

# ADVANCES IN HEART VALVE REPLACEMENTS



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## Introduction



**Adam Pick:** Hi, everybody. My name is Adam Pick, and I'd like to welcome you to the webinar, Advances in Heart Valve Replacements. If I have yet to meet you, I'm the patient who started [HeartValveSurgery.com](http://HeartValveSurgery.com) almost 15 years ago in 2006. The mission of our website is very, very simple. We want to educate and empower patients with heart valve disease. This webinar, which has had registrations - from over 500 patients across the world - was designed to support that mission.

During the webinar, you're going to be in "listen-only" mode. I'd encourage you to submit your questions in the control panel that is on the top-right part of your screen. We will do our best to answer those questions during the "Q&A session" of the webinar. Lastly, as we conclude the webinar, I'm going to ask you to complete a five-question survey.


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Agenda


- Introductions
- Heart Valve Disease
- Heart Valve Replacements
- Questions & Answers
- Patient Survey

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Let's look at the agenda for today. I'm going to introduce the featured speakers. We're going to talk about heart valve disease and then we're going to dive deep into heart valve replacements. We're going to conclude with a Q&A session and then have a quick survey.

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**Dr. Arman Arghami**




- Cardiac Surgeon at Mayo Clinic Minnesota
- Specialties include:
  - Heart valve repair
  - Heart valve replacement
  - Atrial fibrillation
  - Coronary artery disease
- Minimally-invasive and robotic heart valve procedures

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For the featured speakers of this event, I am humbled that they are taking time away from their very busy practices at the Mayo Clinic to help educate our community.


I'd like to start by welcoming [Dr. Arman Arghami](#) to the webinar. He is a cardiac surgeon at Mayo Clinic in Minnesota. His specialties include heart valve repair, heart valve replacement, atrial fibrillation, and coronary artery disease.

Dr. Arghami has a very unique focus in minimally invasive and robot-assisted techniques that we're going to learn about today.

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**Dr. Mackram Eleid**

- Interventional Cardiologist at Mayo Clinic Minnesota
- Specialties include:
  - Heart disease
  - Heart valve disease
  - Coronary artery disease
- Transcatheter aortic valve replacement (TAVR)
- Transcatheter mitral valve replacement (TMVR)



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Another great member of the Mayo Clinic heart team on the webinar today is [Dr. Mackram Eleid](#).

Dr. Eleid is an interventional cardiologist at Mayo Clinic in Minnesota. His specialties include heart disease, heart valve disease, and coronary artery disease. Dr. Eleid has a focus in his practice specific to transcatheter aortic and mitral valve replacement. That means Dr. Eleid can replace valves using catheters without an incision to the patient's chest or ribs.



## Our Patient Success Stories at Mayo Clinic



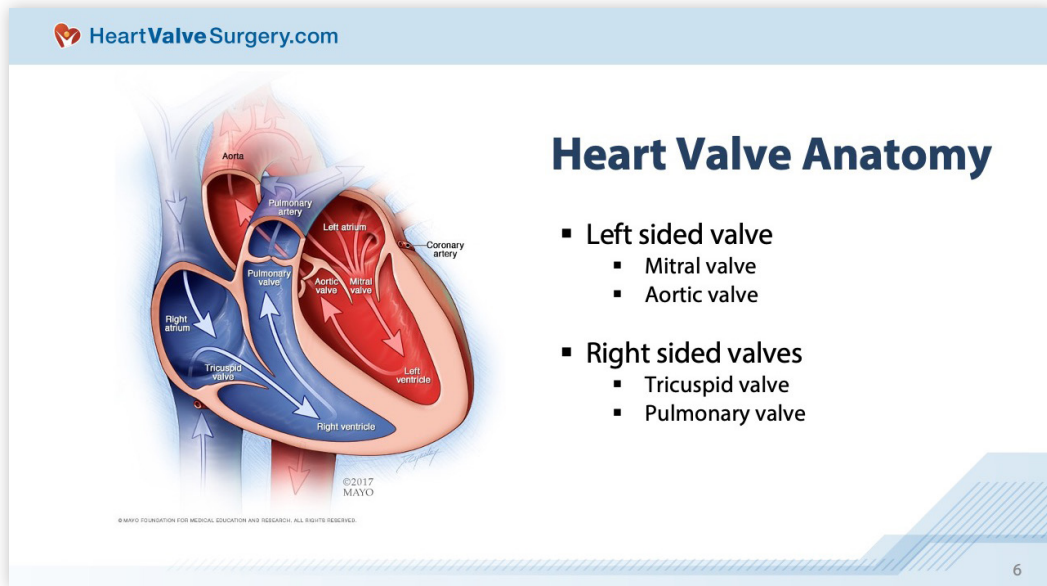
**Adam Pick:** I could go on about the achievements of both Dr. Arghami and Dr. Eleid in cardiac care.

What I love about their work is the smiling faces of their patients. Whether it's Rosemary and Tom Rice, Cheryl Mann, Scott Kinghorn, Herman Kanter, Wes Edens, or Gary Stanko. These are patients from the HeartValveSurgery.com community who have had successful surgical or interventional outcomes at Mayo Clinic.

To give you an idea of the scale and the scope of the Mayo Clinic, whether it's at [Mayo Clinic – Minnesota](#), [Mayo Clinic – Arizona](#), [Mayo Clinic – Florida](#), in 2020, this incredible organization performed over 2,000 heart valve procedures. We are in great hands today with Dr. Arghami and Dr. Eleid.



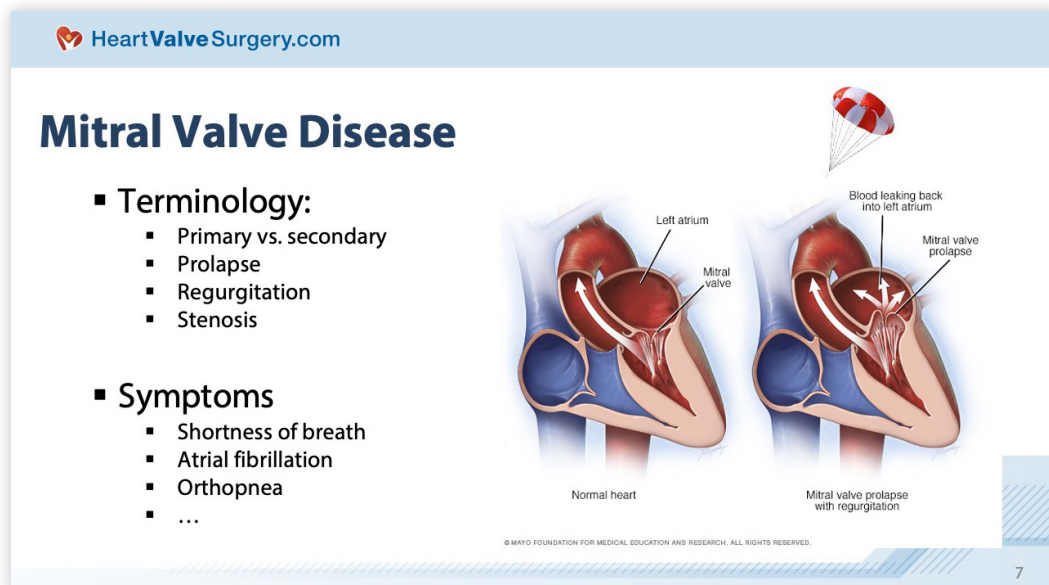
# Heart Valve Anatomy



**Dr. Arghami:** Thanks, Adam, for such a great introduction. I'm pleased to be here and be part of this program and this educational session. I would like to start by explaining the heart a little bit. I know some of the viewers know this very well, but I think we'd bring everybody on the same page. The heart has four valves that are "one-way" valves that are biological masterpieces which are designed to work for 80, 90, 100 years. If you do the math, that means over 3 billion cycles of valve opening-and-closing, which is mind-boggling.

We separate the heart into two sides. The left side of the heart that pumps blood through the rest of the body to nourish and oxygenate it. It has two valves, mitral valve and aortic valve, which will be the focus of today. The right side of the heart, which receives the de-oxygenated blood and sends it to the lung to get oxygen, has two valves - the tricuspid and pulmonary valve. We're going to be focusing on the mitral valve for now.

# Mitral Valve Disease



**Dr. Arghami:** Mitral valve disease is divided in two broad categories. One is primary; one is secondary.

What do we mean by primary disease? We mean that the valve itself is the problem. The mitral valve has two leaflets or two sides that close in the middle like a parachute. Like a parachute has cords to hold it down, this valve can be diseased. It can be stretchy and prolapsed. We call the mitral valve prolapsed. When it prolapses too much, the gap appears between it and it can leak.

Sometimes those cords, like parachute cords, can break or tear, and we call it a flail segment. Part of the valve won't be supported anymore. This can cause the valve to leak and not forward the blood in one direction.

We call that mitral regurgitation. Sometimes the valve can get diseased and tight. We call that a stenotic valve. A stenotic valve doesn't allow blood to easily flow one way, in one direction.

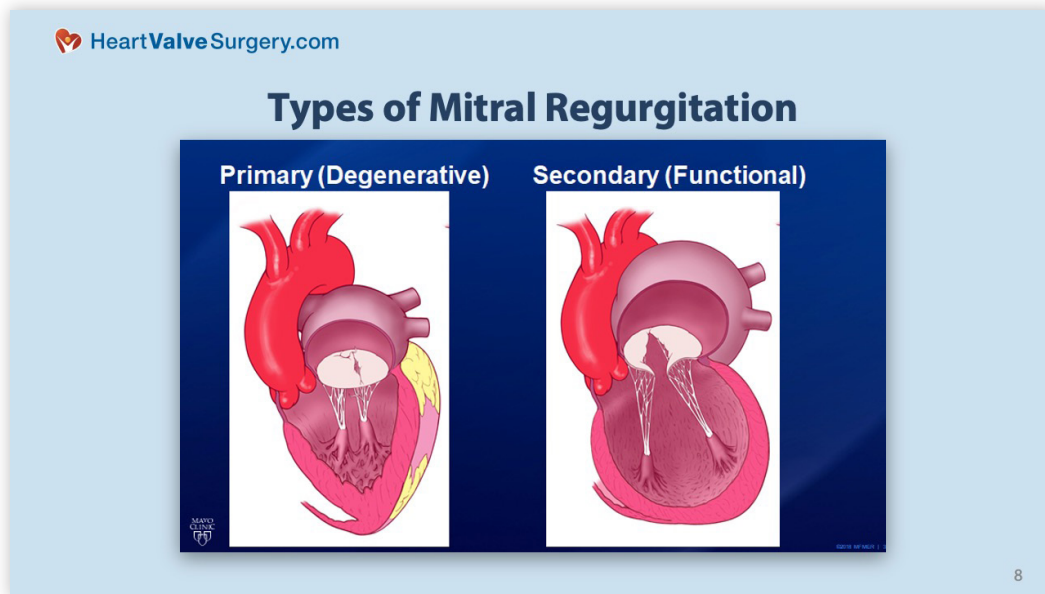
Secondary mitral valve problems are similar problems. But, the main issue is not the valve itself. It's usually something else wrong with the heart that is causing the valve to leak.

What are the symptoms? How will the patient know that they have a problem with their valve? Fortunately or unfortunately, most of the mitral valve regurgitation patients don't have any symptoms to begin with, at least the beginning because the heart is very redundant and can tolerate a lot of issues. The heart won't show any problems until later. Now when the symptoms start is when the heart starts getting bigger and bigger, and it won't be able to squeeze blood normally anymore. That's when you get short of breath when you do activities - when you climb stairs or walk far distances.

Patients can get an irregular heart rhythm that we call atrial fibrillation. That's from the stretching of the chambers of the heart that starts firing abnormally.

Patients can also have difficulty laying flat because they feel they're suffocating. We call that orthopnea.

## Types of Mitral Regurgitation




**Dr. Arghami:** On the left side of this picture, you have primary mitral valve disease, which you can see on the picture there's a cord that is broken. So, something is wrong with the valve itself.

On the right picture, the heart is enlarged. You can see the bottom chamber is quite enlarged - sometimes that is caused by a heart attack or something like that. It's pulling on those strings and holding the valve down and not allowing it to close properly.

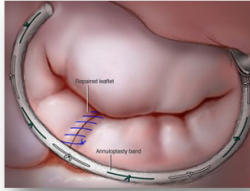



## Mitral Valve Repair vs. Replacement

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### Repair vs Replacement

- What is the difference?
- Can all valves be repaired?
- What are the options for replacement?

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**Dr. Arghami:** Now, what can we do? There are two things we can do, repair or a replacement. The replacement is simple; you cut the old valve out and sew a prosthesis in there. There are different types of replacements that Dr. Eleid is going to tell you about.

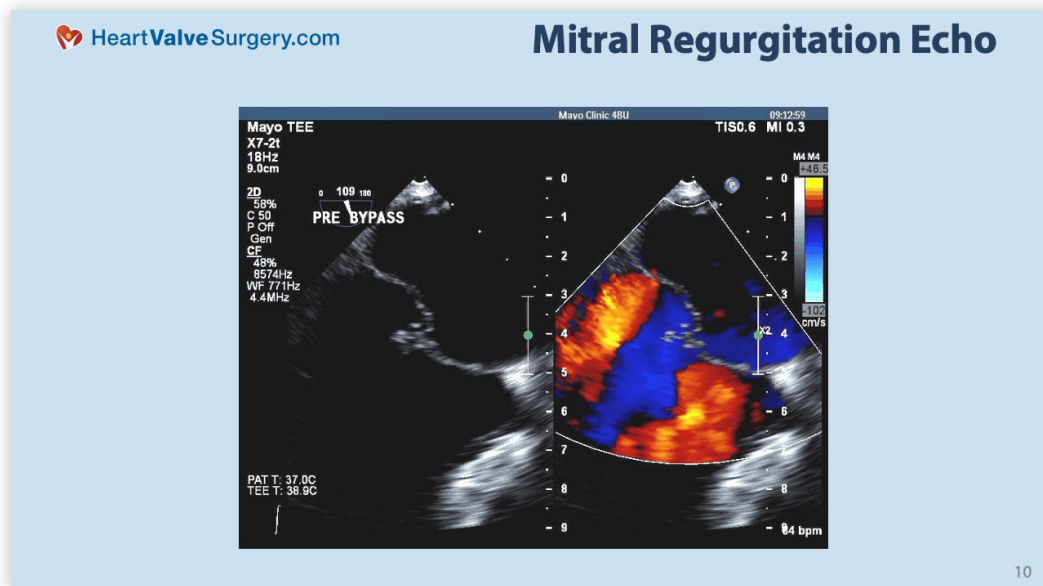
What I'm going to focus on is repairing your valve. That's the better option. So, I'm not going to cut it out. We're going to explain how we're going to do that.

Can all valves be repaired? Not all of them but a good majority, especially those with primary mitral valve problems can be repaired, and I'll show you that. For example, last year at Mayo Clinic, out of all the mitral valve procedures, more than two-thirds were repaired. What are the options for replacement?

Again, Dr. Eleid will go over those.



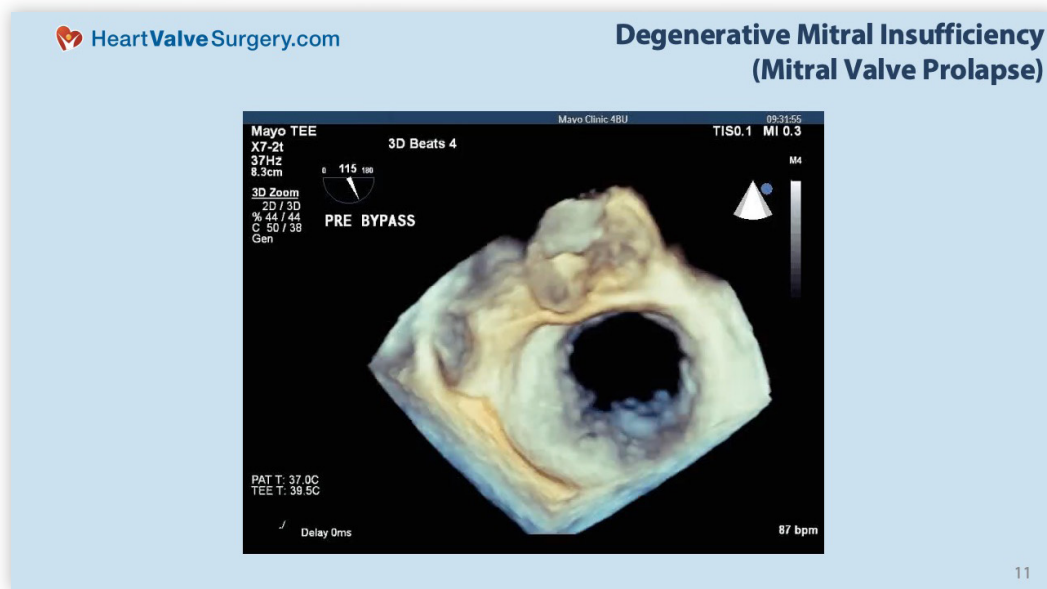
## Evaluating Echocardiograms



**Dr. Arghami:** I'm going to start with an example. This is an echocardiogram of a 64-year old female who came to Mayo Clinic.

As you can see on the left picture, there's a piece of cord that's broken and you see it's swimming in the upper chamber.

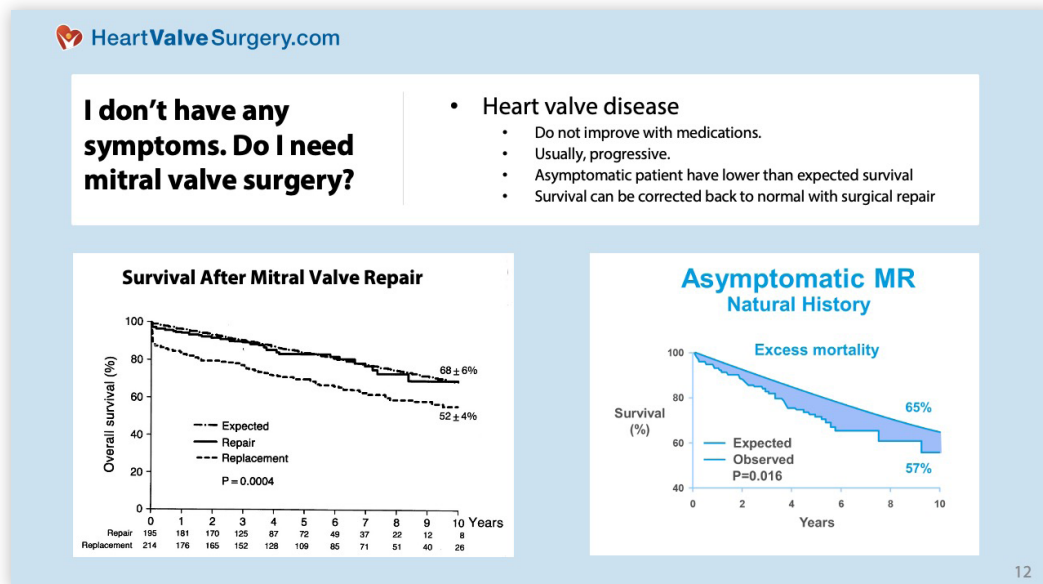
The right picture shows the direction of the blood by the color. The blue part that goes into the upper chamber is abnormal; it's a leakage. You can see the 3D reconstruction of this valve by the echocardiogram, and it's much more visible and you can see that broken cord. We'll get to this patient later on.



One of the most common questions I get is, “Why should I have a surgery if I don’t have any symptoms?”

I have a few answers for those patients. One is these valves don’t improve. The broken cord is not going to attach itself back on, and no medication can fix the leaky mitral valve. They are actually progressive; they get worse over time. The more tension, the more pressure you put on these stretchy valves, the more things can break and leak.

## Understanding Symptoms

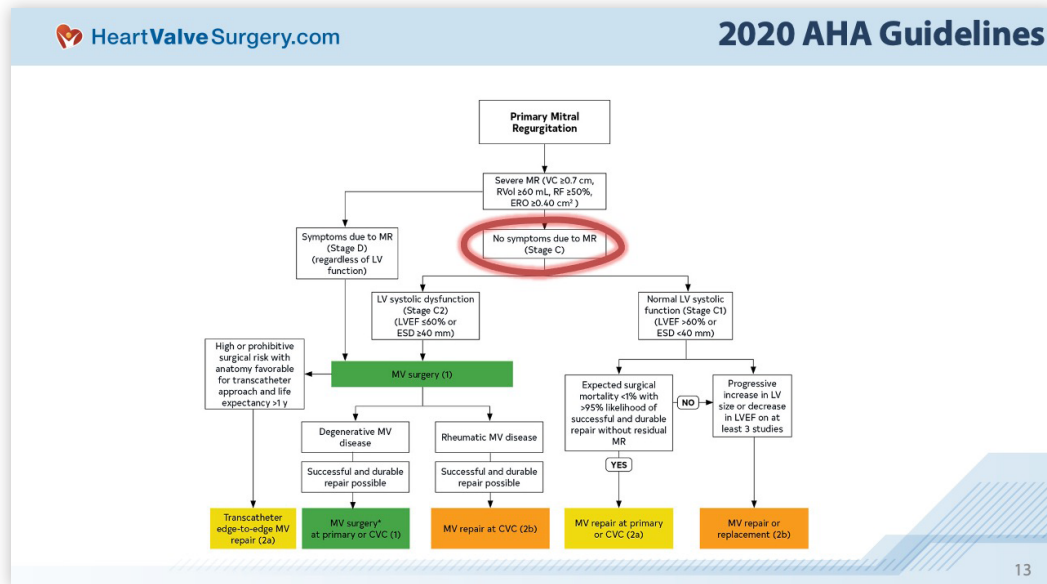


**Dr. Arghami:** The other more important thing is that even in asymptomatic patients, patients who don't have any symptoms, we've shown that they don't live as long as they're expected to.

That is very important. More important than that, we've shown that if you repair the mitral valve, you can bring back patients life expectancy to where they're supposed to be, like as if the patient never had the disease.

That doesn't happen if you replace the valve. A normal life expectancy only happens if you repair the valve.


## ACC / AHA Heart Valve Guidelines



**Dr. Arghami:** Using this data for many years now, the American Heart Association has been recommended early surgery for defective mitral valves even in asymptomatic patients.

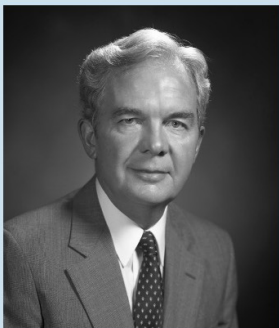
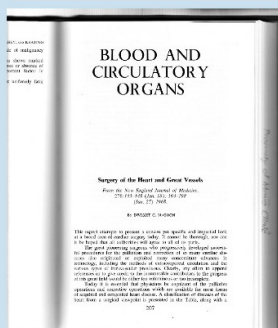
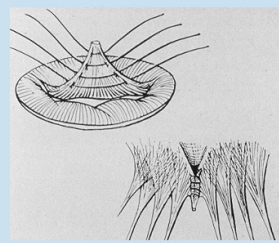
If a cardiac center can offer more than a 98% chance of repair, that means that they can offer surgery even in an asymptomatic patient.

## Mitral Valve Repair Insights



**Dr. Dwight McGoon**

- First description of a mitral valve repair in 1968.

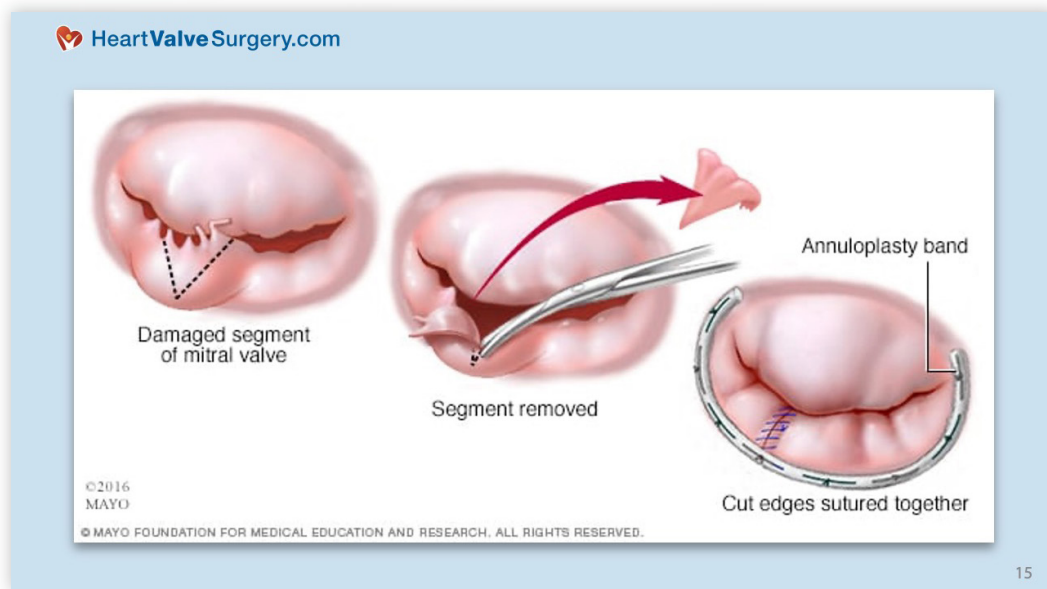




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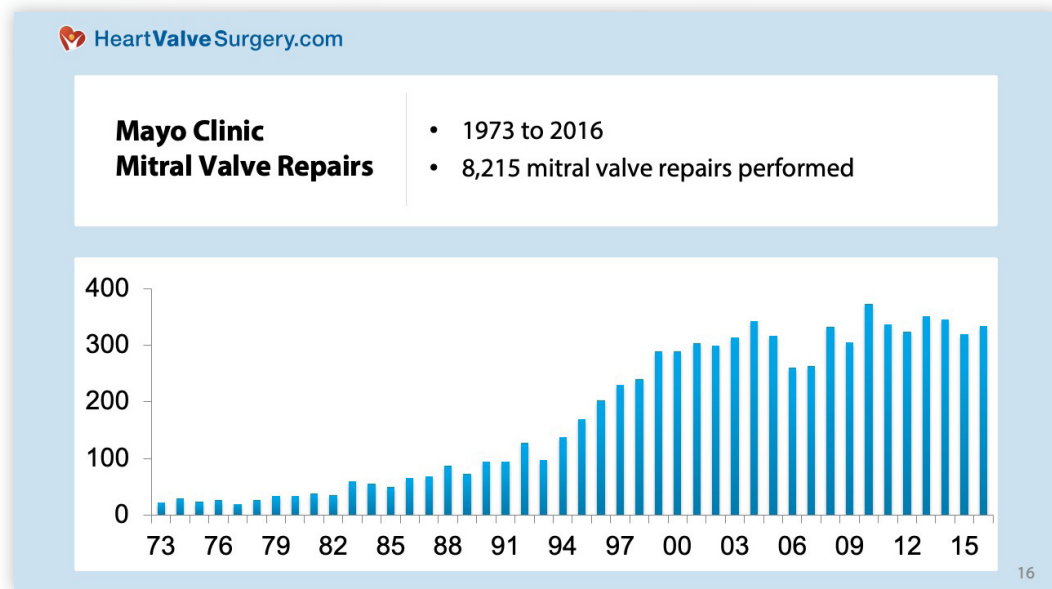
**Dr. Arghami:** Another common question is, “How do you actually repair a valve?”

I would like to share a piece of history with you. This is a picture of Dwight McGoon, one of the pioneers of cardiac surgery at Mayo Clinic. This is his first description of a repair of a mitral valve with a broken chord in 1968. That’s the dawn of cardiac surgery. Using this awesome description and this technique over the past few decades, we have perfected this technique.







We have been able to create this simplified and really effective technique. We call it a “triangular resection” where we cut a piece of valve in a triangle, or a pie shape, where the broken chords are. We repair it and then we reinforce the valve with a band around it. We call this an annuloplasty ring.



Using this technique, we have been able to repair over 8,000 mitral valves in the past few decades with very good success and very low risk at Mayo Clinic.

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Mayo Clinic Robotic Experience

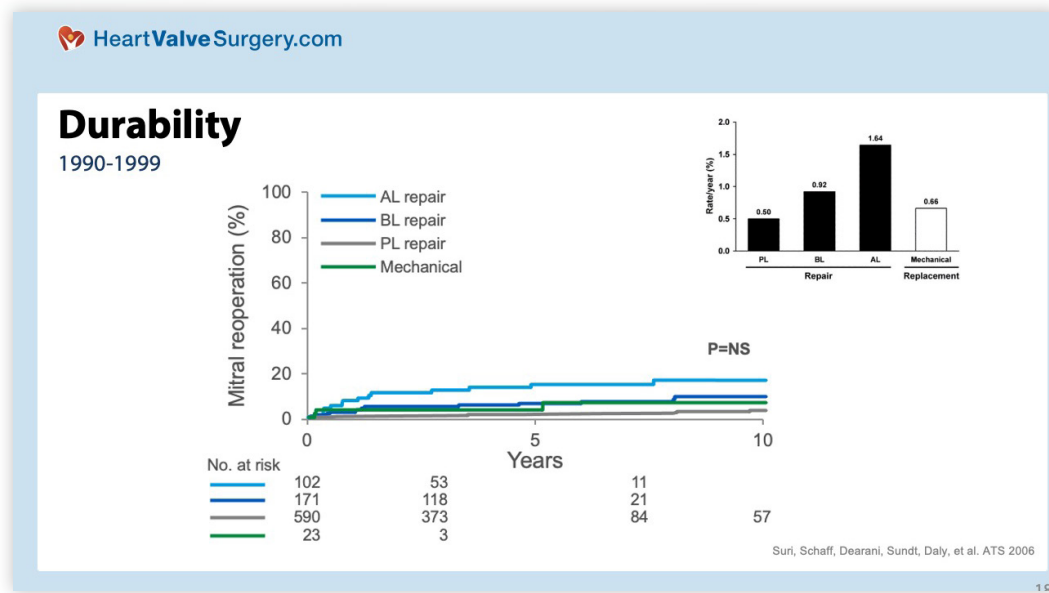


- **Very low operative mortality**
  - Mortality Rate: 0.7%
  - NYHA Class I or II: **<0.1%**

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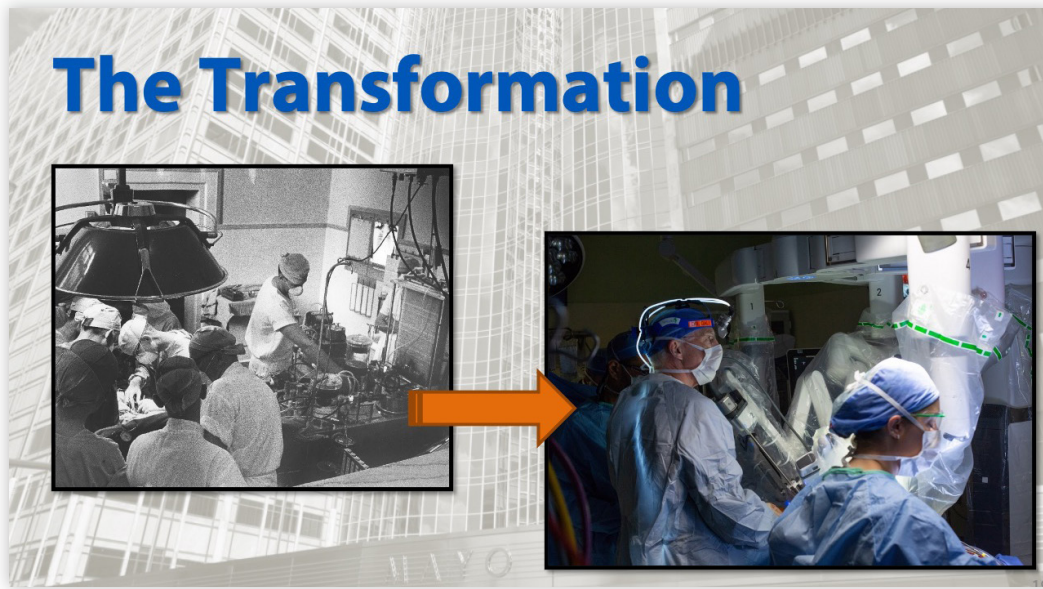
The risk of mortality in our patients at Mayo Clinic is 0.7%.

If you only look at those patients who have very minimal symptoms, the risk is less than 1 in 1,000 patients.



The second most common question I get is, "If you repair the valve, what are the chances of the valve not breaking down again in the future?" This is a very important question.

The durability is great. There are two leaflets on the mitral valve. If you only repair the posterior one, which is the most common leaflet to be the problem, the chances of the patient needing another surgery in 10 years is only 5%. It's better than a mechanical valve replacement. If you repair the anterior leaflet, the risk are still pretty good in the 10 to 15% chance. So, there is a 85% chance that valve is still working in 10 years. If you repair both leaflets, the chance for reoperation is somewhere around 10%.



At Mayo Clinic, we gathered many decades of experience and we brought it to the 21st century by applying new technology (i.e. the robotic technology).

Now, we can offer the same proven and durable repair through three different approaches - the median sternotomy, which is dividing the breastbone; incision between the ribs, we call mini-sternotomy; or with a few tiny little pokes in the right chest with the robotic assistance.



## Same Repair... But, Three Different Approaches



Median  
sternotomy



Mini-  
thoracotomy



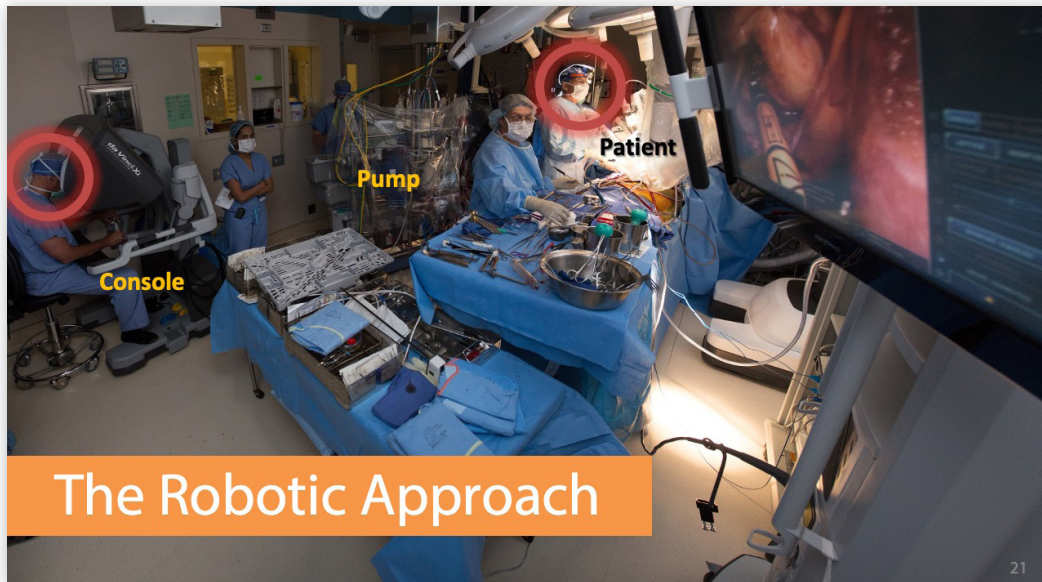
Robotic

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I'm going to show you a few pictures of the robotic technique. This is a robotic operating room.

They say there's 10,000 steps to a robotic – or any cardiac surgery that every step is important. As you see, the patient is on the right side of the picture.

## Robotic Mitral Valve Repair



**Dr. Arghami:** There's a cardiopulmonary bypass in the middle of the picture. One of the unique things about Mayo Clinic is that we use two surgeons - one sits at the console and one at the bedside to help with the robotic arms.

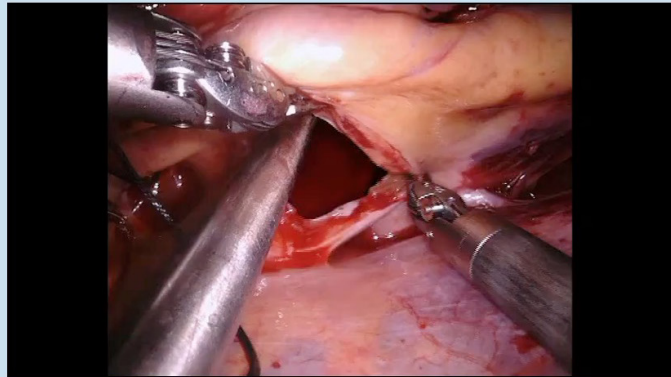
This allows two sets of trained eyes to look at the mitral valve and to come up with a great plan for the repair, which is going to be durable and great.



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The robotic repair doesn't mean that the robot does the surgery. As you can see here, the surgeon moves these joysticks and the robotic arms move accordingly, and that's where the surgery starts.

## Posterior Leaflet Prolapse Repair



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We make a small incision on the side of the heart, get into the left atrium, as you see. That's the chord that was broken that you saw in the picture. I'm going to cut this piece out in a triangular fashion, like a piece of pie, and this is magnified by the way. The mitral valve is almost like a half-dollar size. This is sewing the leaflet back together. We use permanent sutures. We tie it down. You can almost see that the valve doesn't look like it was cut. This is that band I told you about. We're putting it around to reinforce the mitral valve to allow these leaflets to come closer and meet further in the middle and be more efficient.

We're putting some water (or saline) behind the valve, and we're testing it. This specific case, there was a little leakage left, and that's why the mitral valve is not a science, it's an art. Here, we decided to put an extra stitch in that area we call a cleft where naturally there's a division between the two sides of the same leaflet, and sometimes it leaks. Again, it's more of an art. We have to see what's wrong, and every patient requires a different repair. It's unlike a replacement. We test it again, and this time it looked great.





We close things up, and we check with the echo on the table while the patient's still asleep, and we make sure all that blue color, which represents the leakage, that was going backwards is not there anymore.



Outcomes

## Benefits

-  ICU time (**14** vs 28hrs) <sup>1</sup>
-  Length of stay (**3.5** vs 5.3 days) <sup>1</sup>  
Labs and Medications
-  Less Transfusions
-  Less use of narcotics
-  Faster return to work  
(half at 4<sup>w</sup> vs. 8<sup>w</sup>)

<sup>1</sup> <http://dx.doi.org/10.1016/j.mayocp.2013.06.022>



What's the benefit of the robot?

It's much smaller incisions.

The patients stay in the hospital and in the ICU half the time.

There's less bleeding. So, less blood transfusion.

Patients use less narcotic pain medicine, and we all know about the opioid crisis we have. When they go home, they have a faster return to work, almost half the time.

### ▪ **Mayo Robotic Mitral Valve Surgery Results**

- Over 900 robot mitral valve repairs since 2008
- Successful valve repair in all
- No conversions to sternotomy for valve repair
- Major complications <0.1%
- Reoperation rate n=5, 0.8%\*


\* In 619 pts from 2008 – 2016

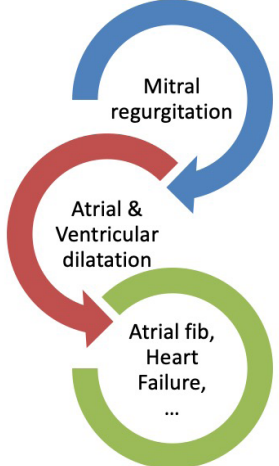
26

At Mayo Clinic, we have been able to do more than 900 robotic cases since 2008 when we started it. We have been able to successfully repair all those valves.

We have not had to convert a robotic case to a sternotomy for a valve repair reason. Major complications are less than 0.1%, and reoperation rate is less than 1%.

## Early Operations





### Early Operation

- In degenerative mitral valve disease with severe regurgitation early surgical repair should be considered.
- Valve repair is better than replacement
- Mitral valve repair can bring the survival amongst these patient to near normal.
- Robotic surgery is an alternative to open repair and can be applied to all types of valve pathology.


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**Dr. Arghami:** When I summarize my part, I want to mention this. In degenerative mitral valve disease, when there is severe regurgitation, consideration for early repair should be given.

Repair is always better than a replacement. Mitral valve repair can bring the survival back to normal among those patient almost as if they didn't have the disease. Robotic surgery is an alternative to open surgery. It can be applied to all sorts of valve problems. Now, what if the patient can't have surgery? What if the patient is in a difficult situation and cannot undergo surgery?


That's where I'm going to hand the talk to my best friend - Dr. Eleid.


## Patients That Can Not Tolerate Surgery

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### What if patient can not tolerate surgery?

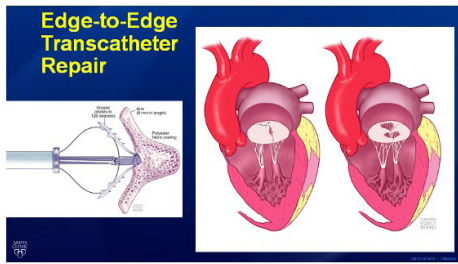
- MitraClip
- Clinical Trials





Braille biomedical, Braille biomedical, CardAQ 1" G, GardAQ edwards, Cephea, Direct flow medical, Twelve medtronic, M-valve, Edwards fortis, HighLife, Navigate, Neovasc tiera, PermaValve MID, Sinomed, Tendyne abbott, SATURN TMVR, Mitraltech, Caisson, Others: MitraHeal, Mitralisat, Mitraltech, Mehr Medical Mitralclip, Mitralix MAESTRO Nakostech, St. George ATLAS Transcatheter Technologies Trellis.

### Edge-to-Edge Transcatheter Repair



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**Dr. Eleid:** That was a great description of mitral repair. It's really amazing to see what you guys do in the operating room. Armand and I work together seeing patients with valvular disease. I'd like to thank Adam again for the opportunity to present here to the attendees - many of whom are patients.

The question of if a patient cannot tolerate surgery is a common scenario. We have patients with mitral regurgitation who are higher risk for surgery due to comorbidities such as a prior heart surgery, for instance, or lung disease or some other organ disease.

In those patients, we have transcatheter options, which has been a huge evolution in the last ten years. The edge-to-edge repair technique mimics a surgical technique called the Alfieri stitch where the posterior leaflet is clipped to the anterior leaflet in the middle.

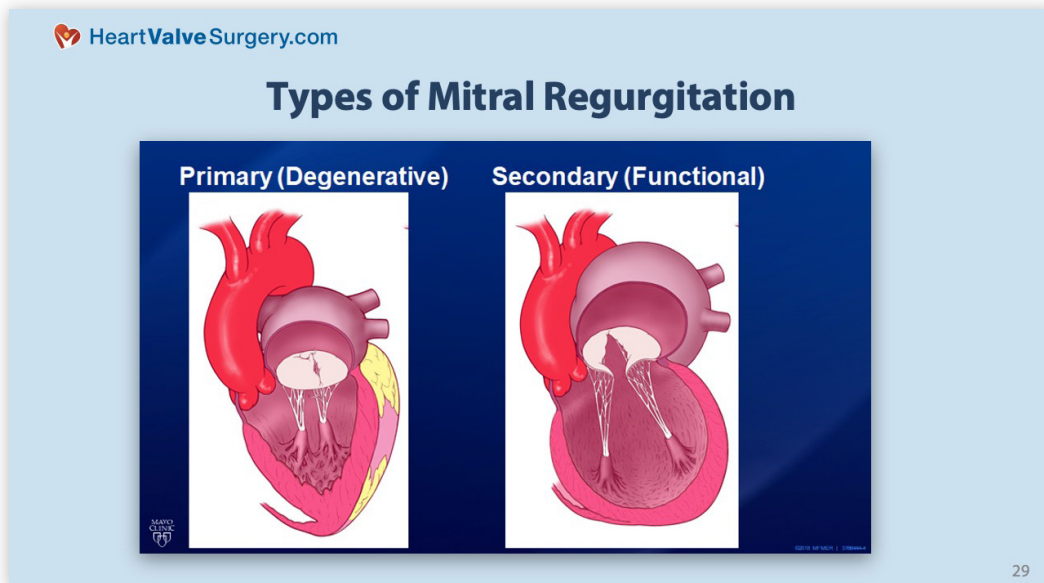
You can see on the figure down below that it creates a double opening mitral valve with the edge-to-edge repair technique, and this is currently commercially available through the MitraClip system, and there's also another device under investigation called PASCAL that can achieve this as well.

This is particularly useful for patients that have a degenerative mitral valve with a ruptured cord and have a central location of leakage. But, there's also a lot of exciting therapies under development, transcatheter replacement valves that can be delivered through the femoral vein in the leg through a minimally invasive approach. Several of these are in the clinical trials now where they're in the early feasibility stage that is being studied closely to look at safety and efficacy.

Other therapies are also in a larger trial phases. Patients that have primary mitral regurgitation may be candidates for these studies.



## Transcatheter Mitral Valve Therapies & Clinical Trials



**Dr. Eleid:** We did briefly discuss the differences between a primary mitral regurgitation and secondary, but I just wanted to reiterate that.

The secondary mitral regurgitation is more of a disease of the ventricle rather than the leaflets themselves, and this is also a common problem that we're seeing, and patients with secondary mitral regurgitation are often not good candidates for surgery, so transcatheter therapies are needed.

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## Transcatheter Therapies for Secondary Mitral Regurgitation

**MitraClip**



**Randomized TMVr Trials**  
New Therapy vs MitraClip  
i.e. pivotal CLASP IIF trial



PASCAL vs MitraClip

**Randomized TMVR Trials**  
New Therapy vs MitraClip  
i.e. SUMMIT pivotal



Tendyne vs MitraClip

**SUMMIT Trial**  
**APOLLO Trial**  
**ENCIRCLE Trial**



**COAPT: Percutaneous Repair or Medical Therapy for Secondary MR**



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The MitraClip was studied in patients with secondary mitral regurgitation, and one of the largest trials was the COAPT trial. That was done here in the United States. You can see curves on the bottom of the screen that show both survival and rehospitalization that were less with edge-to-edge repair in these patients

One of the keys is that all these patients in the trial were optimized on heart failure medications and had rigorous medical treatment first to make sure that they needed a mitral valve repair.

We also have other options for patients with this problem that are being investigated.


I mentioned the PASCAL device, which is similar to MitraClip, and that's being tested in a randomized trial, which achieves a similar edge-to-edge repair.

Then there's also the Tendyne valve, which is a self-expanding valves that's delivered through a minimally invasive transapical approach. So, that's another hybrid procedure that our surgical colleagues will get access in the ventricle at the apex and then advance a valve through there.

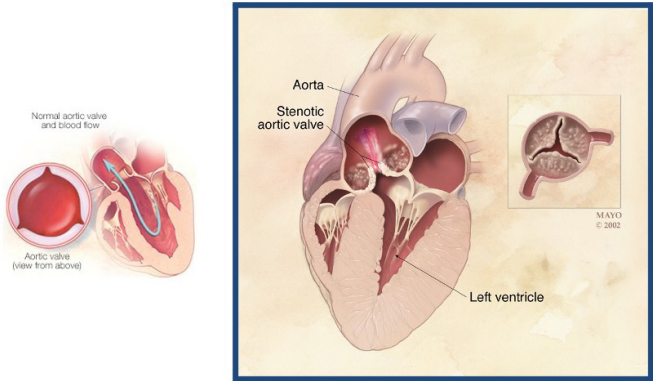
Then we also have other types of valves, one of which is called the SAPIEN M3 valve. That is also being studied for patients that have secondary mitral regurgitation.

There is lots of exciting innovations in this area. We are evaluating patients for these trials when they come to Mayo Clinic.

# Aortic Stenosis

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Aortic Valve Stenosis



- Prevalence**
  - 4% in 70-79
  - 10% in ages 80-89
- Only effective treatment is aortic valve replacement**

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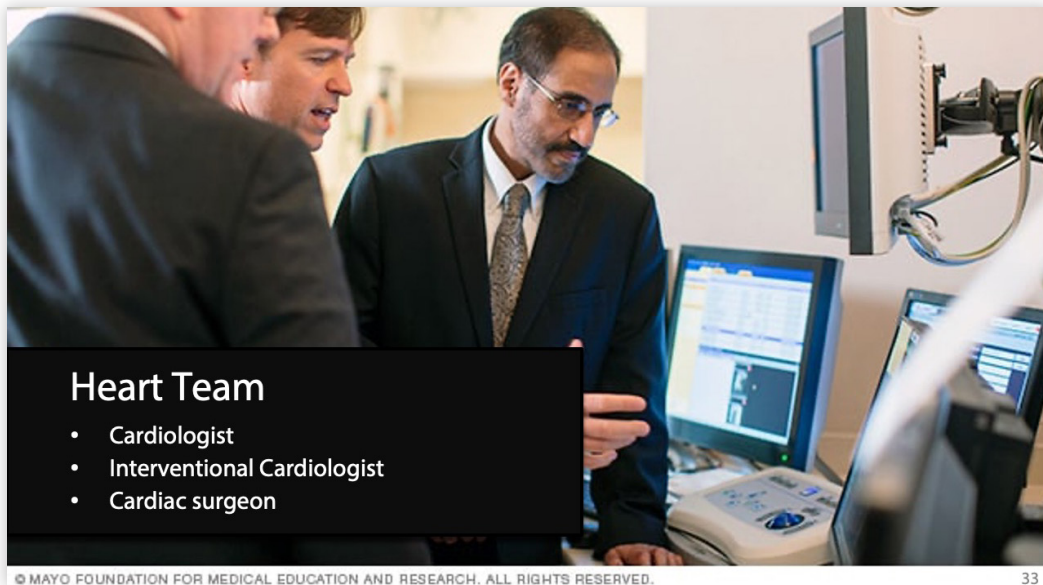
**Dr. Eleid:** I'd like to transition to aortic stenosis. This is another common problem that we face. Over 10% of people over 80 years of age will develop aortic stenosis that may require intervention.

Aortic stenosis is a common disease of aging, but it's also common in younger patients who have a bicuspid aortic valve. Up to 2% of the population may have a bicuspid aortic valve meaning that two of the leaflets are fused together instead of having three leaflets. This diagram shows a normal aortic valve. On the left, you can see the large opening of a normal aortic valve, but when it becomes stenotic, the valve no longer opens normally. This puts the heart under a lot of pressure, and the ventricle has to generate a high pressure in order to get the blood out of that small valve.

The only effective treatment for aortic stenosis is an aortic valve replacement.



## Mayo Clinic Heart Team Approach




**Dr. Eleid:** We approach patients with aortic stenosis in a “heart team” approach at the Mayo Clinic.

Dr. Arghami and I see patients together and oftentimes with our cardiologist colleague as well.



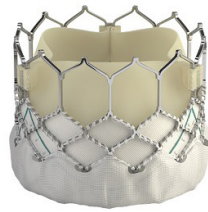
Together, we try to determine what the best option is for the patient using a team approach. This is really critical to make sure the patients know all of the options and have the best information to make the best decision.



## Aortic Valve Replacement Options



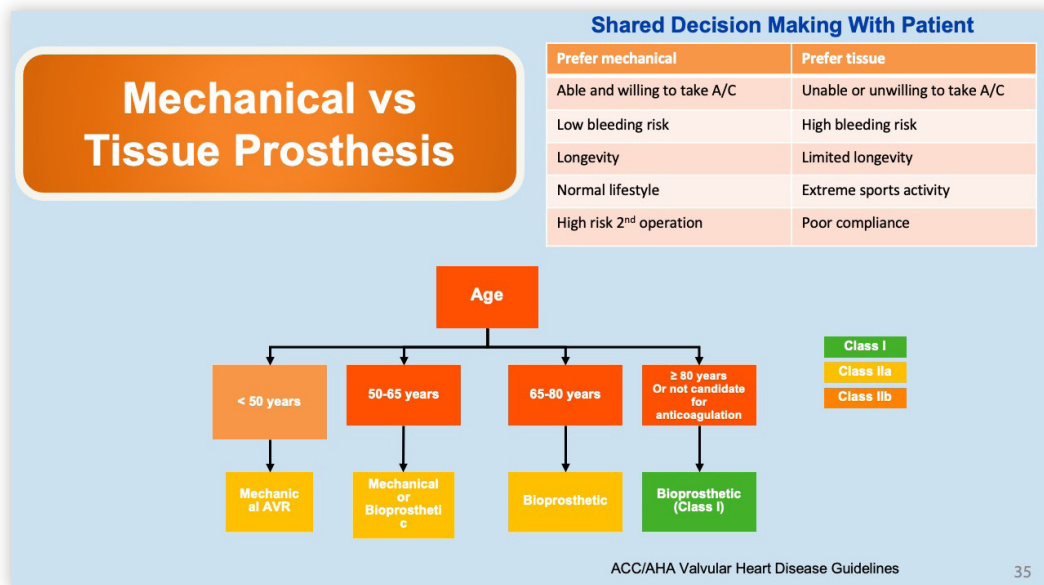
### Aortic Valve Replacement Choices

| Mechanical  | Tissue   | TAVR  |
|---|--|---|
|  <ul style="list-style-type: none"> <li>• Durability 30 years</li> <li>• Requires Lifelong Warfarin Anticoagulation</li> </ul> |  <ul style="list-style-type: none"> <li>• Durability 10-15 years</li> </ul> |  <ul style="list-style-type: none"> <li>• Durability Still Under Evaluation</li> </ul> |

**Dr. Eleid:** We have different replacement valve options. This is a really critical decision. When a patient is faced with having to have a valve replaced, one of the first questions is, “What type of valve should it be?” You can see on the left, a mechanical aortic valve a bileaflet prosthesis that has two discs that open and close. Mechanical valves have the best durability of 30 years or more, but they also require warfarin anticoagulation, and this is one of the important considerations.

Tissue valves are usually either made out of cow pericardial tissue or pig valves. They typically have a durability of 10 to 15 years, sometimes more, and occasionally even less than that. Tissue valves don’t necessarily require anticoagulation. The transcatheter aortic valve that we’re implanting nowadays are perceived to be similar to the surgical tissue valves, but long-term data is still not available. So, there is still some uncertainty about the durability of the transcatheter aortic valves, and this is being closely looked at as patients are followed in the long-term trials that led to the approval of the transcatheter aortic valves.

## Shared Decision Making: Mechanical vs. Tissue Valves



**Dr. Eleid:** One of the biggest questions to ask patients regarding mechanical versus a tissue valve is the ability and willingness to take anticoagulation.

We have a “shared decision-making” discussion with all of our patients about which type of valve they want, and we take into account many factors, the updated American College of Cardiology guidelines that have an algorithm based on age, which is one of the factors that we take into account.

In terms of aortic valves, we know that patients who are in their 50s generally benefit the most from a mechanical valve – typically 50s or younger in terms of long-term survival. There’s several trials that show a survival benefit of mechanical valves compared to biologic or tissue valves in patients who are in their 50s or

younger.

On the other hand, it's reasonable to choose a bioprosthesis in most patients who are 65 or older.

A lot of different details need to be taken into account - the patient's bleeding risk, their longevity, how long do we expect you to live, and that's oftentimes a very difficult thing to predict for anyone, but also lifestyle, and what would be the risk of a second operation as well.

Now that we have "valve-in-valve" therapies as an option, that also comes into play and how suitable would that valve be to accommodate a transcatheter valve 10 to 15 years in the future. Those are all important questions that we ask for each

## Key Criteria for Aortic Valve Treatment Selection

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### Aortic Valve Treatment Option Decision

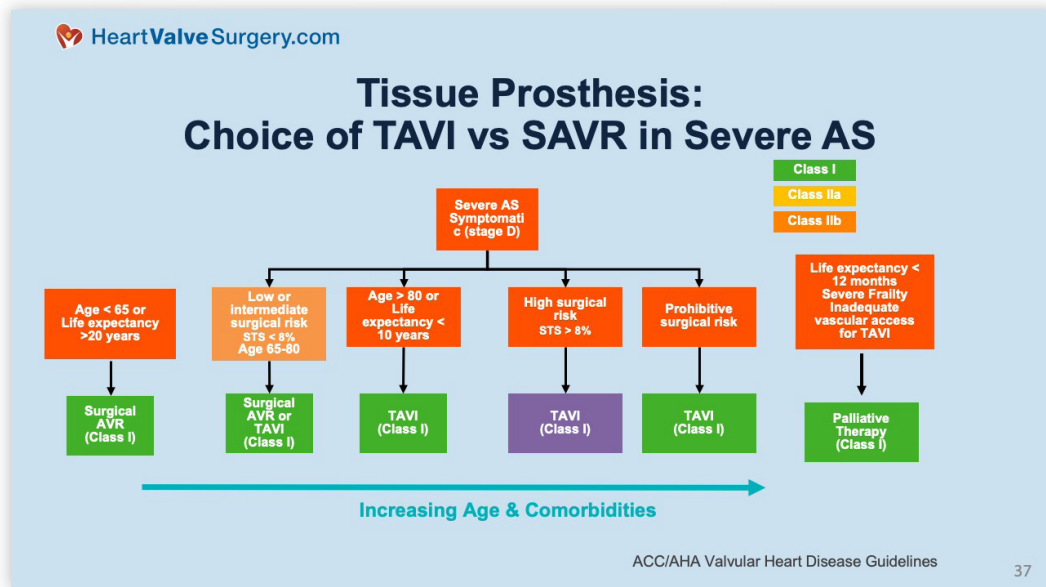
- Society for Thoracic Surgeon (STS) risk score
- Frailty
- Kidney disease and other medical problems
- Other necessary procedures
- Anatomic considerations

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**Dr. Eleid:** We also take into account the risk profile of our patients in terms of what is the risk of open-heart surgery, which is based on a risk score that takes into account over 20 different variables.

We also take into account patient's frailty, which is generally their strength and physiologic reserve, their ability to tolerate stress. Then we look at other comorbidities such as kidney disease and whether or not anything else needs to be done.

For instance, "Does a patient also need bypass grafting surgery because of severe coronary disease or can it be treated with stents?" Those are all very important questions that we have to assess in determining the best treatment.




If we had made a decision about a tissue valve for our patients rather than a mechanical valve, then we also take into account their age and surgical risk in determining surgery versus TAVR.

The ACC guidelines recommend surgery as the Class 1 indication for patients who are younger than 65 and have a life expectancy of more than 20 years, and part of that is because of the track record of surgical aortic valve replacement and a little bit more long-term follow-up of surgical aortic valve replacement that we have available.

TAVR or TAVI as it's shown here – transcatheter aortic valve implantation – is reasonable for most other groups of patients with aortic stenosis. So, if they're 65 or older, it's considered a Class 1 indication for surgery. There's a lot of options for most of our patients, and we take into account a lot of factors.



## TAVR Clinical Trial Findings

| <b>Key End Points- PARTNER 3 Trial of TAVR Compared to Surgical AVR</b>  |                  |                   |  |                      |
|---|------------------|-------------------|--|----------------------|
| End Point   | TAVR (N = 496)   | Surgery (N = 454) | TAVR vs. Surgery (95% CI) <sup>†</sup> | P Value <sup>‡</sup> |
| New-onset atrial fibrillation at 30 days — no./total no. (%)§¶  | 21/417 (5.0)     | 145/369 (39.5)    | 0.10 (0.06 to 0.16)                    | <0.001               |
| Length of index hospitalization — median no. of days (inter-quartile range)   | 3.0 (2.0 to 3.0) | 7.0 (6.0 to 8.0)  | -4.0 (-4.0 to -3.0)                    | <0.001               |
| Death from any cause, stroke, or rehospitalization at 1 year — no. (%)§   | 42 (8.5)         | 68 (15.1)         | 0.54 (0.37 to 0.79)                    | 0.001                |
| Death, KCCQ score of <45, or decrease from baseline in KCCQ score of ≥10 points at 30 days — no./total no. (%)  | 19/492 (3.9)     | 133/435 (30.6)    | -26.7 (-31.4 to -22.1)                 | <0.001               |
| Death or stroke at 30 days — no. (%)§   | 5 (1.0)          | 15 (3.3)          | 0.30 (0.11 to 0.83)                    | 0.01                 |
| Stroke at 30 days — no. (%)§  | 3 (0.6)          | 11 (2.4)          | 0.25 (0.07 to 0.88)                    | 0.02                 |

**New Pacemaker:** TAVR 6.5%, SAVR 4.0%, P = NS  
**New LBBB:** 22% TAVR vs. 8% SAVR

Mack MJ, Leon MB et al N Engl J Med 2019

**Dr. Eleid:** This is a slide from one of the most important trials of transcatheter aortic valve replacement that was published two years ago. This was the PARTNER 3 trial. This led to approval of the balloon expandable SAPIEN valve in patients who were considered low risk for surgery that had isolated severe aortic stenosis.

One of the findings of this trial was a reduction in combined end point at one year in patients who had transcatheter valve replacement instead of surgery. This was a combined end point of mortality, stroke, and rehospitalization. This just shows some of the percentage risks for patients at different time points.

We see atrial fibrillation on the top was less common with transcatheter valve replacement than surgery and death or stroke was also less common with the transcatheter valve replacement compared to surgery. Length of stay, of course, was less as we would expect.

This is one of the reasons that Dr. Arghami and I are performing transcatheter valve replacement on more and more patients. This has really been a revolution in cardiology, one of the biggest breakthroughs in the field of heart surgery and cardiology in the last decade.

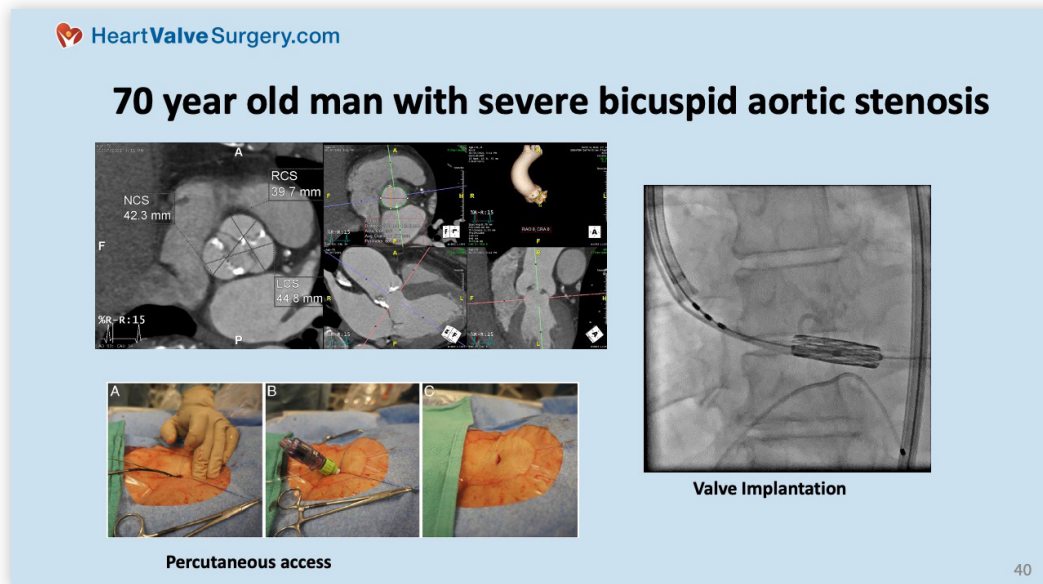
One point here that I would just add on that slide is that pacemaker risk is still a little bit higher with transcatheter valve replacement for patients to be aware of. Even though it was not statistically different in this low-risk trial, we do see that it's higher in most patient groups. The left bundle branch block is a conduction change that can occur with TAVR, and that is higher and more common with transcatheter valve replacement than surgery.

Transcatheter valve replacement is done with moderate sedation nowadays, so our patients can be – are awake but sedated and comfortable. They're breathing on their own, and the procedure usually takes one to two hours. So, it can be completed very rapidly.

Usual length of stay in the hospital is about one day for most patients. We do an echocardiogram immediately at the end of the procedure to make sure everything looks good and then some patients have to be monitored with a rhythm monitor after discharge.

Most patients don't require any rhythm monitoring after discharge from hospital.

## Bicuspid Aortic Valve Considerations



**Dr. Eleid:** This is an example of a different scenario of a patient with a bicuspid aortic valve who is 70 years old and opted to proceed with transcatheter valve replacement after we looked at the anatomy in detail. You can see some of the computed tomography images on top there. You can see that there's fusion of two of the leaflets of the valve, the left and right cusp, and some calcification in that area of fusion. We felt that the anatomy was favorable for transcatheter valve replacement, and there were no other indications for surgery. That's a very important point, because many of our bicuspid patients will benefit more from surgery, particularly our younger patients and those who have a descending aortic aneurysm.

In this case, our patient had a great result with transcatheter valve replacement. You can see this video of valve deployment. You can see the contrast being injected into the aortic root. We use that as a guide to deploy the valve. This is the balloon expandable valve being deployed. After ten seconds, the patient has a brand new aortic valve. So, it's really amazing.

### TAVR in Bicuspid Aortic Valves – TVT Registry Data

- 2,691 patients with BAV compared to tricuspid AV patients



**Randomized  
Trial needed!**

| End Point<br>30 Day<br>Outcomes: | Bicuspid Aortic<br>Stenosis, % | Tricuspid Aortic<br>Stenosis, % | P<br>Value |
|----------------------------------|--------------------------------|---------------------------------|------------|
| All-cause mortality              | 2.6                            | 2.5                             | .82        |
| Stroke                           | 2.4                            | 1.6                             | .02        |
| Life-threatening<br>bleeding     | 0.1                            | 0.1                             | .99        |
| Major vascular<br>complication   | 0.9                            | 1.0                             | .68        |
| New pacemaker                    | 9.1                            | 7.5                             | .03        |
| Aortic valve<br>reintervention   | 0.2                            | 0.3                             | .79        |

Makkar R et al. JAMA 2019;321:2193-2202.

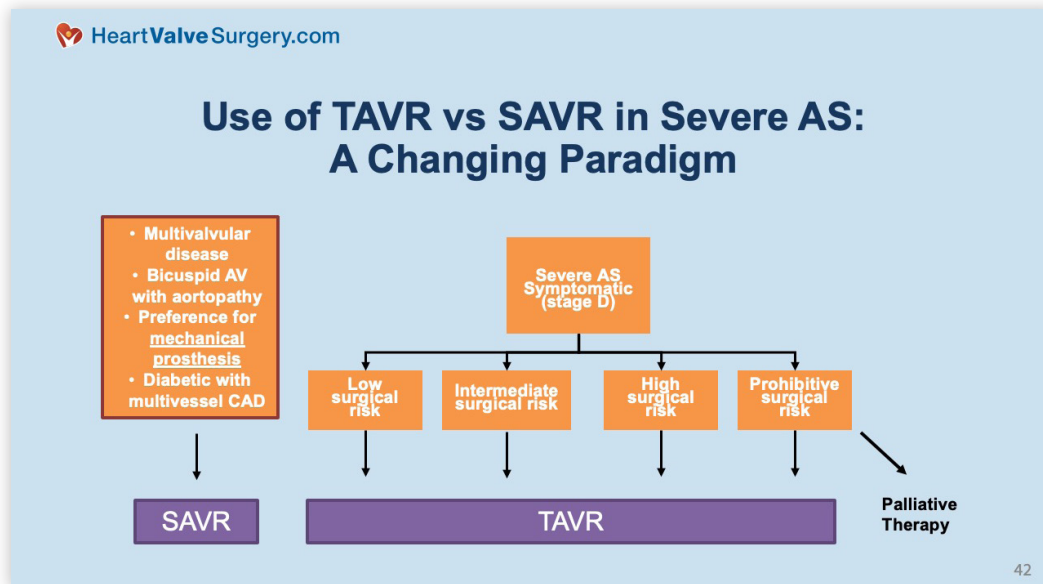
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**Dr. Eleid:** Bicuspid aortic valve have not been formally approved for TAVR, and actually they've been excluded from a lot of the clinical trials. So, it's still an area of question. We still don't have a randomized trial for patients who have bicuspid aortic stenosis. We do have a lot of observational data, and this is data from the Transcatheter Valve Therapies Registry that showed comparable outcomes in patients who have a bicuspid valve with aortic stenosis compared to tricuspid, undergoing transcatheter valve replacement.

There was a signal for slightly higher risk of stroke, 2.4% versus 1.6%, so that's something that we think needs further evaluation, and also a slightly higher rate of pacemaker as well, 9% versus 7.5%. Many are supporting that a randomized trial be done in patients with bicuspid aortic valve and that's something that we're still waiting for.



## SAVR vs. TAVR: A Changing Paradigm

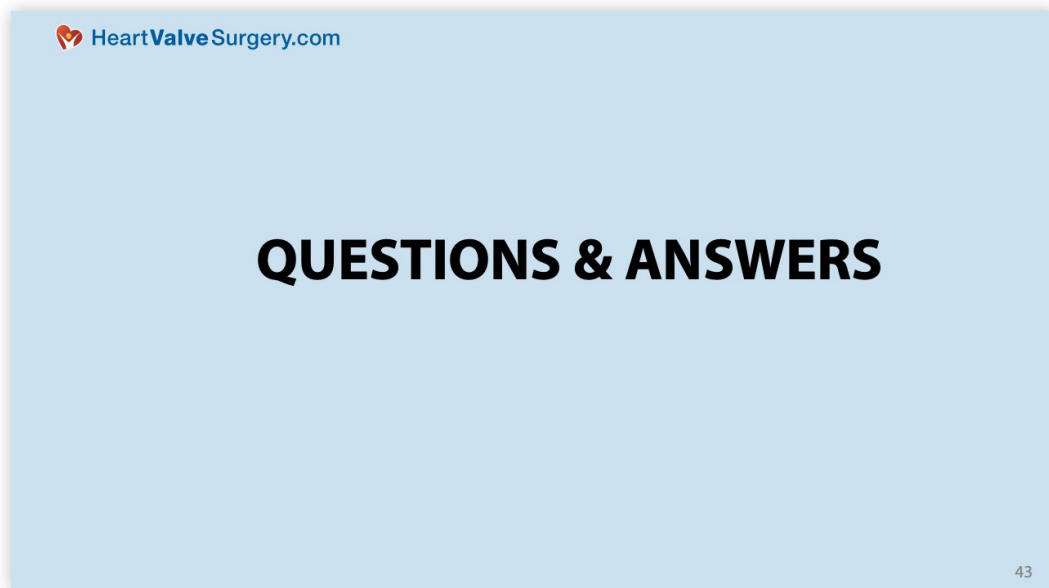


**Dr. Eleid:** It's really a changing paradigm in deciding about transcatheter valve replacement and surgical aortic valve replacement. Many patients who have isolated severe aortic stenosis will be good candidates for transcatheter valve replacement, but there's a lot of other scenarios where surgery is still the best option.

That includes patients who have multiple valve lesions who are good candidates for surgery, bicuspid aortic valve with aortic aneurysm, those patients who would benefit the most from a mechanical valve, and another example is patients who have diabetes and severe coronary disease that would benefit more from bypass surgery as well at the time of their valve replacement. Those are just a few examples, and a lot of these factors need to be taken into account.



## Questions & Answers



**Adam Pick:** On behalf of the patients, thanks so much for putting together that presentation to make us very familiar with your paths and approaches to managing and treating valvular disorders. We have received a whole bunch of questions that have come in from the patients on the webinar.

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Polymer Valves



Brent asks, “What is the latest update on polymer valves? Is it possible these valves can last a lifetime without any drugs? Are there any other new types of heart valve materials we should know about?”

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To start, let’s talk about something that our community is very fascinated with, which is medical technology and some of the new therapies and new materials that are coming out. This question comes in from Brent about polymer valves. He says, “What is the latest update on polymer valves? Is it possible these valves can last a lifetime without any drugs? And are there any other new types of heart valve materials we should know about?”

**Dr. Arghami:** I can take that one. Very good question, Brent. The field is always growing and investigating. We have come a long ways from the initial valve types. I don’t know if any of you have seen the ball-and-cage valve, which was historically an important valve but not being used anymore. Polymer valves are also very fascinating with good promises. They’re still in development. There have been one or two human tests that I’m aware of, but like anything else, we just have to wait for the technology to mature. As soon as they’re available, whether they can be implemented surgically, or the polymer has the promise of being flexible and hopefully be able to be implemented through TAVR technology and not require surgery and have the valve for a very long time.

In terms of other valve types, again, there's a lot of areas of investigation, improving tissue valves and whatnot. One of the things Mayo Clinic researchers are working on is trying to create a valve that is impregnated with patient's own cells so there's no rejection or there's no reaction, if you may say. It has the promise of being as your own valve, literally. Again, a lot of this are in the future, and the future looks bright.

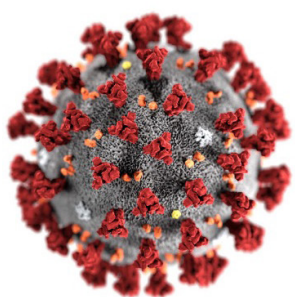
**Adam Pick:** I think the patients are all wondering, "How far in the future do you think it might be before Mayo Clinic, for example, is growing patients' own valves?" Can you guesstimate?

**Dr. Arghami:** It's hard. As you and your listeners know, medical devices are not like iPhones that you can print out a new version every year. They have to go through rigorous work to make sure they're safe, they're durable; they don't have any long-term reactions. It will be soon, but I can't promise any time.

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COVID-19 Vaccine

Amy asks, "My son has moderate aortic valve disease due to stenosis and regurgitation. We believe he will need a replacement. I am concerned about him getting the COVID-19 vaccine given the reports we've seen about myocarditis. Any advice for a mom?"



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**Adam Pick:** Moving onto the next question about the COVID-19 vaccine and we get a lot of questions about this given this very difficult and trying time in healthcare. Amy asks a really great question "My son has moderate aortic valve disease due to stenosis and regurgitation. We believe he will need a replacement. I'm concerned about him getting the COVID-19 vaccine given the reports we've seen about myocarditis. Do you have any advice for a mom?"


**Dr. Eleid:** Yeah, I think I can definitely feel for Amy and wanting to do the best thing for her son. I'm not sure how old her son is, but I assume he must be relatively young. There are some reports of higher – slightly higher risk of myocarditis in younger males. When you weigh that small risk with the risk of COVID-19 infection, particularly in someone whose immune system might be weakened by cardiac surgery, I think that would really favor vaccination in most cases. I think most likely he would benefit from vaccination.

**Adam Pick:** A quick follow-up to that would be for any patient on the line who might be getting ready to have a valve procedure or who may have just had a valve procedure, is there any reason that you know of which someone should not get vaccinated?

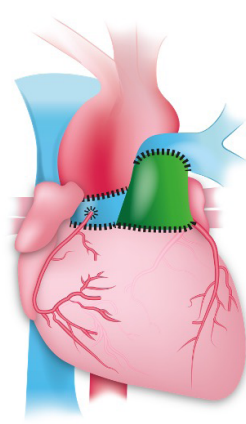
**Dr. Arghami:** For our surgical patients, our current advise is to distance at about two weeks so we don't mix symptoms or any other overlapping issues between the surgery and the vaccination.

**Dr. Eleid:** I would agree with that. I think there's some very infrequent scenarios where some patients should – like patients who've had a stem cell transplant should check with their transplant doctors, but the vast majority of people will benefit.



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Ross Procedure



Stacy asks, "I'm in my late 40s and very outdoorsy (hiking, kayaking). I need a new aortic valve due to calcification / stenosis. I've been reading about the Ross Procedure. I understand it's a two-valve procedure. Is the Ross less durable because of that? What are the doctors' thoughts on this?"

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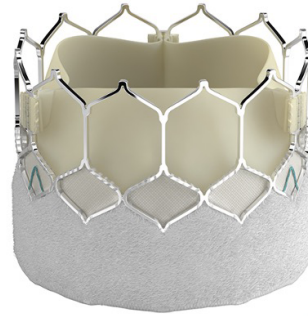
**Adam Pick:** Moving on to another form of valve replacement – we haven't talked about it yet, so I'm thrilled that Stacy asks this question. It's all about the Ross Procedure, and she says, "I'm in my late 40s and very outdoorsy." She does hiking, kayaking. "I need a new aortic valve due to calcification and stenosis. I've been reading about the Ross Procedure. I understand it's a two-valve replacement. Is the Ross less durable because of that? What are the doctors' thoughts on the Ross Procedure?"

**Dr. Arghami:** Very good question, Stacy. I'll take this, Mack, if you're okay. Ross Procedure – just going to briefly explain it to those listeners who don't know about it – is removing your – so it's for treatment of the aortic valve, but you remove the pulmonary valve. If you remember from the first slide that I showed, that's the right-sided valve. You cut that out from the own patient's heart, put it in the place of the aortic valve, and then put another prosthesis for the pulmonary valve, the reason being the pulmonary valve is in a less pressured system, so the blood pressure on the right side of the heart is not as strong as the left side of the heart, so it should last longer and it's – I don't want to say less important valve but it's – has less effects. You give the patient their own valve on the left side, which is important.

The benefit – the other benefit is because both valves are tissue, your own tissue – the other one is animal tissue – you don't have to be on blood thinners. Now, this is a little bit of a controversy, and there are some proponents and opponents of this technique because you turn one valve problem into potentially two valve problem; now you've changed two valves. It does have its own merits, especially in the younger population, especially those that cannot tolerate or should not be put on blood thinners on a mechanical valve. One of the good examples is young females that are planning to have kids and get pregnant That's not conducive for somebody on Warfarin. There are a few other examples. Ross Procedure is good in the younger population, and it requires a good discussion between the patient, the surgeon, and the cardiologist to come up with a good reason and plan, a very good question.

**Adam Pick:** I love the way you contextualized the appropriateness of the Ross Procedure by age and gender as it is a very unique procedure. To Stacy, I had a Ross Procedure preformed over 15 years ago. So far, I've been free from any form of re-operation. If you have any questions, you can simply email me at [adam@heartvalvesurgery.com](mailto:adam@heartvalvesurgery.com), and I will do my best to answer any questions you have about the Ross Procedure.

Eli asks, "I am 93 with an Edwards TAVR (size 23 mm) implanted 3/29/17 and with a current left ventricular ejection fraction of 65-70%. Should this valve fail, what is the current likelihood of a successful valve-in-valve transcatheter insertion of another tissue aortic valve of adequate size to function well for at least several years?"



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Moving on, Dr. Eleid, I'm hoping you can take this question. Eli is asking about valve-in-valve.

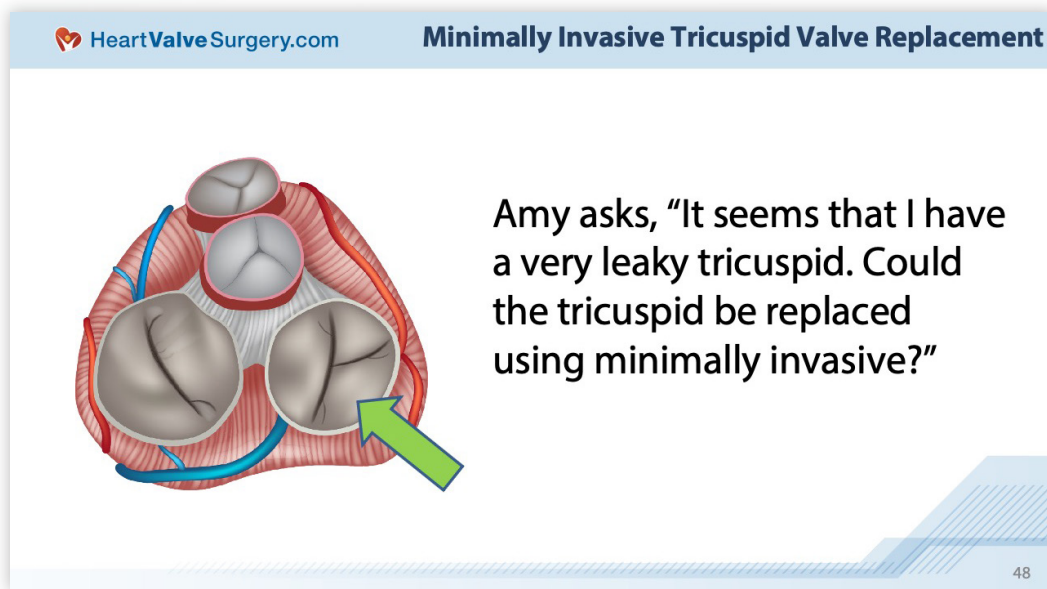
One thing we've been talking about at HeartValveSurgery.com is the lifetime management of valve disease, which sometimes gets overlooked. Eli's a testament to that.

Eli asks, "I am 93 with an Edwards TAVR, size 23 millimeter, implanted in 2017, and I've got a current left ventricular ejection fraction of 65 to 70%." Go, Eli, "Should this valve fail, what is the current likelihood of a successful valve-in-valve transcatheter insertion of another tissue aortic valve of adequate size to function for at least several more years?" Thoughts on this, Dr. Eleid?

**Dr. Eleid:** Yeah, well, I really like the way Eli thinks, and I think he must be a go-getter. This is great to see, but usually what we have to do – I think in many patients, we do have some evidence now that TAVR in a TAVR is feasible and the safety of it is comparable to the first TAVR in many patients.

I think the one group of patients where we have to be even more careful is those patients who have a smaller aortic root. That's true also for surgery too. With TAVR, the open cells – you can see this image of this sapien valve that is open cells, so that allows for blood to flow freely. The sinuses of valsalva above the valve need to be large enough to accommodate a valve-in-valve because when that new valve goes in, it will push the leaflets off to the side, and we need to make sure those leaflets don't prevent flow through the coronary arteries, which are right in that area.

A CT is used for planning of that, and most patients will be candidates for that. It depends on their anatomy.



**Adam Pick:** We're going to move onto a question that comes from Amy about a valve we haven't talked about much today, which is the tricuspid valve. She asks, "It seems that I have a very leaky tricuspid valve. Could the tricuspid be replaced using minimally invasive techniques?"

**Dr. Arghami:** Tricuspid valve is the opposite valve of the mitral valve on the right side. They actually go hand-in-hand. A lot of times when you have a leaky mitral valve, you can get a leaky tricuspid valve. Even more recently, we tend to repair those tricuspid valves at the same time that we fix the mitral valve. I don't know if she also has mitral valve problem or if that has been treated before. It can be treated, and I can do that robotically as well. As I mentioned, we do it very frequently together, so it's a very doable procedure and almost always can be repaired. Replacement can also be performed but less likely is required. There are also anthro-based options, which again, Dr. Eleid can allude to it, which is also possible.



**Dr. Eleid:** No, that's exactly right. Yeah, in the patients who are not good candidates for surgery who have severe tricuspid regurgitation, we do have several transcatheter options that we're investigating. There aren't any approved options, but we have clinical trials. Some of these are very viable options.

One is edge-to-edge repair option similar to what we showed you on the mitral valve. Then we also have a replacement valve option, too, that is a randomized trial, so it's very exciting.

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Pig Valve Replacement In Mitral Position

Veronica asks, “I’ve seen some interviews on Adam’s website that suggest a pig valve is better in the mitral position. Why is that?”



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**Adam Pick:** Great, and let’s now talk about a specific type of valve, the pig valve. This is a question that comes in from Veronica. I know, Dr. Arghami, you mentioned earlier about the advantages of always doing your best to have the patient have a mitral valve repair procedure done but at times – I’m imagining that that’s just not possible and you need to replace the valve. Veronica asks, “I’ve seen some interviews on Adam’s website that suggest a pig valve is better in the mitral position. Why is that?”

**Dr. Arghami:** Well, as you said, Adam, I think sometimes it does require replacement. A lot of times are not the primary mitral valve disease or sometimes the secondary mitral valve disease that requires that, so it's not a problem with leaflets.

Now, in terms of the valve types or brands, I would like to caution your viewers again to be cautious and a lot of times maybe trust the data and trust the surgeons in this regard. As you can imagine, a device or a valve that takes 10, or 15, or 20 years to really show the durability and the consequence of it, it's really hard to study. Somebody has to follow somebody for 10, 20 years to realize oh, this valve that was put in 20 years ago was good or not. We're talking about a very small, subtle variation.

At Mayo Clinic, we use the valves we have adequate data or we have good reasonable suspicion that they will last as promised. There are new technologies that companies try to investigate, which is great, and they try to come up with data, but some of those claims, you have to read the fine prints and make sure that this is not just a promise and it's actually been studied. That's one of the things I want to caution your viewers to be aware of.

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The Future

Adam asks, "How will heart valve replacement procedures transform during the next 10 years?"



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**Adam Pick:** Excellent advice. I just have a question for you both. If you were to look ten years into the future... What and how do you think heart valve replacement procedures will transform going out to 2031?

**Dr. Eleid:** I think one thing we're seeing now is that there's really been an explosion of excitement with the transcatheter valve technologies, and this is allowing for treating patients that previously many of whom couldn't be treated.

One of the things is we are able to treat more valve disease in the next ten years. That's good because our population is aging, and we know valve disease comes with age as well. With the aging population, we need to have less invasive treatments. I think it's going to become more successful. We're going to get better at selecting for transcatheter replacement versus repair. We're going to learn more and more about the best candidates for which procedures. I think some of the highly successful things like surgical mitral valve repair that Dr. Arghami showed you will continue to be a great option for patients.

Do you see that changing at all, Dr. Arghami, that your robotic techniques?

**Dr. Arghami:** I think they're just going to improve, as well. I think as we've seen in the last ten years, we've gone from an incision this big to now literally tiny pencil-sized incisions, and it just continues to get better and better. The technology continues to improve, right now cannulating without cutting in the groin, which was another incision in the body that we have eliminated.

In terms of surgical valves, as I alluded to earlier in the first question, there are technologies that can grow your own valve, if you want to say, and the more durable, the more or less reactive the valves are. We're going to learn more which valves are durable, which techniques that reduce the calcification of the valve are more useful.

The future is just going to be less invasive, less bothersome to the patient's lifestyle, and more durable.



**Adam Pick:** Fantastic, and I know we just talked a lot about the future. I just want to bring everybody back to the present. In the present, I want to be very thankful to you, Dr. Arghami and Dr. Eleid, to put together this presentation, to answer the patient questions. On behalf of our community, the folks you've already treated, and the folks that you'll treat in the future, we can't thank you and the team at Mayo Clinic enough. Thank you for being with us today.

**Dr. Eleid:** Pleasure.

**Adam Pick:** To all the wonderful members of the community, please don't exit just yet. I want to take a moment to thank you for being part of this session today and learning all about the advances in heart valve replacements. It's always great to have these community events so that in real time, we can learn together, get educated, and feel empowered. On that note, I want to thank you as we wrap up this wonderful webinar with a survey that is going to appear on

## HeartValveSurgery.com Resources for Patients

Since 2006, [HeartValveSurgery.com](http://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.

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[Heart Valve Learning Center](#) - Visit the Heart Valve Learning Center to access over 1,000 pages of educational information about valvular disorders.

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