think, well, this valve will wear out in 10 years and we'll have to come back and do a redo heart surgery, which as you might imagine, is more complicated.

Valve-in-Valve Transcatheter Reoperations



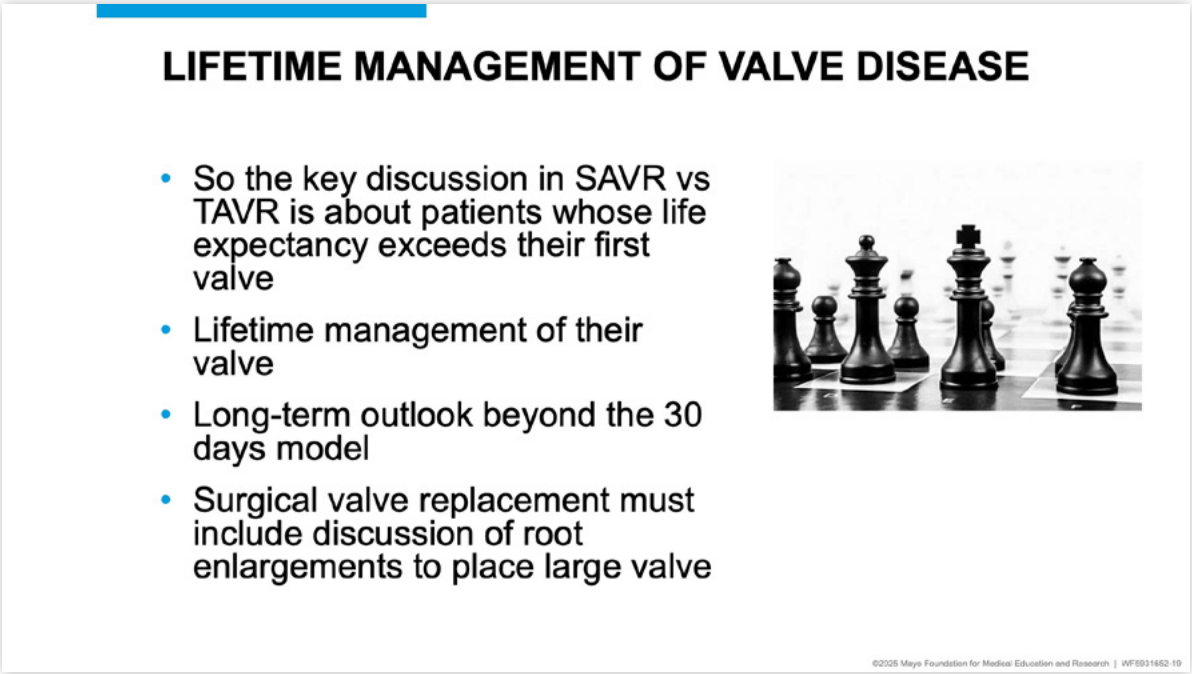
Dr. Haney: Now, we have other options. We can put valve in valves; we can put transcatheter valves inside prior biologic surgical valves; we can sometimes put them in prior TAVR valves. As we think about that math, the "Russian Nesting Doll" analogy occurs because if we start off with a certain size, everything we put on the inside of it continues to get smaller and smaller, and we need to make sure that we have big enough valve space. It becomes, again, a chess match. It is a much more complicated decision making process, I think, which is still beneficial for patients, because no longer it's just sternal saw and then sternal saw. We have lots of options, but it becomes a more complicated question.

TAVR Explants On The Rise



Dr. Haney: TAVR valves do have problems and just like surgical valves, they sometimes can get infected, they can have leaks, and there's plenty of transcatheter valves that come out and we become more accustomed to removing them. As we do them more frequently and with younger patients, there are patients then that we have to go and operate on after a transcatheter valve; especially as you're younger, you get a transcatheter valve, and then we get to a point where you need a new valve, and we say, you know what, unfortunately, we just can't put another transcatheter valve in this one, then we're doing operations.

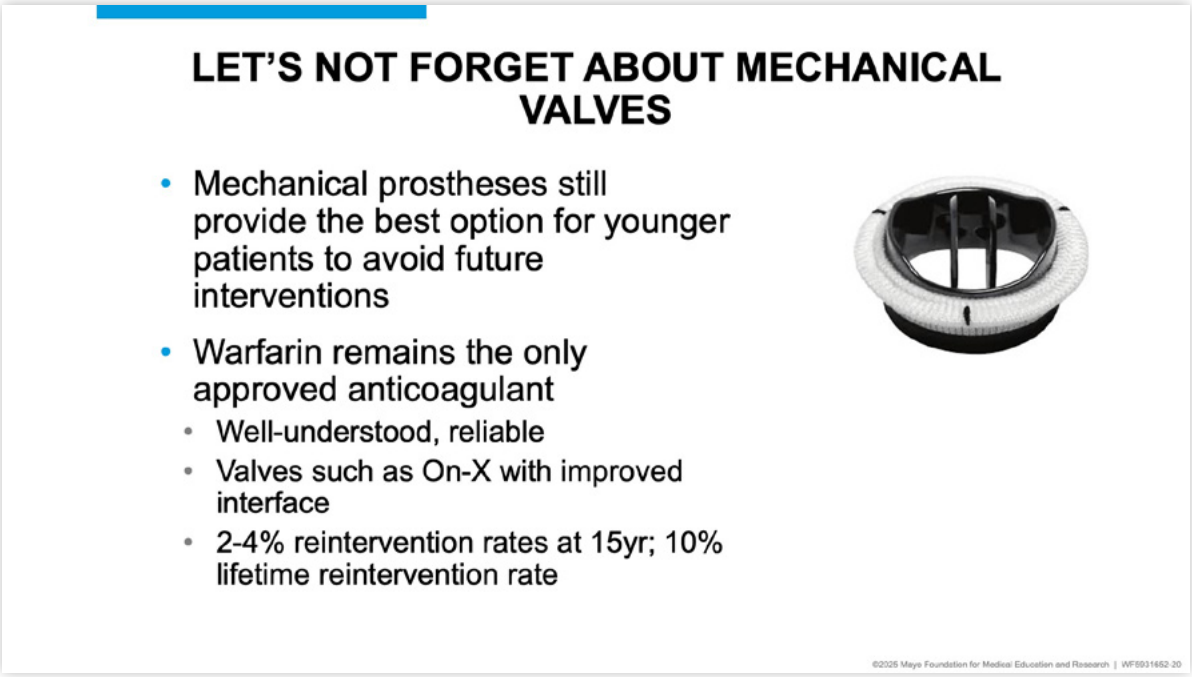
Chess Vs. Checkers for the Lifetime Management of Heart Valve Disease



Dr. Haney: In some cases, this decision making process is a sort of pay me now or pay me later experience, and that's where this point is very key. I think the biggest key here, and all of the questions we can answer specifics all day long, but the real key is you want to talk to your surgeons about this chess game. What are we going to do over the lifetime of this? What is step one now and what is step two, step three, step four? That's some of the decision making process.

This is a little bit different than we used to do to be honest with you, and frankly, the way in which we measure surgeons is not really geared towards this, because sometimes this involves doing more complicated surgeries upfront, which carry a little more risk, but we still often are judging surgeons by what happens in the moment. This requires a little bit more long-term approach.

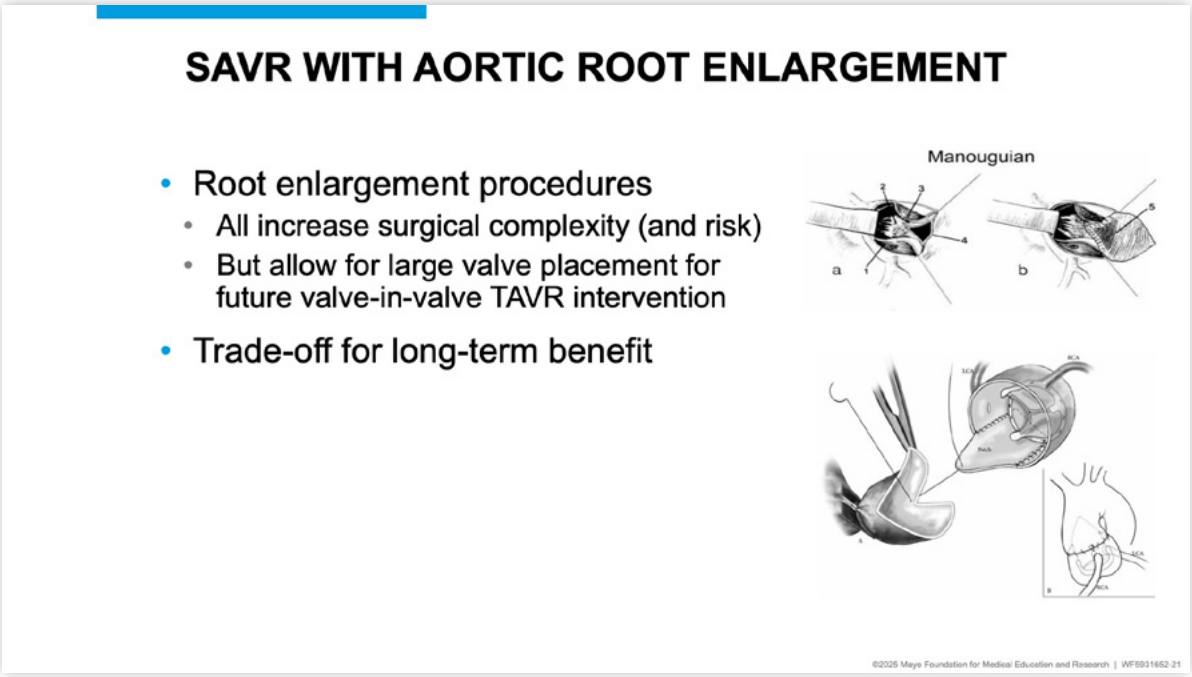
Let's Not Forget: Mechanical Valves



Dr. Haney: A little plug for mechanical heart valves; in general, mechanical heart valves are beautiful things. They work really well, and if you take care of them and take Coumadin, the lifetime re-intervention rate is very low. For patients younger than 50, mechanical heart valve still remains a very, very good option with admittedly the medical problem you have for life, which is that you have to be on a blood thinner, but a blood thinner is very compatible with normal lifestyle. If you're not an MMA fighter, you probably can be on Coumadin and live a normal, active, healthy lifestyle. Those are good options.

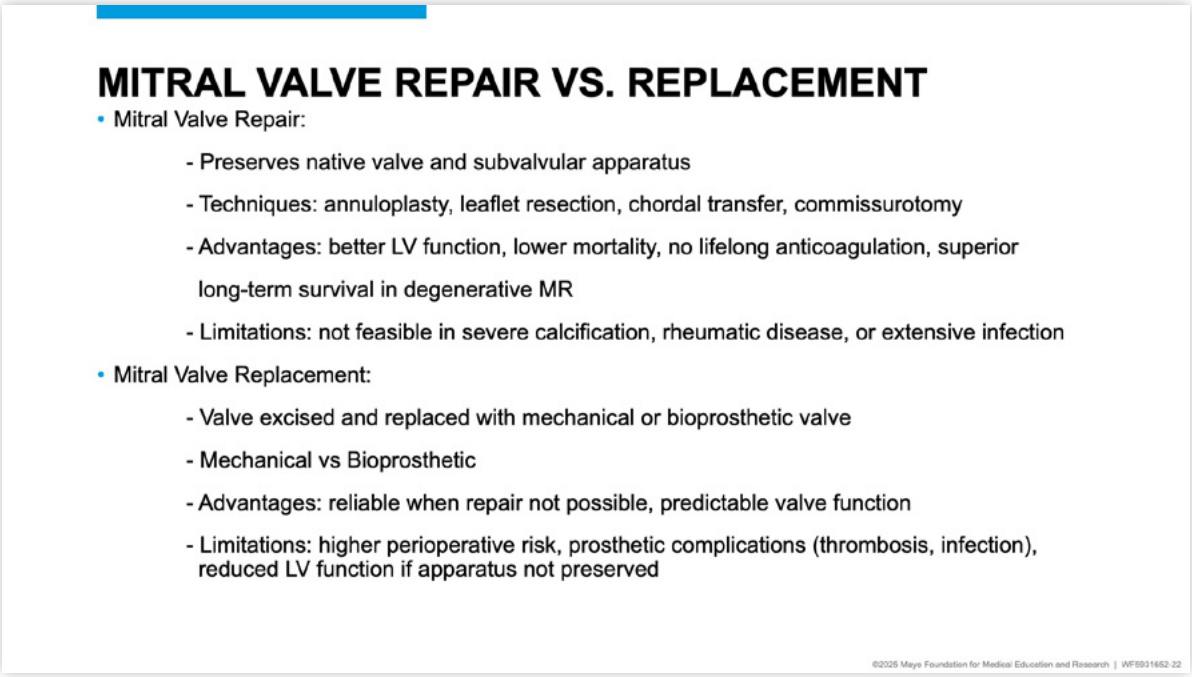
When you're thinking about the chess match and you don't want a mechanical valve, as I mentioned, we're thinking about what's the next chess move. One of the options then is if we're going to put in a surgical valve, a biologic valve that will wear out over time, we would love to set you up for getting a transcatheter valve inside of it down the road, and sometimes even two, again, the Russian nesting dolls. That means that the bigger valve we can get in you, the better. Now, the valve we can get in is determined by what your anatomy is.

Aortic Root Enlargement Techniques



Dr. Haney: The annulus is like a certain size, so sometimes it requires these kind of approaches where we open up the tissue where we have to do more complicated things like sewing patches in to expand the place so we can put bigger valves in to set you up for further success. That requires, again, more complicated surgery upfront that should be discussed with the surgeon, whether they're comfortable doing root enlargement procedures. I think that's a critical thing if you're going to do surgical valves in 20, 25, 26.

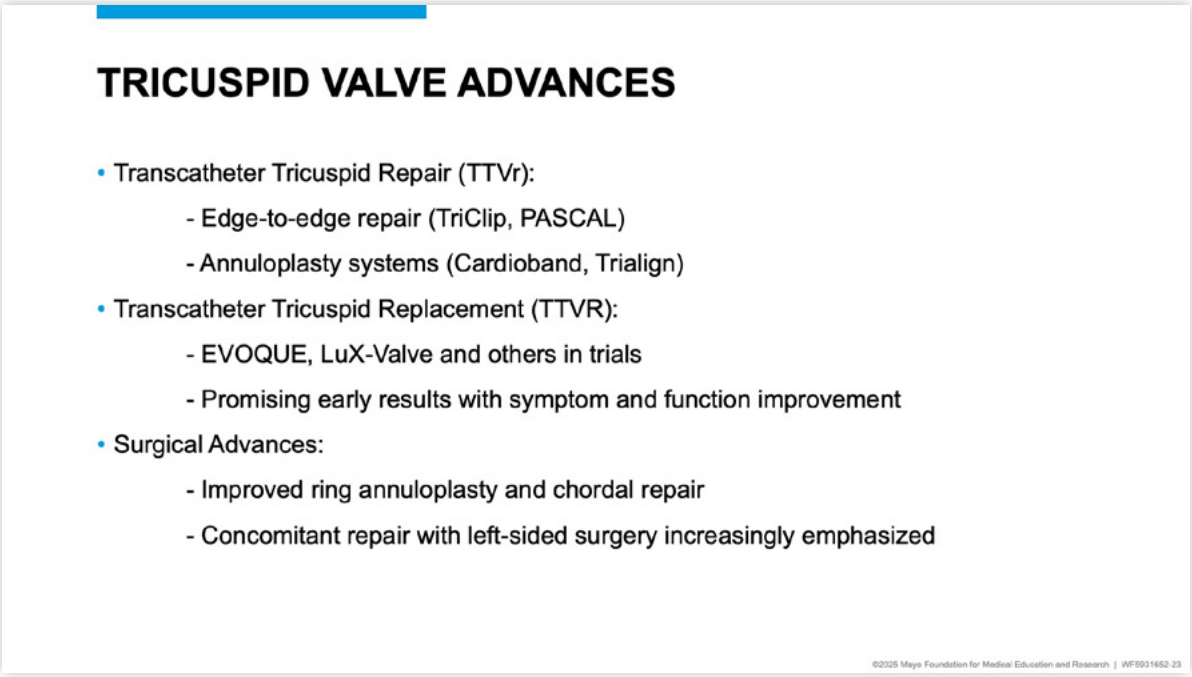
Mitral Valve Repair and Replacement



Dr. Yoon: Okay, and I'll take over at this point. Now we are done with the aortic valve issues. Now we are at the mitral valve. There are mitral valve repair and there's a replacement. Preferably, if possible, everyone should get mitral valve repair because it is a better operation. It preserves native valve and all the sub-valvular structures that are in contact between the valve and the heart muscle. The different techniques, you can fix it with a ring angioplasty or you can work with your mitral valve leaflets. You can also work with fixing the chords, and you can also do a commissurotomy, which is opening the commissures. The advantage is that these patients will have a better RV function than traditional mitral valve replacement, lower death, no need for lifelong anticoagulation, and superior long-term survival in degenerative mitral regurgitation.

The limitation is, it's not feasible in severe calcification or rheumatic disease or extensive infection. The other option is mitral valve replacement. In this case, it used to be a lot of the valves were excised. Nowadays much less valve structures are excised; and in fact, some valve replacement is done without excision of any leaflets, and you replace with either mechanical or bioprosthetic valve. Advantage is, it's very reliable when repair is not possible because you can predict the valve functions. Limitations; higher perioperative risk, prosthetic complications such as thrombosis or infection can happen and reduced LV function if you cut out too much valve structures. If you can preserve both leaflets and chords, you could have equivalent heart function as mitral valve repair, but between mitral valve repair and replacement, repair is preferred.

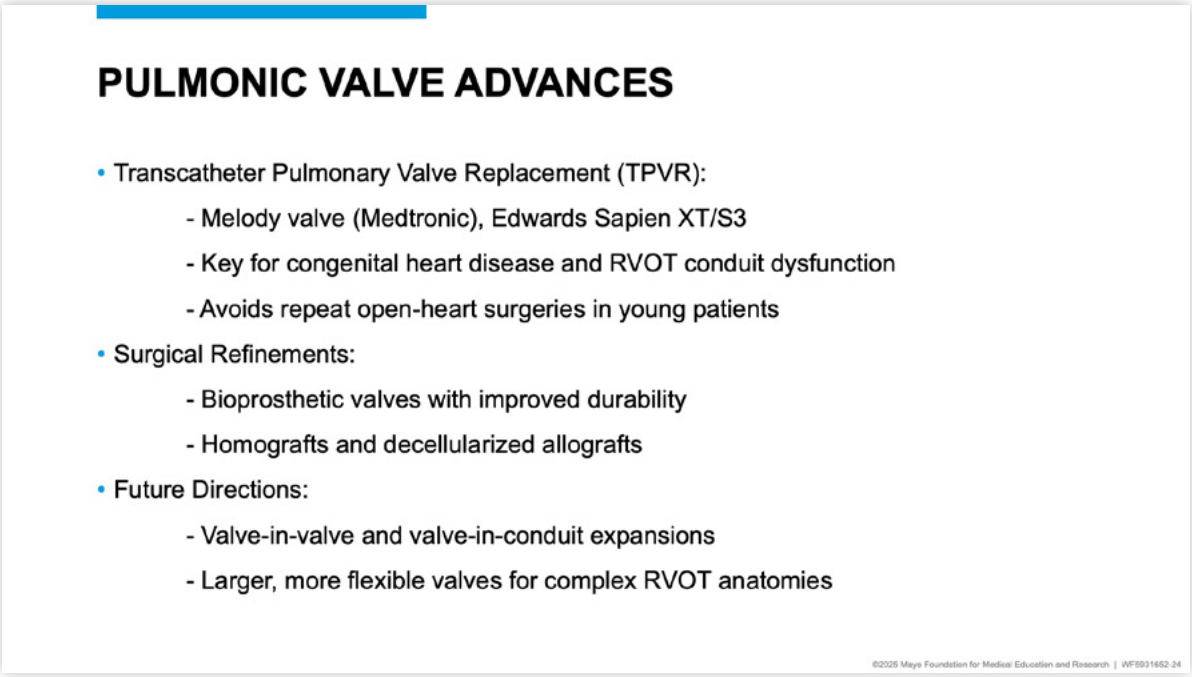
Tricuspid Valve Advances



Dr. Yoon: Tricuspid valve; earlier I said this is kind of the "forgotten valve". The issue was when we operated these patients, the mortality traditionally was high, but we have made some advances over the last 15 years and when you look at the newer data, the mortality is improving and it is to the point where it's very reasonable to perform surgery on tricuspid. Because for long, it was kind of forgotten valve, I think the cardiologist became very interested in managing this valve and a lot of percutaneous technology has developed, such as transcatheter tricuspid valve repair, edge-to-edge repair, annuloplasty system. We also have transcatheter tricuspid valve replacement, such as EVOQUE and other valves. In surgery itself, we are having improved ring annuloplasty and

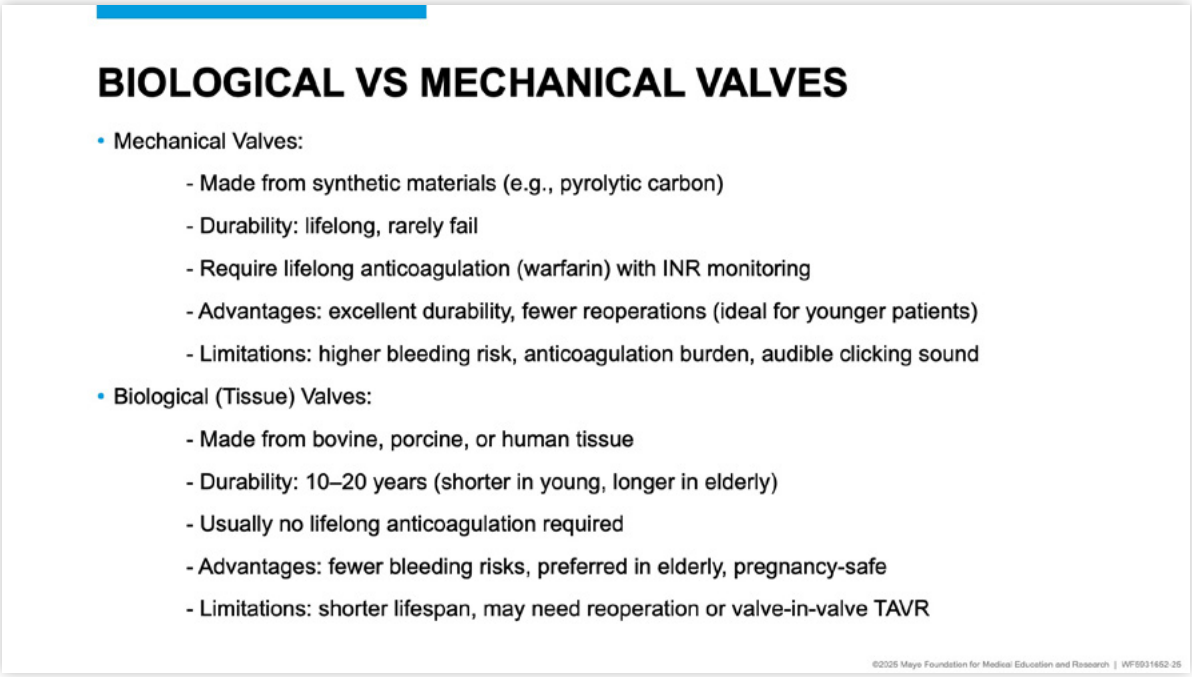
chordal repairs, and we're also not only addressing tricuspid by itself but when we're doing left-sided valves such as mitral valve repair, we frequently repair the tricuspid valve at the same time, whereas in the past, we frequently left it alone. The reason is tricuspid valve by itself is not lethal. It really can have heart failure symptoms, but it was not lethal. Frequently it was left alone, but now we're much more aggressive about taking care of that.

Pulmonic Valve Advances



Dr. Yoon: Pulmonic valve; pulmonic valves always belong to congenital landscape. Hence there were a lot of percutaneous transcatheter pulmonic valve replacement that's been already occurring in the past, especially in the congenital area. With the exponential growth of TAVR, there's a lot of future direction in valve-in-valve and valved conduit expansions. There are more technologies that are learned from other valves being applied to pulmonic valves for future advances.

Biological Vs. Mechanical Heart Valve Replacements

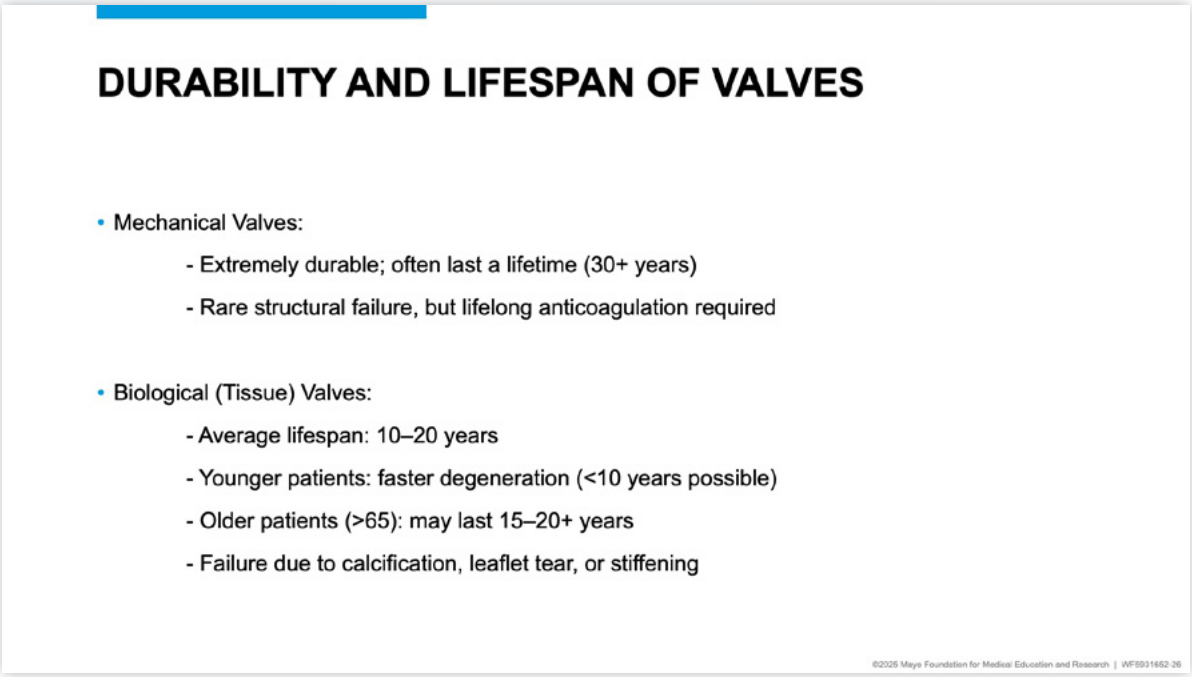


Dr. Yoon: We talked about biologic and mechanical valves a lot. What are the differences? Mechanical valve is made from synthetic material or pyrolytic carbon, and durability is lifelong and rarely fail. However, it requires lifelong anticoagulation, warfarin, and you have to have lifelong INR monitoring. Advantages are it's excellent durability, few reoperations, it's ideal for young patients. Limitations, you do have a bleeding risk, 1% bleeding risk per year, and also there is a burden with anticoagulation. Sometimes you cannot do extreme sports. You may not be able to do black hills when you ski. Also for young people, particularly, sometimes noise, the audible clicking can be really bothersome.

The tissue valve or biological, whether it is a porcine or bovine, they are obtained from animal tissues, including human tissues, the homo grafts. Durability, 10 to 20 years, but there's a caveat to this which we'll go into a

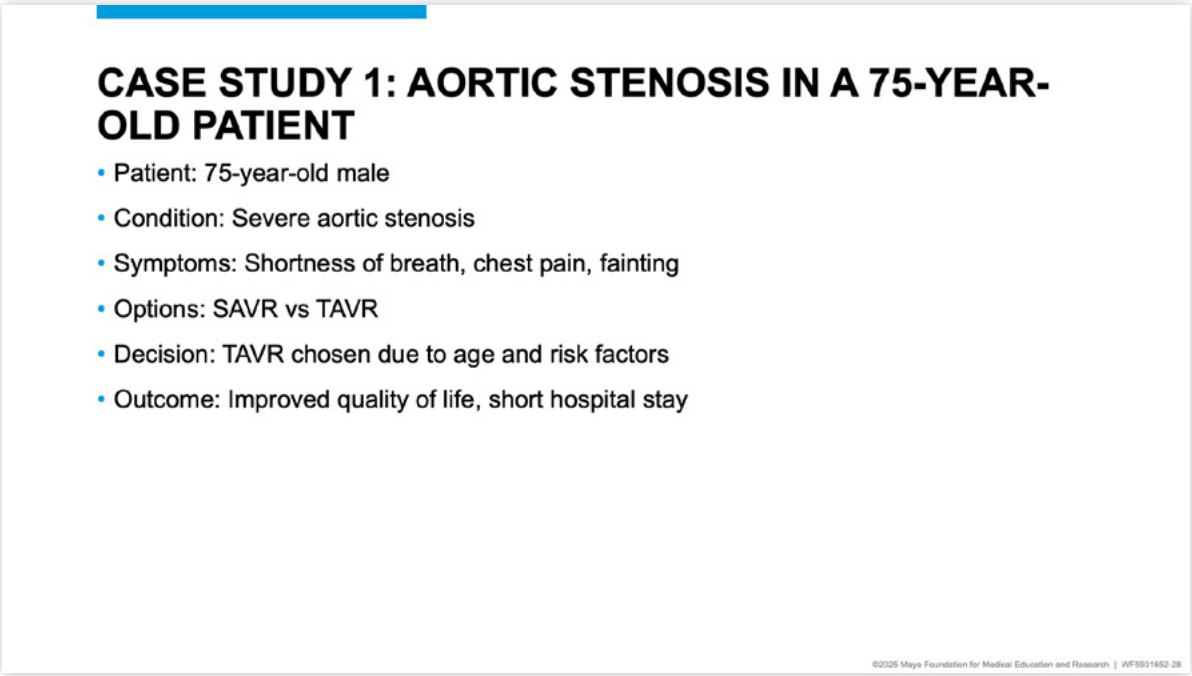
little later. Usually no lifelong anticoagulation required. Advantages are fewer bleeding risk preferred in elderly patients, and also, if you are thinking about having babies and you want to stay off warfarin, this is valve that you can have during childbearing ages, and then eventually have a reoperation with a mechanical valve. The limitations are shorter lifespan, and you may need a reoperation or valve-in-valve, especially in aortic valve arena.

As we mentioned earlier, mechanical valve is extremely durable by lifelong anticoagulation required. Now bioprosthetic, we say 10 to 20 years in younger patients, much faster degeneration. I've seen people degenerate tissue valve within four years in people that are in their early 50s. Older patients aged greater than 65, it may last 15 to 20 years. Occasionally you would see a 65-year-old patient, after 10 years they would fail, but it's certainly not four to five years. Failure is due to usually scarring classification. Sometimes you can have structural problem, such as leaflet, tear, or stiffening.



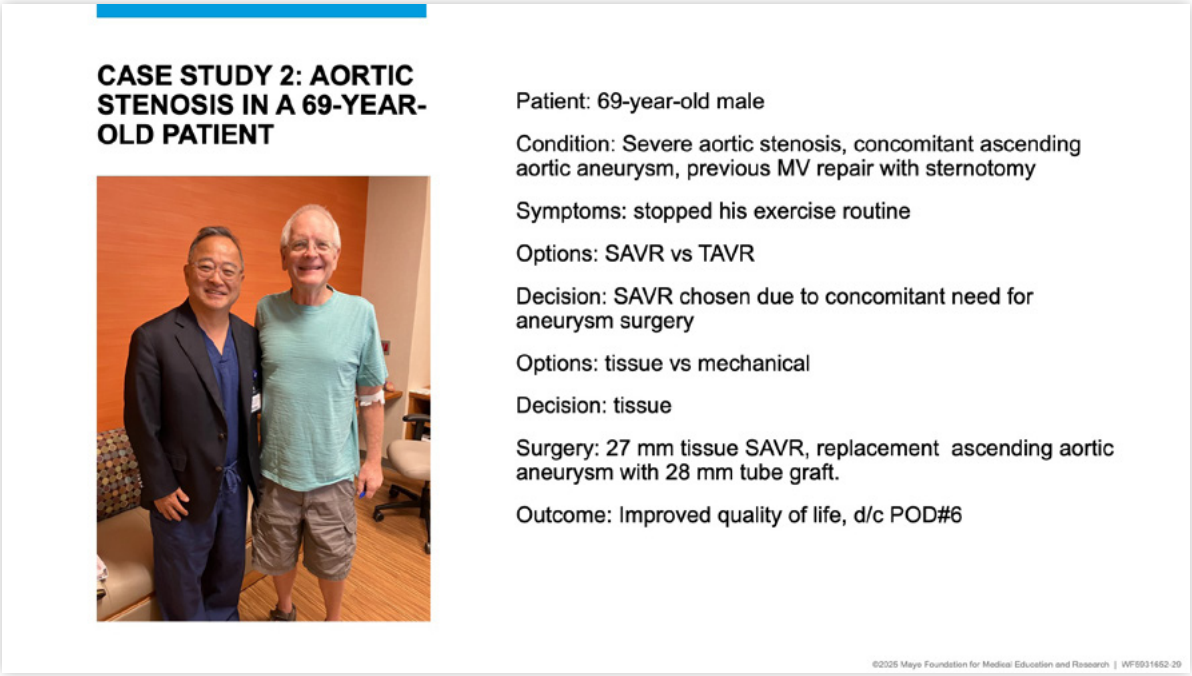
Between different types of valve, the durability is a little bit different. The right-sided valves, such as tricuspid and pulmonic, they typically last longer because it's less lower pressure system. How about transcatheter valves because these are new kid on the block? Well, so far, five to 10 year outcomes are excellent durability, comparable to surgical bioprosthesis; maybe not five to 10 years, but up to eight years. The data shows it's pretty reasonable. Greater than 10 to 15 years, we're beginning to collect the data. Also there is a valve-in-valve possibility for degeneration of these valves.

Patient Case Study #1 (Symptomatic Aortic Valve Disease)



Dr. Yoon: This is case one, aortic stenosis in 75-year-old patient, male, with severe aortic stenosis. Symptoms were shortness of breath, chest pain and fainting. The options, surgical aortic valve replacement or TAVR. Decision, TAVR; it was due to the age and also he had concomitant risk factors that made him higher risk. This is very a reasonable approach. Short hospital stay, got the procedure done, went up next day and improved quality of life.

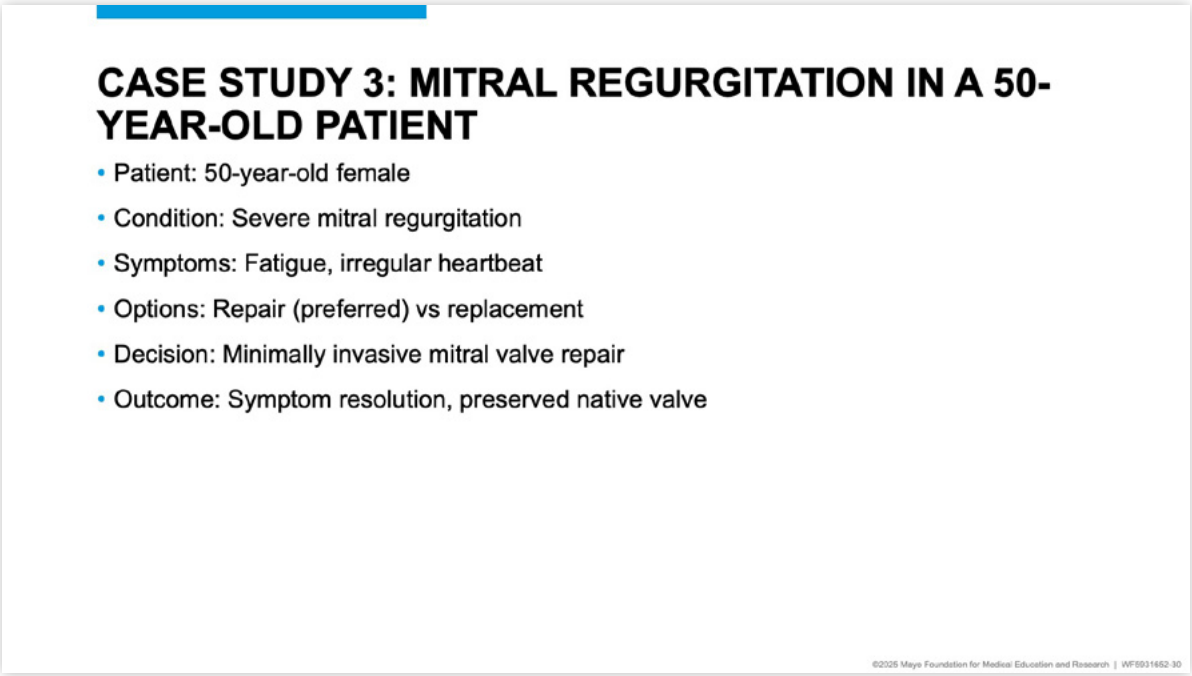
Patient Case Study #2 (Concomitant Heart Valve Disease and Aortic Aneurysm)



Dr. Yoon: Now this is a personal patient of mine, a 69-year-old man, a severe aortic stenosis. He also has AS and aortic aneurysm. He had about 10 years ago, mitral valve repair with regular sternotomy and his mitral valve was still working excellent. His symptoms; when at rest he did not have any symptoms, but he stopped exercising because with exercise it was tough for him. It became symptomatic. Options were surgical aortic valve replacement versus TAVR. Decision was we would do a surgical aortic valve replacement because he needed concomitant aneurysm surgery. Frequently, some patients might

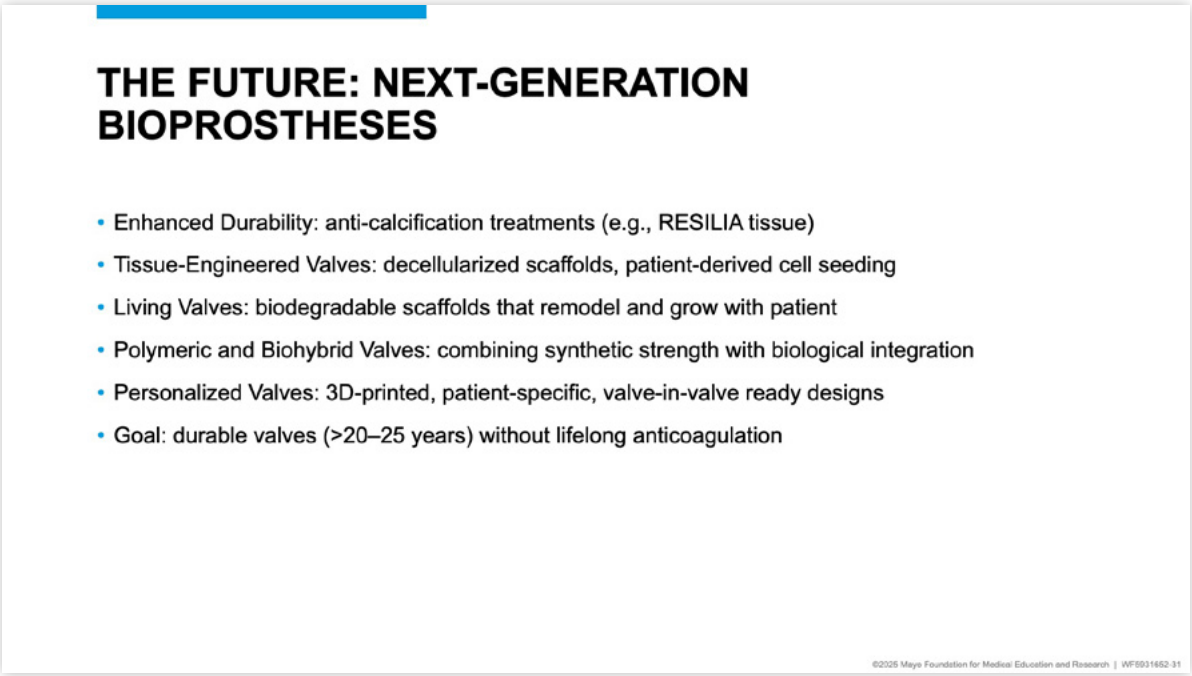
have a concomitant coronary artery disease, so other things that needs to be managed. If you have concomitant disease, the surgical aortic valve replacement is favorite. Decision between tissue and mechanical, he chose tissue, he's 69 years old, and this fits perfectly into guidelines. We did a tissue valve. We put a 27 millimeter tissue valve and took out his aneurysm and replaced it with 28 millimeter tube graft. He was discharged on post out day six, improved quality of life. He's here. This is two weeks after surgery, he's visiting my office.

Patient Case Study #3 (Symptomatic Mitral Valve Disease)



Dr. Yoon: As tissue versus mechanical, recently, in a similar time, I had a 72-year-old gentleman. He needed aortic valve replacement, but his father lived beyond age 95, and he was pretty sure that he wanted mechanical valve and he did not want TAVR. He wanted it open, so we gave him a mechanical valve. Again, this also emphasizes the personal choices, but you do have to have a discussion and have informed consent. This is study three, mitral regurgitation of 50 old female patient, severe mitral regurgitation; symptoms of fatigue, irregular heartbeat; option, replacement, repair is preferred; and decision was she wanted minimally invasive mitral valve repair, a very reasonable approach. She did very well, preserved the native valve successful repair and patient symptom free.

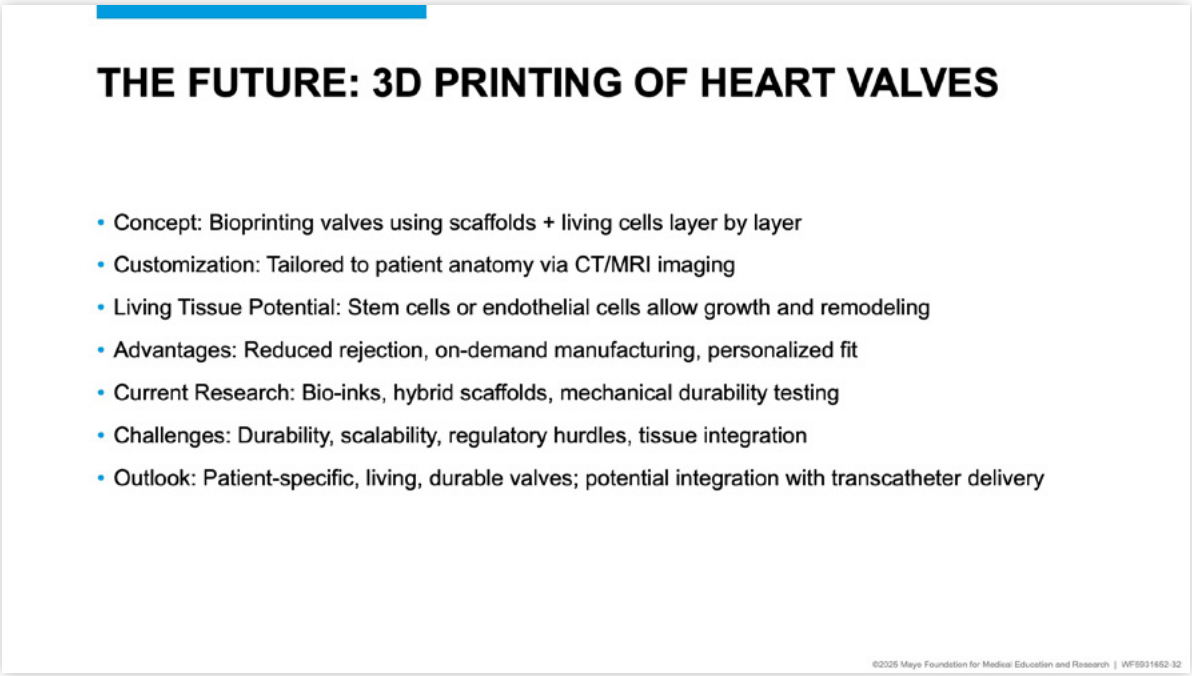
Next-Generation Bioprosthetic Valves



Dr. Yoon: Those were the valves, and there's a current state. What's next? What's in the future? The industry people as well as scientists have been working very hard to improve the tissue valve durability. I think we've made some headways, but there's a lot of work ahead. Recently, with the Edwards Lifesciences company, they created anti-classification treatment, such as RESILIA tissue, and that so far seems to be doing fairly well. Again, the long-term data is still pending. There's a lot of tissue engineered valve studies going on. What they're doing is they bring a decellularized scaffolds. They basically decellularize animal tissue, and then you see them with patient derived cells. This is where the stem cell comes in. This can create living valves. They can be biodegradable

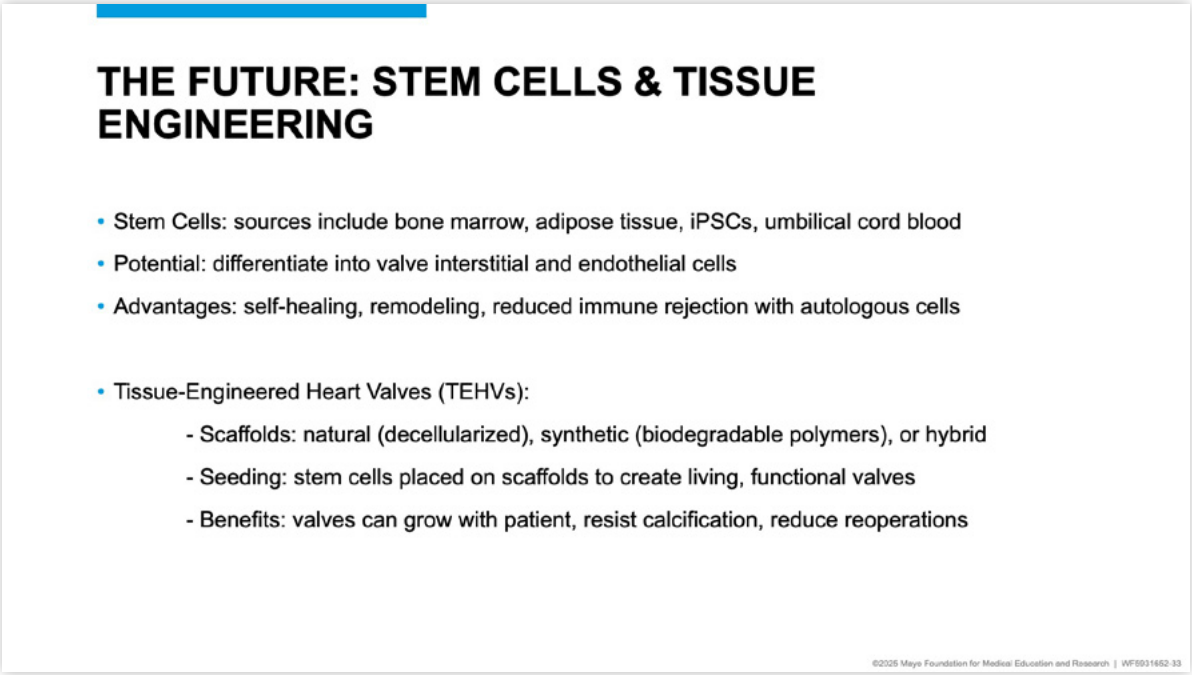
scaffolds. They can remodel and grow with patient. This will be pertinent in pediatric population. Then there's investigations going on in polymeric and bio-hybrid valves, combining synthetic strength with biological integration. This all seems like a science fiction, but based on looking at the advances made in the last 50 years, it's not impossible. You can have personalized valves, 3D printers. You can be patient specific and you can also create valve-in-valve ready designs. Goal is creating durable valves greater than 20 to 25 years without a lifelong anticoagulation.

3D Printed Heart Valves



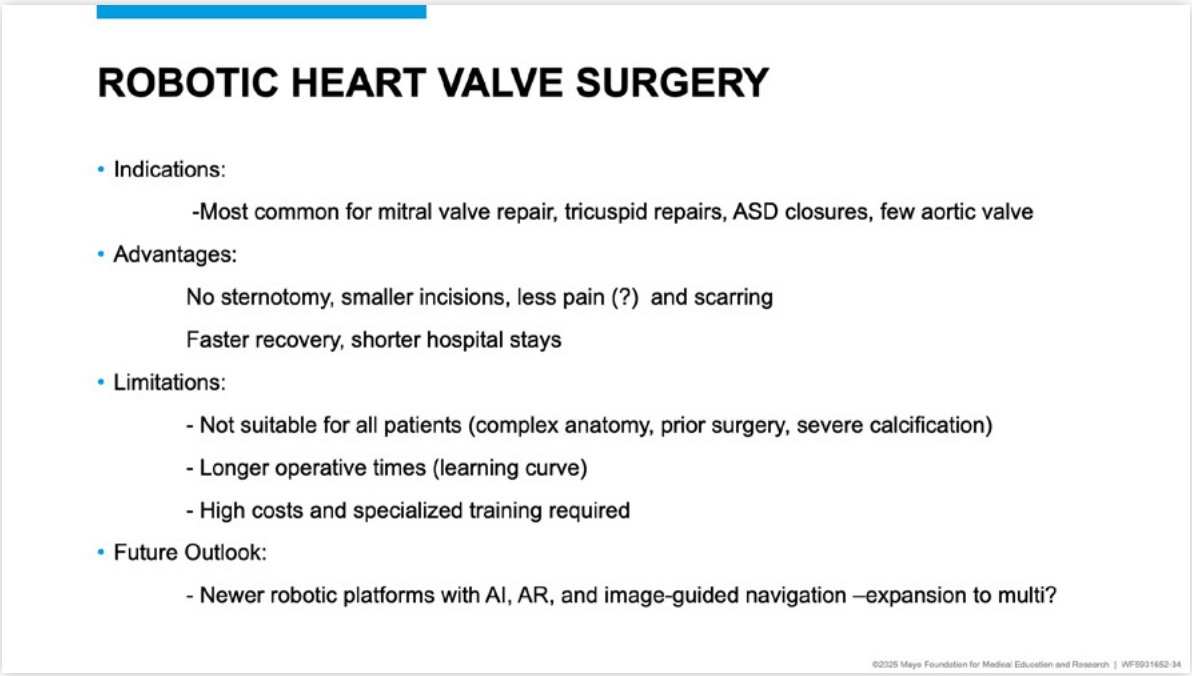
3D printing concept is very interesting. You can do a bioprinting valves using scaffolds and adding living cells layer by layer. If you do that, you can customize it, you can tailor it to patient's anatomy by looking at pre-op CT and MRI imaging, and then you have a living tissue potential by placing stem cells or endothelial cells, which will allow growth and remodeling. Advantages would be reduced rejection, and you can create this on demand, and you can have personalized fit. Current research going on, biolinks, hybrid scaffolds, mechanical durability testing, all of those are already available. Challenges are durability, scalability, regulatory hurdles, and tissue integration. I mean, I think the future is definitely there, but there is a lot of work ahead of us.

Stem Cells



Dr. Yoon: Stem cells and tissue engineering; again with stem cells, as you know, it comes from bone marrow adipose tissue, IPSCs, those are the adult cells that's induced to become pluripotent and then umbilical cord blood. The potential is they can differentiate into valve interstitial and endothelial cells. Advantages would be self-healing, remodeling, reduced immune rejection with autologous cells. With these you can create tissue engineered heart valves, scaffolds, and seeding. Benefits can be valves can grow with patient, resist classification, reduce reoperation. If this can come true, it would be wonderful, and this can also translate into percutaneous delivery system.

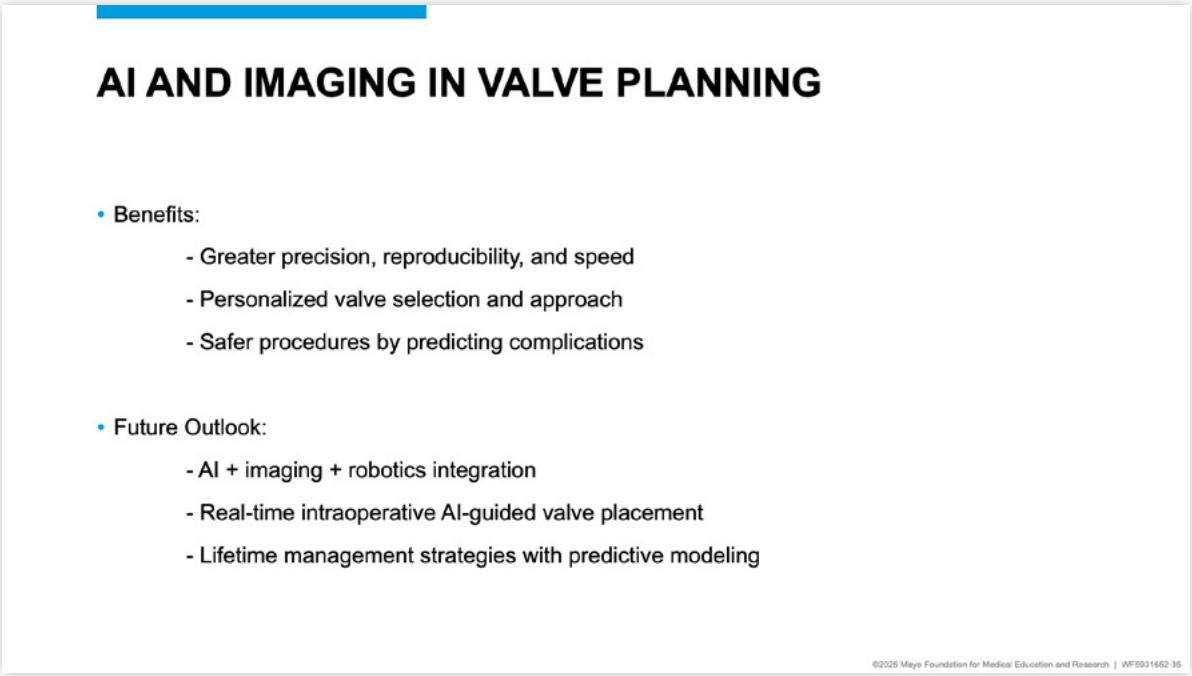
Robotic Heart Valve Surgery



Dr. Yoon: Finally, the robotic heart valve surgery; this is actually combination of a current state plus future because it's already going on. The indication most commonly performed in mitral valve repair, some tricuspid valve repair, ASD closures and few aortic valves. Actually, it's also going on in coronary artery bypass surgery as well in certain centers. Advantages are no sternotomy, a smaller incision; this is actually smaller incision than usually the minimally invasive traditional heart surgery; less pain, and smaller scars, faster recovery, short hospital stays. Limitations; not suitable for all patients. If you have a complex anatomy, you have prior surgery, if you have severe classification,

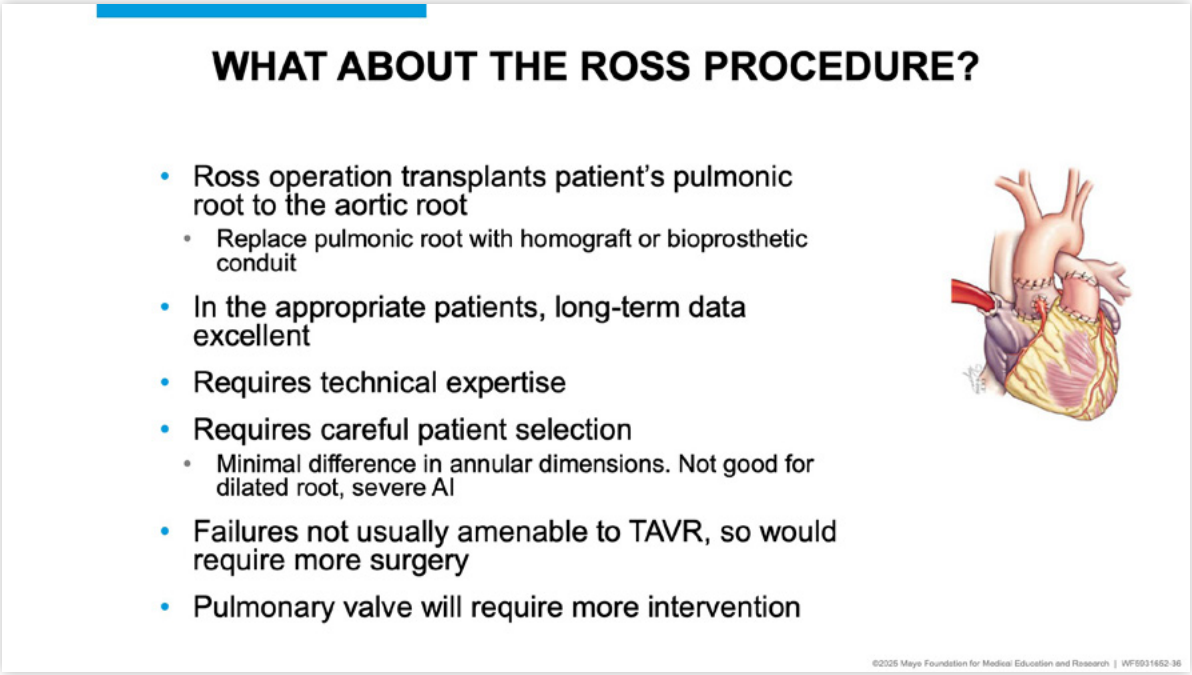
you're not going to be a candidate. It definitely does longer operative times. There's a significant learning curve, but some of the robotic surgeons have become very, very fast out. High cost and specialized training is required. Future outlook; there's a lot of new robotic platforms coming out, and it used to be just one company. Now there are multiple companies, so I'm sure that robots are going to get better. They're also combining with artificial intelligence, and that's going to make things even better. It's going to be image guided navigation. It can expand into taking care of multiple valves and very complex operations.

Artificial Intelligence Imaging for Valve Planning



Dr. Yoon: You can't give a talk without talking about AI, especially at Mayo Clinic. AI is really a hot topic today and it's also true in medicine, especially combined with imaging. You can do a lot of things in valve surgeries, especially in planning operations or planning different procedures. Benefits; greater precision, reproducibility and speed, personalized valve selection and approach, and safer procedures by predicting complications. Future outlook; combined AI and imaging and robotic integration, and it can go anywhere. It can also give us real time interruptive artificial intelligence guided valve placements. Also, it can help us in making decisions in lifetime management strategies with predictive modeling. I think that, that will be something that's very close in future. With this, I'm going to turn over to Dr. Haney.

The Ross Procedure

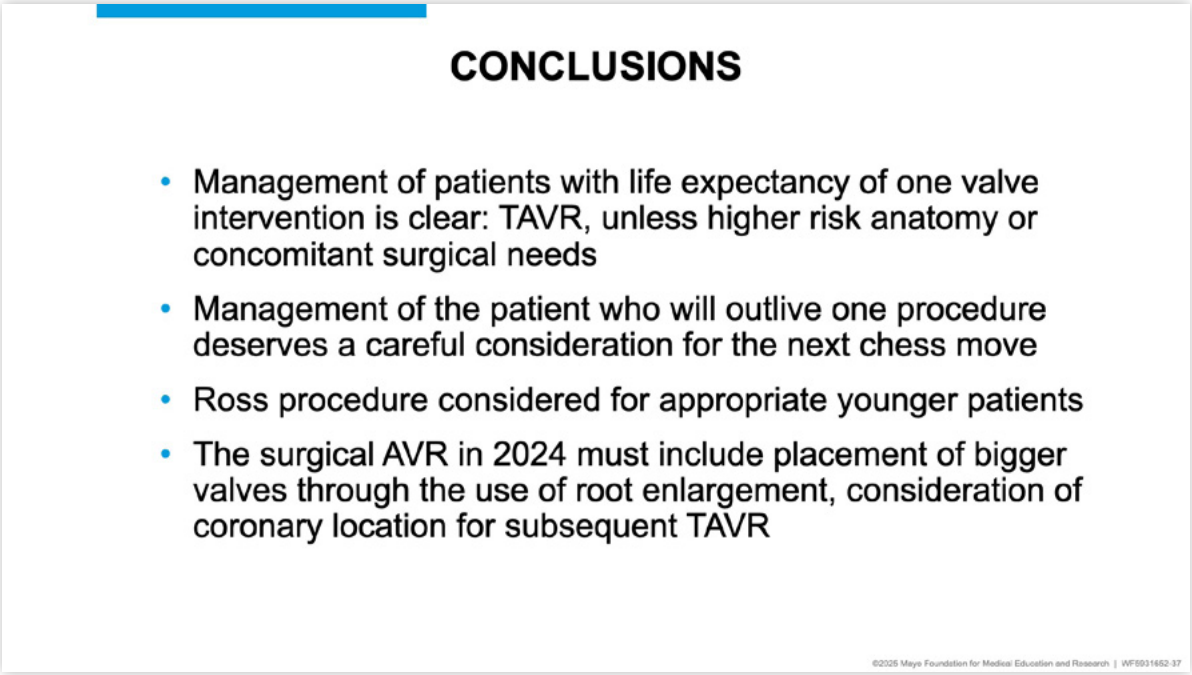


Dr. Haney: Sure, so the other operation that people will frequently talk about for aortic valve pathology and specifically as an alternative to mechanical valve or repeat biologic valves is something called the Ross procedure, and this is named after the surgeon who pioneered it. Basically, the Ross involves using your body's own pulmonic valve, so the valve that we see on the screen that goes from the right side of the heart to the lungs, and cutting that out and moving it over into the aortic position and reattaching the coronary arteries, and then replacing the pulmonic valve with an artificial valve. Now, the nice thing about a Ross procedure is that it avoids blood thinner; it uses your own valve.

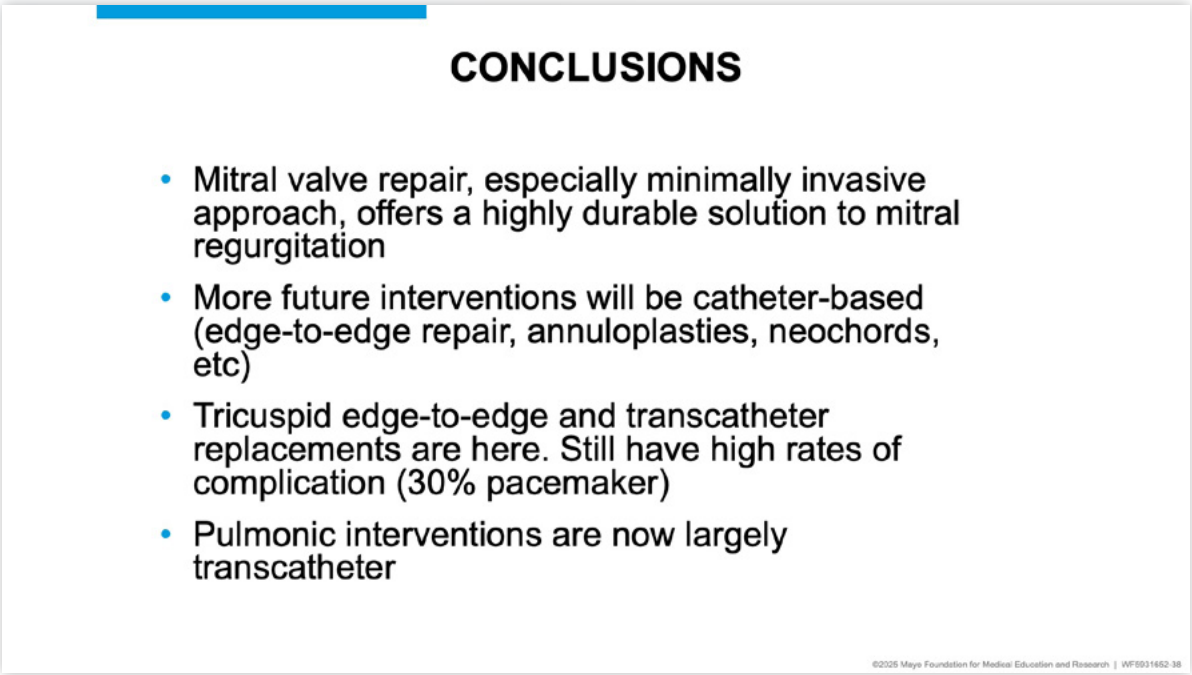
This was designed as a valve operation for children who are growing, who we don't want to put valves in of one size because they're going to get bigger and grow. This is a valve where you use your own and you will grow with the valve. It has been used now for adults. It's not perfect. It's not applicable to every single person. It depends on the size of the annulus. We can't take a small pulmonic valve and put it in a very big dilated aortic position, et cetera, things like that. There's some technical aspects. It's a more complicated surgery, and with more complicated surgery, all of them there's a little more risk of early failure because you're doing more complicated things. When you have early failure, it's not as easy to do things like put in a transcatheter valve because again, that tissue isn't rigid and strong.

The bottom line is, if you are a relatively young person who someone is recommending a mechanical valve to and you don't want to take Coumadin, one option to explore is this procedure, the Ross procedure, as an alternative to a bioprosthetic heart valve. A Ross procedure, similar to what Dr. Yoon was saying, with minimally invasive surgery is a technically complex and more challenging surgery that should be done by people with a lot of training and expertise in this procedure. A Ross is not something I would go to any surgeon for. Classically, it's again, done by congenital surgeons, pediatric surgeons, who then also take care of adults, but it is an option if you're determined to get a biologic valve and do not want coumadin. It can be a good option, again, in the appropriate patient.

Conclusions

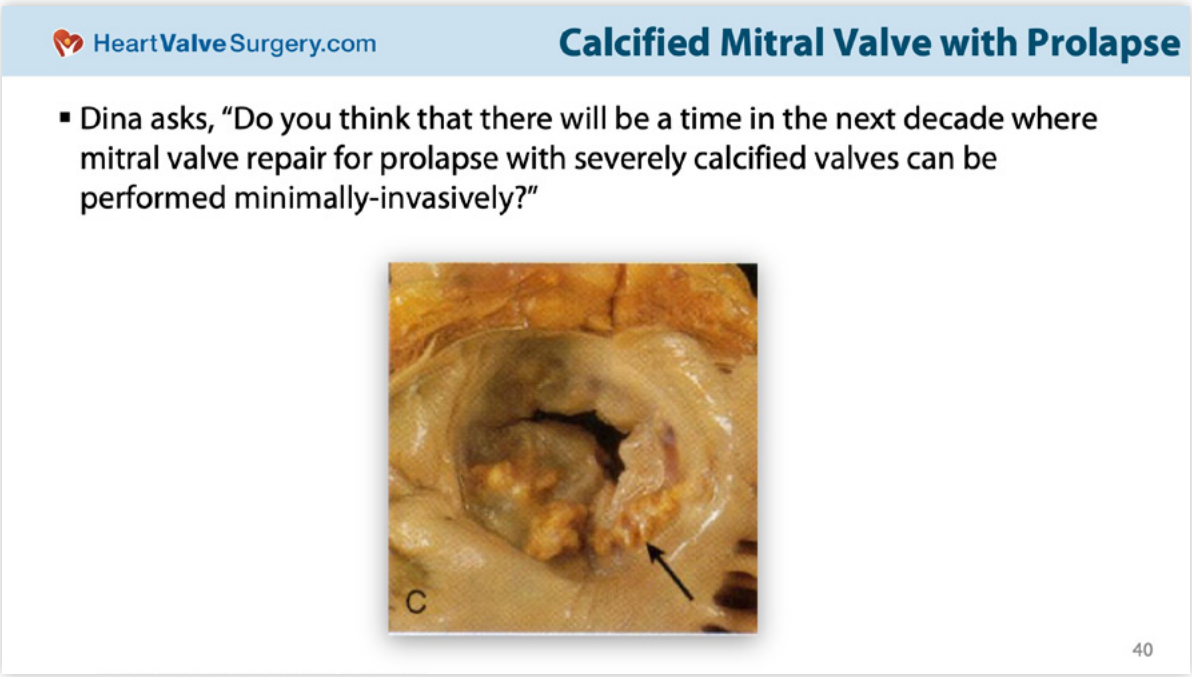


Dr. Haney: The bottom line is that there's lots of options and I've tried to go and answer a bunch of questions on the Q&A already but we're happy to take questions. The bottom line is listen at what we're talking about, whether it's a mitral valve, whether it's aortic valve, more and more things are coming down the pipe that are going to be transcatheter. There's a lot of complicated thought process that goes into it, but the bottom line is, when you're talking about heart valve interventions, you want to think of it as chess, not checkers. This involves asking questions of your surgeon, asking questions of the surgeon of when is the right time to intervene and what intervention are we going to do, and what is the next intervention that we're going to do. I think that's really where I think having a thoughtful conversation with your providers is important.



Again, more and more of our operations or transcatheter things, we have good surgeries. Remember, surgical aortic valve replacement, whether you do it through a sternotomy or a small incision, is a good operation. Mitral valve repair is an excellent operation. Lots and lots of mitral valves can be fixed, and we're going to continue to have more and more catheter based interventions, whether it's on the mitral valve, whether it's on the tricuspid valve, whether it's in the pulmonic valve. The bottom line is the things that Dr. Yoon and I learned in training when we were residents are classically – one of my mentors said, don't train to do the things that your mentors do because it will inevitably change about the time you're in practice, and that's certainly been the case and we're going to continue to see changes in the technology, changes in the interventions that are offered to you all. What really I think fundamentally it requires is thoughtful conversations with surgeons, with doctors and providers to figure out what's right for you, the patient.

Questions and Answers:



Adam Pick: I cannot thank you enough for these important remarks about the present and future of heart valve surgery. In the time that we have left, we're going to shift over to a "Rapid Fire Q&A". I would encourage everybody to keep asking their questions, but let's get right to it. The first question comes in from Dina, and she asks, do you think there will be a time in the next decade where mitral valve repair for prolapse with severely calcified valves can be performed minimally invasively?

Dr. Yoon: I can try to answer this one. I think when she said minimally invasive must be through making open surgery, minimal less invasive surgery. It's actually already being done, but if patient has severely calcified valves, it's not the approach is really calcified valves that do have much less success rate in repairing it. Now in certain countries that are being done, such as in Thailand, or there's a surgeon in Thailand who does this because he really can't afford to put mechanical valve in this young patients. What he does, he pretty much decalcifies these valves, shaves all the calcium off and does it. He's done an excellent job. It's amazing what he does, but we do not have long-term data on those. In the past, doing a valve repair in severely calcified valves has not been a long-term success.

Adam Pick: Great, moving on to a topic that's come up several times today, which is about age, Becky asks, "Will the replacement of heart valves become more common for people in their 80s? If yes, when? I'm 83 and I have a severely leaky valve."

Dr. Haney: I think I can take this one. Certainly we are doing more and more interventions on folks who are in their 80s. That includes heart surgery, and that obviously includes transcatheter approaches. We also have a saying in heart surgery, nothing makes you look your age like heart surgery. I mean, I think as we get older, we like transcatheter interventions, because we just have tougher time bouncing back from big operations. That said, if this is an aortic valve, I'm going to answer as if it's an aortic valve, it could be a mitral valve, but if an aortic valve is leaking, the problem here remember, is that a transcatheter valves don't work well for leakage, so the patient would then need surgical intervention more likely. Yes, the bottom line is if patients are in their 80s, otherwise fairly robust, then they are certainly candidates for these kind of operations and we routinely do surgery in those situations.

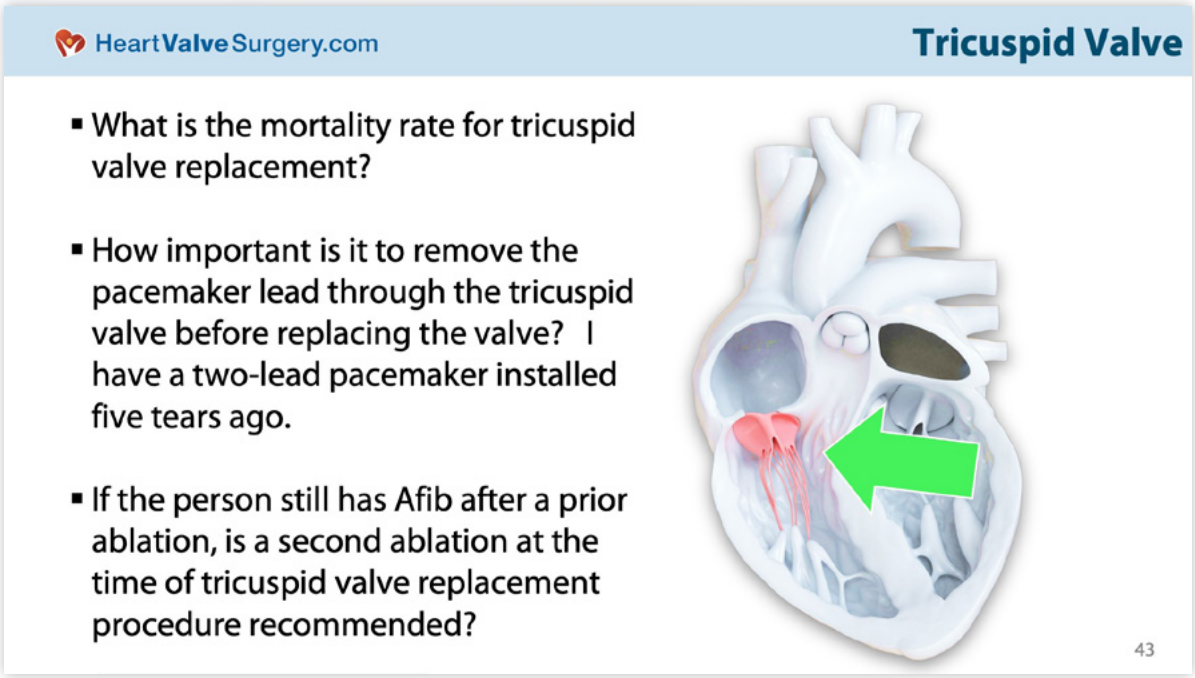
Dr. Yoon: Yeah, you know this patient population mortality is usually calculated to be less than 3% to 4%, and they do fine. Yeah.

Adam Pick: Great, and just for the people on the line, sometimes, like you alluded to Dr. Haney, we get fascinated with age is a number and maybe we can ask this question to you both, what is the oldest patient that you have operated on, if you can remember?

Dr. Yoon: I did aortic valve replacement CABG on a 95-year-old patient, and she lived to be 100.

Adam Pick: Wow!

Dr. Haney: Yeah, I've done the same operation, CABG aortic valve on someone who's, I think, yeah, it was like 94. I had one and did fine.



Adam Pick: These questions came in by several patients. The question is, "What is the mortality rate for tricuspid valve replacement? Is it better or worse than the other valves?"

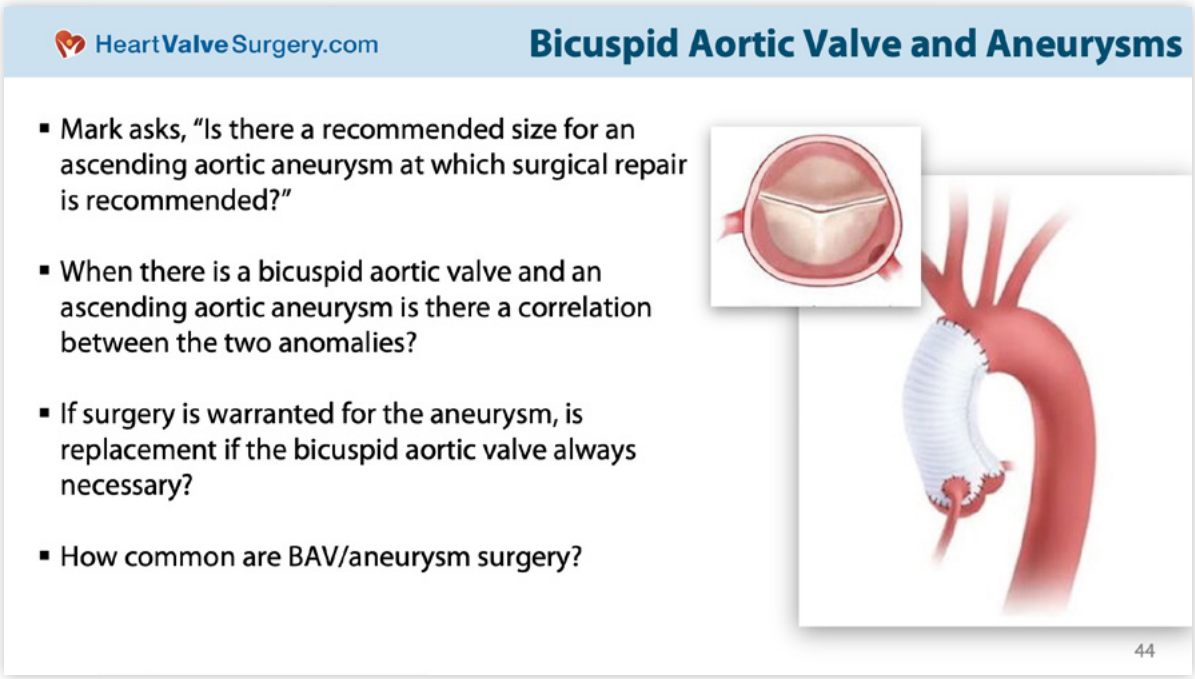
Dr. Yoon: Yeah, it is definitely worse. It's actually double digit mortality, and it's not so much because of the valve itself, because of the ideology of this valvular disease. It is problem with a lot of these patients have wide ventricular dysfunction. We have a lot of good treatment for LV dysfunction, but not so much for RV dysfunction. These patients after surgery, which is actually one of the easiest operations we can do, is that they suffer from RV dysfunction and we have to baby them through postoperatively to get them back on their feet. That's why mortality is high. Now, it used to be double digit over the last 15 years. It has improved and it has come down to single digit. I think one of

those very famous valvular surgeon, he pretty much recommends aggressive management of tricuspid valve when we are in there managing other valves. I think majority of the heart surgeons are following that recommendation. Definitely, the cardiologist interest in this valve has brought us invigorated in managing this valve.

Adam Pick: Great, and we at HeartValveSurgery.com, we know that about 24% of our patients have heart rhythm issues along with their valvular disease. Pacemakers obviously come into play. How important is it to remove the pacemaker lead through the tricuspid valve before replacing the valve?

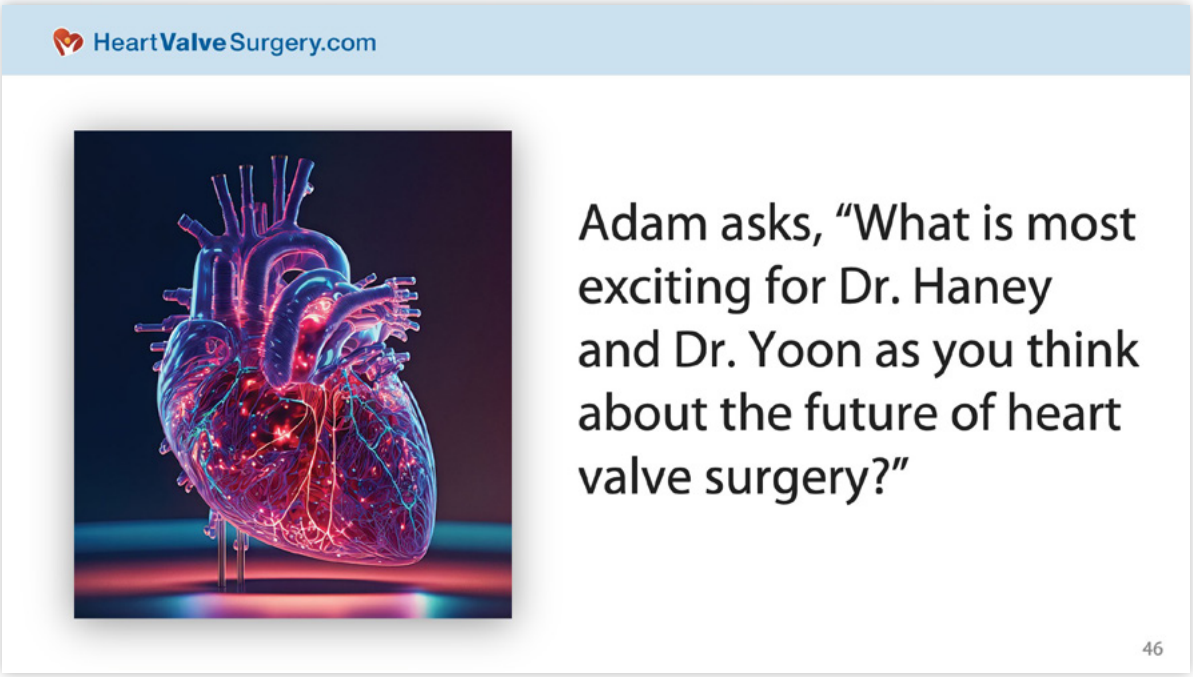
Dr. Haney: It really depends on what the long-term plan is. Again, this is a game of chest, not checkers. If you don't remove the pacemaker leads first, they will get pinned on the outside of the annulus. They can cause some problems with leakage around the valve. They can be replaced. I mean, a valve can be done and pin them in successfully, but it can cause problems seeding the valve. Of course, that requires then putting the leads through the new valve, and that can cause leaflet dysfunction as well. The pacemakers are a little bit of a tricky thing. That is one of the reasons that frequently when patients have pacemakers, and we are doing a tricuspid, we will sometimes put on epicardial leads. We will attach permanent leads to the outside of the heart; they can then run up to the generator or even now the technology is getting much, much better with leadless pacemakers, which we can implant like a little bullet inside the right ventricle and avoid the leads all together. It's a little more complicated thing.

The other question about tricuspid valve and dilated right ventricle, and that gets into a little more complicated problem which is about why the right ventricle is dilated. One of the reasons that they then said, oh, they refused the tricuspid valve is that in this case, it sounds to me as though the tricuspid valve is not working because of the right ventricular problem, and replacing the valve does not fix that. Frequently this happens when people have things like pulmonary hypertension. The tricuspid valve, we might say is the forgotten valve, but it's also the canary in the coal mine, if you will, in that it's not so much the valve as it may well be the heart and the other things going on that the tricuspid leakage is telling us that something else is wrong. That's frequently the opposite of let's say the aortic valve. In that case, I think the right heart, the one thing I'll say about the right heart then is the right heart is remarkably malleable. It will absolutely respond if we are able to fix the primary problem. If there's pulmonary hypertension that's correctable, whether it's by medicines or removing chronic blood clot or fixing a mitral valve, for example, then the right heart can absolutely remodel itself to a great degree, but sometimes fixing that valve specifically doesn't actually address the real problem.



Adam Pick: Moving back over to aneurysms and bicuspid aortic valves, we know that there's an association with them, and we know that most likely about 18% of the folks on the line today who have aortic valve issues, are going to have aneurysms. This is a conversation all about the future at times of cardiac care. Is there anything new that Dr. Yoon and Dr. Haney you can share about the treatments of aneurysms going out looking into the future?

Dr. Yoon: Yeah, if you think about the aortic aneurysmal disease as aortic or descending aortic aneurysm disease, again, this is a type of operation that had traditionally very, very high mortality and complication morbidity. A lot of the centers are creating aortic center, which is actually great for the community because what has happened is whereas cares were scattered, now in this one community, they know where to send all these aortic patients to, especially when they're in emergency situation with aortic dissection. That has driven outcomes to improve significantly in this very high complex operations. Also, I would say over the last decade, there's been a change. It used to be, if you look at traditional literature talking about aneurysm resection, when do you do it. They talked about 6.5 centimeter, but over the years, it has come down. Also, not only are you looking at just the size, is that on big six feet three guy, or is it depended on a small female. Now you have size index. Also genetic is becoming a huge topic on this because right now at the Mayo Clinic, we do very aggressive genetic testing and they can help us identify if you actually are genetically predisposed, and those patients sizing criteria is totally different. I think having aortic centers, not just surgical but medical and surgical combined heart team for the aortic disease is a great advance for our society.



Adam Pick: I love, Dr. Yoon, how you talk about it's not just about the next great innovation, but it's about a multidisciplinary team coming together to look at the outcomes and enhance the process to get better outcomes in the future. That's brilliant. I've got a question for you. It's all about you individually. When you look out into the future of valve therapy, Dr. Haney and Dr. Yoon, what is most exciting to you?

Dr. Yoon: For me, it may be far off, but you go to a meeting and the scientists show you this cell that they created. They pretty much like decellularized the heart, and you see this kind of a cellophane thing. It's almost like watching the movie cocoon, the aliens, the shiny and glistening and transparent, and then seeding these with stem cells and then creating a heart, like personal heart organ. I mean, to me that's like I hope it happens in my lifetime, but I mean, the way the science is advancing, especially with how the computer is helping us advance our knowledge, it may not be far off. I've had a lot of residents doing research with the Carnegie Mellon University in Pittsburgh together, and it was amazing what those guys were doing. I'm very excited about engineers helping us with our tools.

Adam Pick: How about you, Dr. Haney?

Dr. Haney: I think the things that excite me the most, I mean, listen, there's a lot of cool transcatheter technology. We talked about aortic aneurysm. In not too far a distant future, we're going to do most of these ascending aneurysms, meaning the first part of the aorta coming out of the heart, we're going to repair those with sleeves from inside the blood vessel, just like we do in the belly. I think it's very exciting, as I mentioned, the things that Dr. Yoon and I learned when we were training are not the things that we necessarily do every day, and it's not the things we're going to do in 10 years. I think what excites me personally is I think the breadth of all of these options and that concept of having a patient-centric discussion and a therapeutic relationship with the patient, and considering each of these options for the individual patient, and having that chest match. A lot of this stuff is not stuff I'm going to personally do. The concept of you can't teach an old dog new tricks; I'm not that old but I'm beyond learning some of this stuff, and the newer generation of surgeons are going to do things that I could never do. I think there will be though continued roles for surgeons and physicians to be thoughtful with the patient and help understand them and pick what's right for them, and then provide continued care to manage their disease for their entire lifetime. That's what excites me personally.

Adam Pick: Wow! Thank you both for sharing your own personal insights and excitement about valve therapy for all the patients on the line. On that note, I want to go ahead and thank Dr. Haney and thank Dr. Yoon for being with us today. I would also like to go ahead and thank all the members of our community. It's so fun to get together and learn from the experts about what we can do both today in the present and what we hope is going to be happening in the future.

Patient Resources

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

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

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