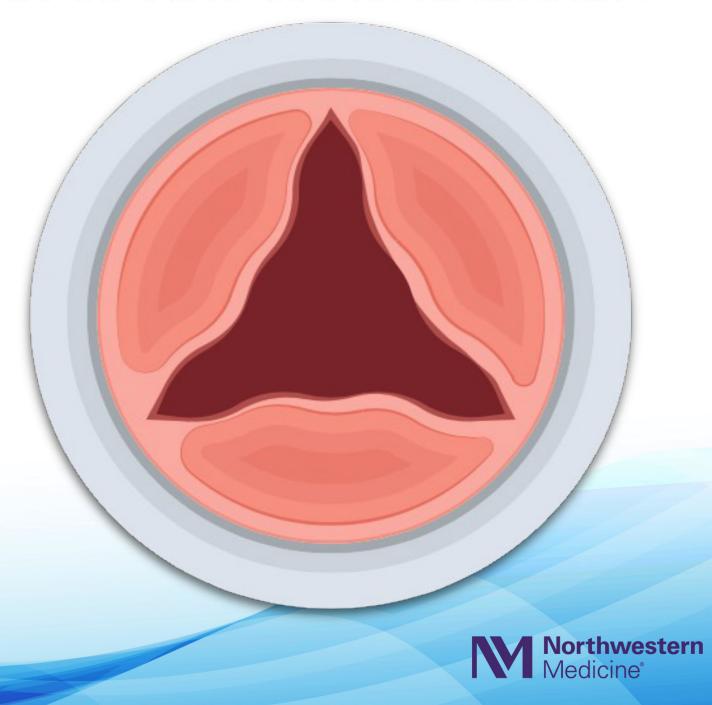


LIFETIME MANAGEMENT

OF HEART VALVE DISEASE



Featured Speakers



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Learn More.



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





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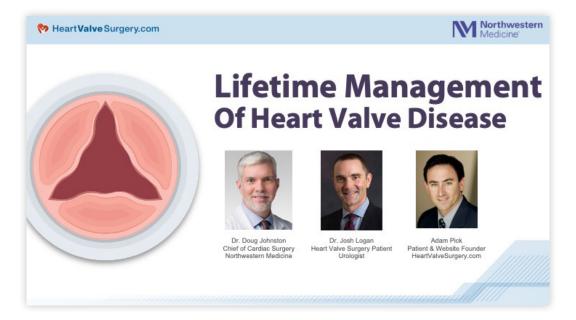
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Introduction



Adam Pick: Hi, everybody. My name is Adam Pick and I'd like to welcome you to the webinar titled "The Lifetime Management of Heart Valve Disease". If I've yet to meet you, I'm the patient who started HeartValveSurgery.com all the way back in 2006. The mission of our website is very simple: we want to educate and empower patients just like you. This webinar, which has had over 975 registrations from patients in countries all over the world, was designed to support that mission.

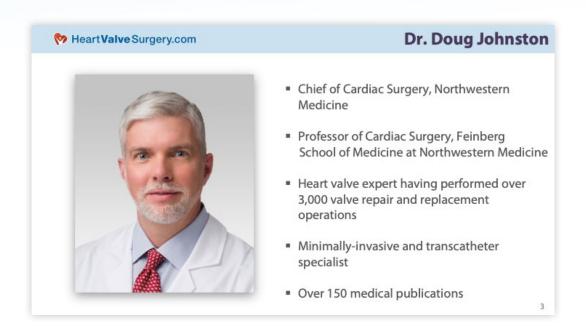
Throughout the webinar, you're going to be in what's called "listen-only" mode, but I'd encourage you to submit your questions in the control panel that's on your screen.





Adam Pick: Let's look at the webinar for today. I'm going to introduce the featured speakers. We're going to learn several heart valve disease insights. We're going to better understand patient needs, look at some therapeutic options and strategic considerations. Then, we're going to have a really great patient success story of Dr. Josh Logan, and then have a "Q&A" section so please submit your questions. Lastly, I'm going to ask you to complete a very quick five-question survey as we wrap up the webinar.





Adam Pick: When it comes to the featured speakers of the webinar, I am honored that they are taking time away from their very busy practices to be with us today. To start, I'd like to introduce you to Dr. Doug Johnston. I've been very fortunate to know Dr. Johnston for over ten years. He is the chief of cardiac surgery at Northwestern Medicine. He's a professor of cardiac surgery at the Feinberg School of Medicine at Northwestern. If there's one thing I know about Dr. Johnston, he is a heart valve expert. He's performed not 1,000, not 2,000 but over 3,000 heart valve repair and heart valve replacement operations. When it comes to the approaches, Dr. Johnston is a minimally invasive and transcatheter specialist. Dr. Johnston is also very into research, and he's been featured in over 150 medical publications. Dr. Johnston, thanks so much for being with us today.

Dr. Doug Johnston: Adam, it's great to be here as always and really looking forward to it.





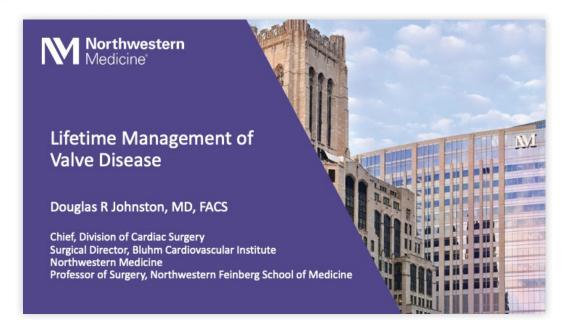
Adam Pick: I could go on, Dr. Johnston, about your achievements and your accolades, and I don't want to make you blush, but what I really love doing is showing the results of your work and the team at Northwestern. What you see here are the pictures of the smiling faces of those patients in the HeartValveSurgery. com community who have gone to Dr. Johnston and his team at Northwestern and had very successful results. Whether it's Jane, or David, or Paul, or Janet, or Janice, and on the line with us today, all the way from Anchorage, Alaska, is <u>Dr. Josh Logan</u>, who just had minimally invasive aortic valve replacement surgery with who? Dr. Johnston. Dr. Logan, thanks so much for being with us today.

Dr. Josh Logan: Thanks for having me, Adam. It's good to be here.

Adam Pick: So, we've got a world-renowned surgeon. We've gone one of his patients, and now it is time on behalf of our community to welcome you both. Dr. Johnston and Dr. Logan, thanks for being with us today. We're going to start this webinar with Dr. Doug Johnston.



Physician Disclosures



Dr. Doug Johnston: Even though this is not a CME event, we always have a disclosure slide. I think one thing to note when you talk to surgeons is a lot of us who do work on valve disease work closely with the companies. We're going to answer some questions about valve durability and how we do valve-in-valve procedures.



Disclosures

- · Edwards Lifesciences Consultant
- WL Gore Consultant, research support
- · Artivion Research support and Steering committee Proact-Xa
- · Terumo Aortic Consultant, research support
- · Abbott Consultant
- · Medtronic Consultant, research support

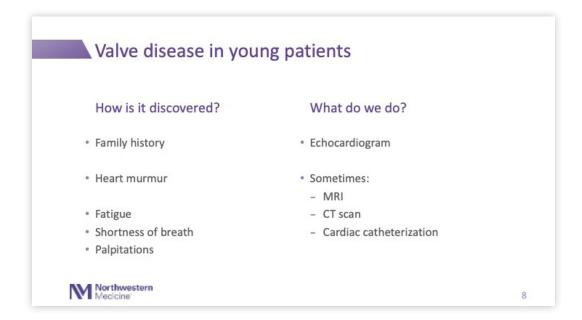


The only way we get better at that is if we are tightly involved in the engineering process for new devices. I just put this up here for this talk just to remind us all that this is a back-and-forth with a very big group of people including a bunch of engineers who develop these devices and that we have to thank them for their efforts to continuously improve what we have to do.





Heart Valve Disease In Young Patients



Dr. Doug Johnston: So we're talking about lifetime management today, and it is one of my favorite things to talk about in heart surgery. Adam knows, and I told him today, he has to cut me short because I could talk for hours about this.

When we're talking about lifetime management, the first decision we make is usually going to be in somebody who's relatively young. Young is very relative in 2023. We have 80-plus year olds running marathons and working long hours. The age at which you find out you have a valve problem is the age that we start thinking about how this is going to go for the rest of your life.



We think about a bunch of things. How is this discovered? There can be a bunch of different ways that you could come to attention. It could be a family member; it might be a mild symptom.

Often, this comes as a huge surprise, otherwise healthy people who are just like what? I have this valve problem?

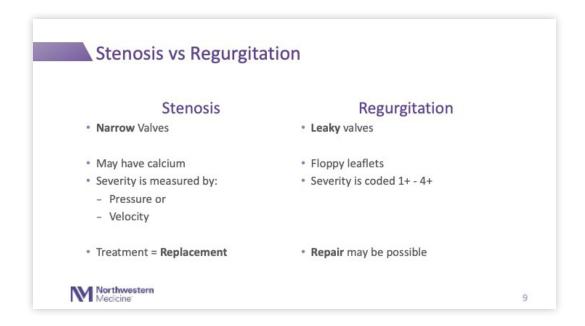
This is something totally new, and it's scary, especially when you may hear the words "open heart surgery" as the first thing that comes to mind.

What do we do for you? All of you who have valve disease are going to get an echocardiogram. That's the baseline study. You may be recommended a bunch of other studies off-the-bat, and that may be a little bit overwhelming, but all of it is designed to get a better idea either what the valve's doing, what the heart's doing, or what else is going on with you that we might have to treat in the OR.





Stenosis vs. Regurgitation: An Overview



Dr. Doug Johnston: So broadly, you probably heard these terms, stenosis and regurgitation. It's worth just going over just briefly because the treatment is somewhat different. Stenotic valve means narrow. That's just the scientific term. Often, those valves may have calcium. There are other reasons for thickening, but when you read your echo report, the way that we measure the severity of stenosis is by pressure or velocity. You're going to see some terms about that.



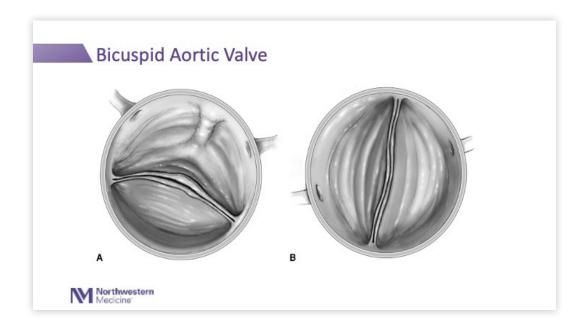


By and large, with rare exceptions, the treatment for a stenotic valve is going to be replacement.

Regurgitation, on the other hand, which is a leaky valve, often means floppy leaflets. The severity is coded a little differently. It's one-plus to four-plus. It sounds very unscientific. There's some fancy measurements in there, but that's the scale. The difference from stenosis is that in some cases, depending on the valve, repair may be an option for a leaky valve. So, it's at least something we're going to consider.



Bicuspid Aortic Valve Insights



Dr. Doug Johnston: Let's talk about a few of the conditions that you may be dealing with that would lead to the decision for heart surgery in a young patient. So bicuspid aortic valve, one of the most common ones – this is obviously a very old drawing in black-and-white. On the left side is the most common form, which is essentially of the three leaflets of the valve, two are stuck together at birth. This is a way the valve was formed. People say it's the most common congenital heart disease. It's not really a disease; it's just a different way that the valve has formed genetically. On the right is a bicuspid valve where both – it's only two leaflets. This is a much more rare form, but this is what it means, bicuspid versus tricuspid, which is a normal aortic valve.



Bicuspid Patients

- 1-2 % of the population
- 331 Million in United States
- 5 M Bicuspid valves
- At least 250,000 will need surgery within 10 years for valve or aneurysm

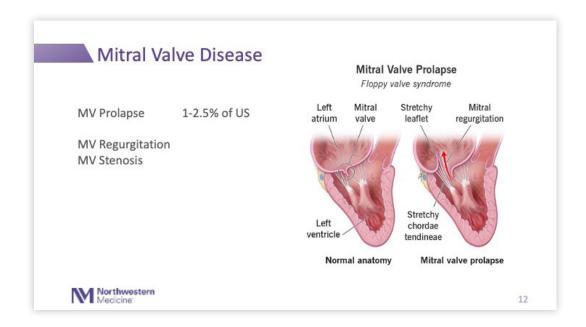


Dr. Doug Johnston: Bicuspid valve disease, really common. One to two percent of the US population, indeed, the world population, has a bicuspid valve. That's a lot of people. If we think our population is 330 million, there's at least 5 million people in the United States with bicuspid valves and probably 250,000 of those people are going to need surgery in the next ten years. So, there are a lot of people who may not know they have the problem but will come to attention either because (i) the valve or in the case of bicuspid valve or (ii) sometimes the aorta is involved with an aneurysm.





Examining Mitral Valve Disease



Dr. Doug Johnston: The next most common disorder is mitral valve disease, and many of you have heard the term mitral valve prolapse. If you look in the literature, they're going to say one to two-point-five or three percent of the US population. It may be higher than that that has prolapse. All prolapse means is of the two mitral valve leaflets, they're supposed to close like a door closing where it closes flat in the same plane. If those leaflets rise up above that plane and they're a little bit floppy, that's prolapse. Prolapse doesn't mean you have a leaky valve.



Prolapse is incredibly common. It can be associated sometimes with palpitations; sometimes that's how it's found. A portion of patients with mitral valve prolapse will go on to develop mitral valve regurgitation. It's one of the most common reasons for us to do a mitral valve repair.

Mitral stenosis is more common as people get older. In some parts of the world where rheumatic heart disease is still a thing, mitral stenosis can happen in very young patients, and there are few more rare conditions that lead to mitral stenosis.



Understanding Patient Needs



Dr. Doug Johnston: I'm going to talk in a little bit more in the end about tricuspid and pulmonic valve disease, a little bit less common. As a general principle, since we're just talking about lifetime decision-making, what we're really talking about is what's wrong with the valve, what else might we need to consider, and what's wrong with the valve, what I mean is it a leak where we might think about repair? Is it a narrowing where we're going to think about





replacement?

What do patients want? What do you guys want? You want information, number one. You want to know what's going on. That's the purpose of why we're here today. Most of you want a normal lifestyle, and I think this is where if there's one thing you take away from this webinar today is that **if somebody tells you there's only one option for your valve, that's time for a second opinion.**These days, there are a lot of good options, and many of them are consistent with a normal lifestyle. It may mean that there's another intervention in your future, but if you can go 10, 15, or more years without taking blood thinners, that may be very important to you.

Also in consideration for timing an intervention for valve disease is the question – are people asking you to limit your exercise or limit your work? I take care of a lot of unique populations of patients, people like Josh who are super active, people who are out in the wilderness doing all kinds of cool stuff who don't want to be limited on their free time; also don't want to be limited in their work, people like pilots, people in the military where really, an exercise restriction means you can't do your job. That's very important. If any of you were ever told your valve's not ready to have an intervention, but I don't want you to do anything serious in terms of exercise, that's also time for a second opinion because limiting your lifestyle for months or years, waiting for a future intervention may not be right for you. That's a discussion between you and your team.

Many of you want a small incision. Of course, all of us want a small incision, and that's always going to be part of the discussion. I think more than anything else – next one – you want a fast recovery. If you need something done, you want to get up and running again and back to the rest of your life.





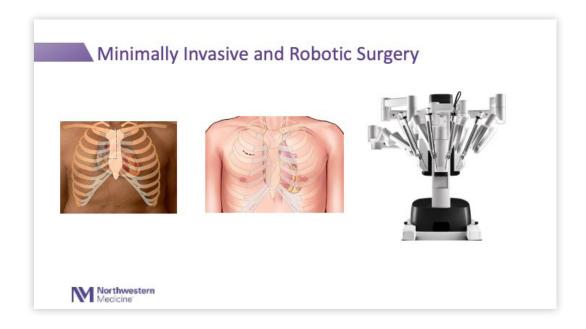
Dr. Doug Johnston: So lifestyle, increasingly, is one of the things I hear from patients that's most important to them.

So how do we think about this at Northwestern? Our valve center strategy comes down to one thing: it's about the patient. We have to get to know what's wrong with your valve. We have to get to know what's going on with your heart and everything else in your chest that might affect what procedure we can do, and we got to know you as a person and what is important to you. Your priorities may be very different if you are a 35-year-old who races motorcycles for a living. That's a former patient of mine. Or, if you're an 85-year-old grandmother who just wants to be able to run around after the grandkids. Those are two different thought processes, two different lifetime management strategies. So patient-centric and lifetime-centric, and that's the way we think about it.





Minimally-Invasive Considerations



Dr. Doug Johnston: Let's talk a little bit about small incisions, because all of you are interested in this. I'm often asked, can procedure X be done with incision Y?

There are some ways we can think about this globally that will help us to understand this. I think if you start from the principle that if you have a relatively straightforward valve problem, you need one valve repaired or replaced, then there's often a minimally invasive approach for you.

If your heart has a bunch of things going on and you need a bunch of different things done, or if you've had prior heart surgery, it may be possible to do a small incision, and a transcatheter approach may be possible, but in general if you need heart surgery, think about this...





Which is the most important thing for you, safety, whether you're going to survive your operation, how long you're going to live and what your lifestyle is after your operation, or how big your incision is and the scar that you're going to show at the beach?

The way we think about this is safety is number one. Durability, effectiveness, lifestyle are number two. Number three is incision size. If we can do the same operation with the same safety and the same durability, then a small incision is great.





Robotic Mitral Valve Repair Advantages



Dr. Doug Johnston: So just want to show you a brief video about what it looks like to repair a mitral valve with the robot. This is Dr. Kevin Hodges, who is joining us from the Cleveland Clinic at the end of this month or next month, performing a mitral valve repair with the robot. It's a brief video here. What you see on the screen there, the robot is cutting out a floppy part of the posterior, the back part, of the mitral valve.

You see how good this video is? You're going to see one of my videos that was shot in the operating room doing a mini thoracotomy operation with a regular camera. The robot visualization is amazing. This has been a great tool to allow for less invasive mitral valve repair but also more complicated repairs through a small incision. Those tools you see there – it almost looks like somebody's hands doing this. That's called an endo-wrist. That's what makes the robot so cool. You can tie with it. You can sew with it.





There's the leaflet being repairs. Now he's going to sew in this band which stabilizes the valve.

This is increasingly a technique that many patients with mitral valve disease who have primarily regurgitation can be evaluated for. Not everybody's a candidate, and we don't have time to go through all the pluses and minuses of robotic surgery, but increasingly, tools like this are going to allow us to do more complicated operations through small incisions. There's the nice repaired valve on echo.

We have to have perspective with respect to that and then offer the patients that will impact them in the most positive way, so we always need to consider what is next if and when another valve is needed, right?

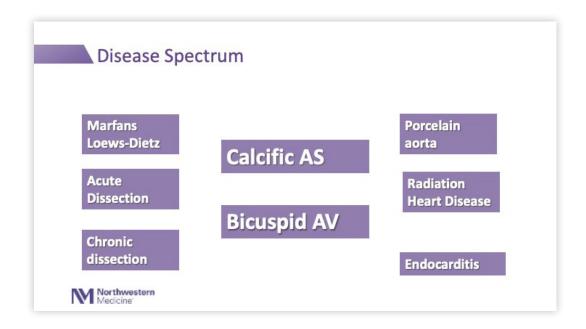
Examples: I just talked about dysmetabolic syndrome, 64-year-old gentleman, diabetes, hypertension. He's 64 years old. This was a woman, actually. Only 3.5 years into the valve, so this is early, right? But the patient also had a high bleeding risk, so I had to use another tissue valve. This time I switched to a different type of tissue in hopes that we might get a little more mileage out of it, and I made sure I put a big valve in. The point being that the clock is different for every human being.

45-year-old gentleman who had a transcatheter valve in who had chronic renal failure, a sick heart, and they put a transcatheter valve in him, but it didn't last very long. People with renal failure will really burn through a tissue valve quickly, so we took that out and put a mechanical valve in there.





Complex Aortic Valve Disease Management



Dr. Doug Johnston: Talking about aortic valve disease, it's actually a little bit more complicated discussion because so many things can affect the aortic valve. I just put this up there to show the spectrum of disease that people might be told their valve needs something done. It's a huge spectrum from patients with bicuspid aortic valve where they might be amenable to a very small incision surgery, to patients with where the aortic valve is part of a spectrum of aortic disease that might require a very extensive repair. The good news is that the expertise exists to do really good work on all these things, but they're all different.

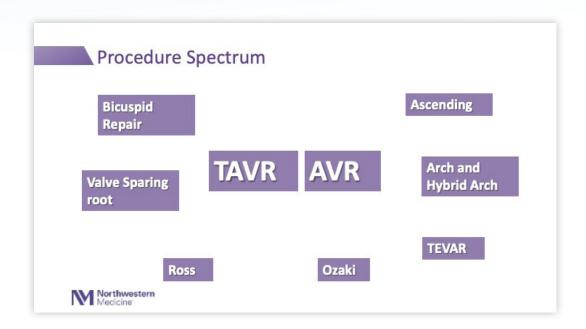




The key is find the right team, the right surgeon, the right cardiologist, the right team who's going to help them. Let them work with you to understand the spectrum of what's going on. If we're doing our jobs, we offer and treat people with blood thinner in the appropriate scenarios, so if a patient has a thromboembolic event, stroke, a thromboembolism, if their valve is deteriorating, if it's severely deteriorated, it's become stenotic, we should probably have them on anticoagulation. If we do a valve-in-valve – we haven't figured this out yet. Is everybody supposed to be anticoagulated, or some supposed to be anticoagulated?

Tissue valve is not a free pass. If we look at nationally, one third of people who have tissue valves are on blood thinners, real anticoagulation like Eliquis or Warfarin. Remember, you've got a disease. We're trading it for a different one. What are people afraid of, and what do they need to think about? Device selection. We talked about that. Operative method, also, right? We need to think about is it minimally invasive. Do we need to do a root enlargement? Do we have to replace the whole root? We have to treat the aorta?





On the next slide is a little bit about what we can do for the aortic valve. You're going to hear a lot about the terms TAVR, transcatheter aortic valve, and SAVR, or surgical AVR, lots of other procedures that may be appropriate in certain circumstances, but those are the big two we're going to be talking about, both for the first intervention and the subsequent ones.

Patient	Valve	Aorta
Robust vs Frail	Shape	Root
Other Medical Problems	Leaky or narrow?	Ascending
	Extent of calcium	

So, let's think about a young patient with aortic disease, and young is in parentheses for a good reason, because as I said, young active people who are in the prime of life and doing a lot of great stuff and have many years to live meet that definition. They might need multiple interventions. First thing we're going to want to know, what's going on with the patient? Is this someone where the valve is the only problem, or is this somebody with multiple medical problems that make them high risk for surgery where we really need to think about getting them through the operation safely?

Number two, what's going on with the valve? Leaky or narrow/ Is it bicuspid or tricuspid? How much calcium? Number three that's unique to the aortic valve is what's going on with the aorta, the major blood vessel that leaves the heart? Next slide?



Adam Pick: Dr. Johnston, for folks who might be newly diagnosed, could you maybe very quickly help them understand the relationship between a potential valvular defect in the aortic position and the aorta, how those two play together?

Dr. Doug Johnston: That's a great question, Adam, and they play together in a very complex way. Easiest one to talk about is bicuspid valve disease. You may have read or heard that if you have a narrow valve and the blood is essentially squirting through this narrow opening that it can make the aorta dilate. There is some evidence that that happens, enlarge or dilate. More likely is just that the same genes that make your valve bicuspid affect the strength of the ascending aorta in some patients. The flipside is also true. If you have an aorta that is expanding, it can pull on the valve leaflets and give you aortic insufficiency or a leaky valve. So there's a tight interplay between the valve and the aorta, and that's why there's not a one-size-fits-all for aorta valve disease.

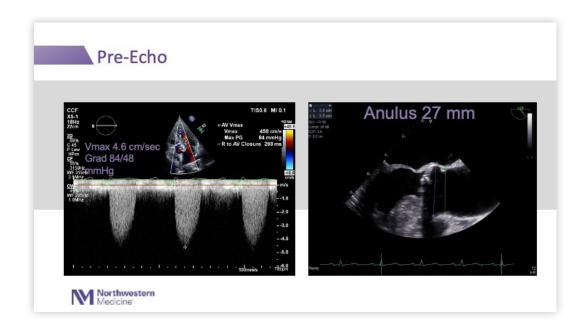
Patients will often say well, I've got an aneurysm and narrow valve. Can I have a transcatheter valve? The answer is maybe. It really depends on what the aneurysm shape is and how it relates to the valve. It's a very complex interplay, and part of it is simple. We need an echocardiogram and we need a CT scan in pretty much everybody who has a ortic valve disease to figure out which of those things is right to do.

Adam Pick: Thank you.





Patient Case: Bicuspid Aortic Valve



Dr. Doug Johnston: Very quickly, just an example of a patient with typical bicuspid valve disease. This is the evaluation we go through here at Northwestern. First is an echo. We talked about measuring pressures; that's often called the gradient across the valve. Magic number there is 40. If you have a gradient greater than 40 millimeters mercury, that's considered severe. That's the range where we're often going to talk about surgery. You can see those readings there. Then the echo also gives us some measurements of the annulus; that's the ring that holds the base of the valve, what's the size of the valve. Gives us a little information about the aorta but it's not as good as a CT. patients I know me included don't always understand, this idea of trading diseases. I've got aortic stenosis. I've got symptoms. I need a valve to help out, but what you're alluding to here – and correct me obviously if I'm wrong. What you're saying here is by getting that bioprosthetic valve, now you have a different type of disease. Is that what you're suggesting?





So one pearl I want to leave you with today... If anybody tells you there's only one thing to do, get a second opinion. The other one is if somebody wants to operate on you based on an echocardiogram alone, don't let them operate on you because the state-of-the-art in 2023 is 3D imaging, meaning a CT scan or an MRI, especially for the aortic valve. In this case, we're looking at the ascending aorta to see if it's enlarged. This is a mildly enlarged aorta, 4.3 centimeters. We can do some fancy calculations based on the patient's height, but this is somebody who probably doesn't need aortic surgery at the same time as the valve. The only way we can tell that is with a CT.

Adam Pick:You brought up this concept of getting the second opinion. I'm sure there's a lot of folks on the line. Sometimes they have things like white coat anxiety. How do I tell my referring cardiologist I want to go somewhere else and get a second opinion? It might cause some awkward feelings for them. What is your recommendation for how they should do that or where should they go to get a second opinion?



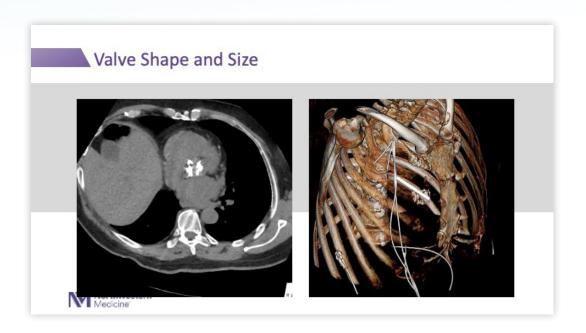
Dr. Doug Johnston: That is a great question. Number 1, you should never be concerned about asking for a second opinion. If you ever get a difficult time about that, you're in the wrong place. That's even more reason to get a second opinion. The way I would say it to your cardiologist, your PCP, your surgeon, whatever it is, I really want to feel comfortable with my decision to go forward with surgery or watchful waiting, whatever the recommendation is. I found out XYZ place that can give me some more information. I'd like to ask you for my records so that I can send them there and then I'd like to discuss it with you after I've talked with this other physician or this other institution. That's a very straightforward thing. Every physician should be used to that.

Like I said, if they're not, if they try to make you feel uncomfortable, you're in the wrong place. Then it's even more reason to get a second opinion. Many places like Northwestern offer virtual second opinions. I do it for patients all over the world. They send the records in, my nurse will gather everything together, and we do a telehealth visit. We can look at the imaging together online. Sometimes it's like, hey, your tests look pretty good. Here's what I would recommend down the road for you if you need surgery and we'll see you in a few years.

That peace of mind for having had somebody else go through it with you, and many patients will get a second opinion with me and stay at home for their surgery. That's fine, too. It doesn't mean that you're committing to go somewhere else. I would absolutely encourage you to do that, even if it's just to get some quick questions answered. You want to go into, especially surgery, with a peace of mind.

Adam Pick: Yes, thank you so much for the patients out there. I always say, when I'm on the line talking to patients, this is not a haircut. This is a really big deal. Be 100% comfortable when you're being rolled into the operating room.

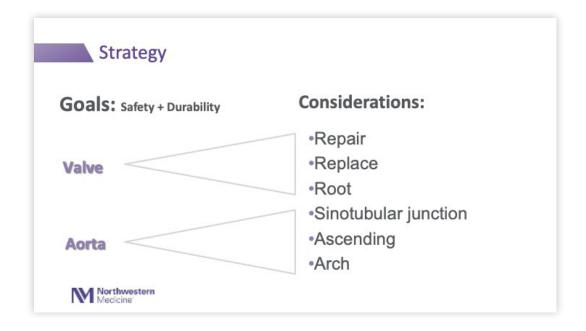




Dr. Doug Johnston: Just an example, this is the kind of view that we can get. We have this 3D reconstruction tool we can spin everything around. If you just click the right arrow, this allows me to see exactly where the incision is going to be on a patient like Josh. I know exactly where the valve is, where the incision is, I know everything we're going to do before we get in there. Again, CT is just a super powerful tool for planning for surgery for valve disease.



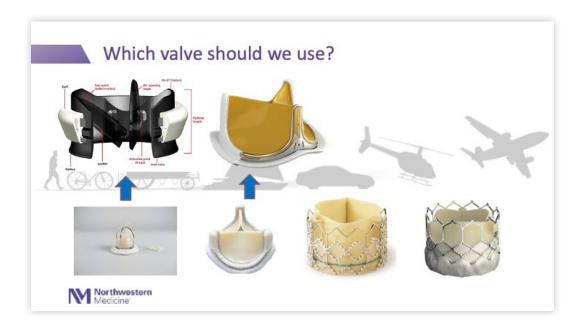
Strategic Approach to Heart Valve Surgery



Dr. Doug Johnston: Just briefly, when we think about surgery, and I'm using the aortic valve as an example, but this holds for many other ones, as we said, our goal, Number 1 goal is safety. Number 2, you could say effectiveness, but durability, lifestyle, those things that are going to carry the patient forward. We have to look at the valve and everything around the valve to think about that.



Heart Valve Replacement Selection

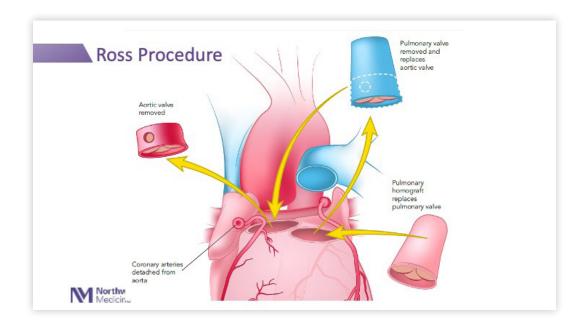


Dr. Doug Johnston: We have come to the very important discussion of, all right, I need a valve replacement. What valve am I going to get? On the left you see this Starr-Edwards valve. That was the first replacement mechanical heart valve to go actually replace in the position the valve was, believe it or not, in the 1960s. There's this idea that there's this inexorable progression of valve technology from that to modern TAVR valves, but we sometimes forget that every category of valve. So, mechanical valves and stinted tissue valves, which is the next one, and TAVR valves are all getting better as technology improves.

Year by year, the data is constantly changing, but what you can be confident in is we have some really good technology to use now, which is a world better than it was when I started my training in 2005 for cardiac surgery, none of the stuff that we use today was available. I mean, that's not that long ago. None of the particular tissue treatment, TAVR was not a thing. That's pretty fast in development of technology. There's great new stuff coming down the road. Stay tuned from the technology standpoint.

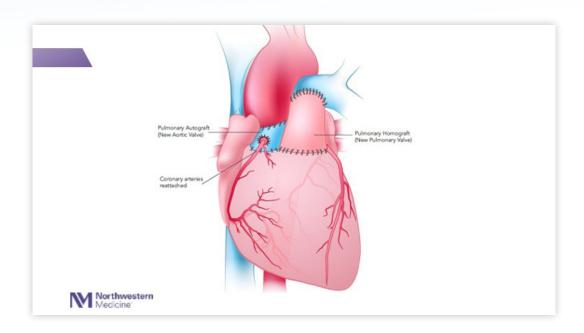


Ross Procedure



Dr. Doug Johnston: I want to make a few comments about the Ross and Ozaki procedure. These are all approaches to replacing the aortic valve. Across the country, this is going to be a minority of patients who get these procedures. There are a lot of reasons for that. Patients have to be very carefully selected,



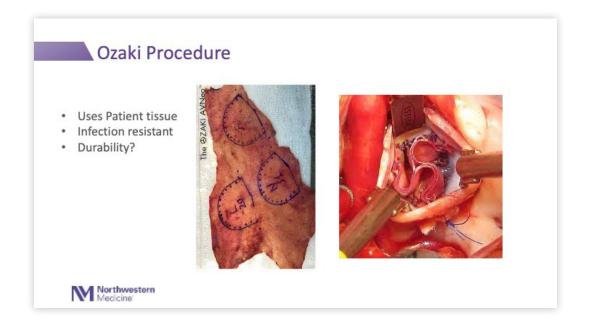


The Ross procedure is taking the pulmonary valve and putting it in the aortic position. Then we use a cadaver pulmonary valve to replace the pulmonary valve. There are particular groups of patients that really benefit from this: the very young, patients with small aortic roots, and as we get more understanding of the longevity of this procedure, I think the indications are going to slow expand.

There are some limitations. It's not a minimally invasive operation. It's a maximally invasive operation. It involves two valves, both of which have the potential to go bad, but the good news is that the durability over all is very good for the Ross if done in a modern way. But, in the right patient, this can be a great option.



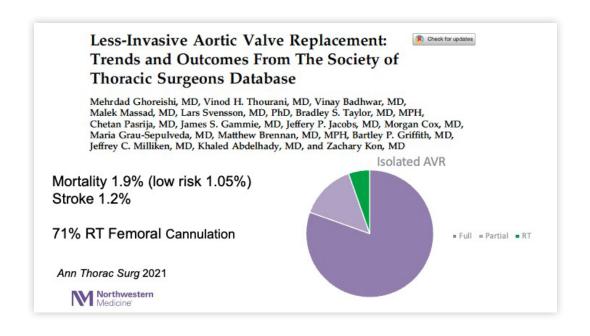
Ozaki Procedure



Dr. Doug Johnston: This is the Ozaki procedure, which is using your own pericardial tissue to create a heart valve. Then I don't want to leave us thinking that everybody needs a replacement. As we talked about, mitral valves are often minimal to repair. Some bicuspid valves, if they're not narrow, are also minimal to repair.



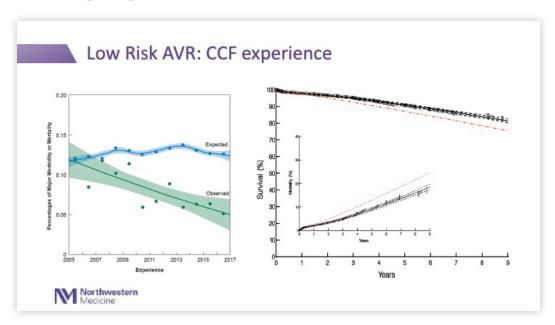
Research Update: Prevalence of Minimally-Invasive Techniques



Dr. Doug Johnston: Just want to briefly talk about, as we lean into talking to Dr. Logan. Minimally invasive aortic valve replacement, which even though it's a relatively standard procedure for people like me and at places like Northwestern, nationally it's not done very often. This is a pretty recent study looking at studies across the United States. That dark purple in the pie chart there is the number of patients who had a full up and down incision for their aortic valve replacement. Less than a quarter of people in the United States are having minimally invasive surgery, even if the only thing being done is just putting in a standard valve. You've got to look around a little bit for this.



Research Update: Risk and Survival of Heart Valve Surgery



Dr. Doug Johnston: For patients who are otherwise healthy and have an isolated aortic valve replacement, this is a study that we just published that I did when I was in Cleveland. On the left side, it shows that between 2005, which is when I started practice, and 2017, which is before intermediate risk patients were getting to TAVR, the risk of surgery declined almost threefold.

The risk of surgery currently is much, much less than what it was even 15 years ago. The caveat there is that is at centers of excellence. That is not every hospital, every surgeon who achieves those outcomes, but at a center of excellence that does a lot of valve surgery, on the right, shows the survival after an aortic valve replacement is actually better than general population.





You can be assured that you're going to do well for the long-term if you're in the right hands for surgery.

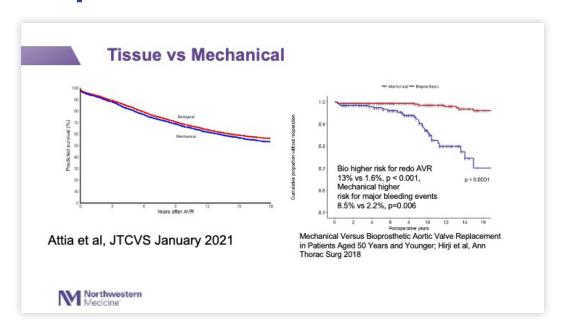
Adam Pick: I've got to ask. I'm sure patients are wondering about the term "centers of excellence". What constitutes a center of excellence for valve therapy?

Dr. Doug Johnston: I wish you could go to one easy place and find that. There's not a national adjudication of valve quality. We're working towards that in a lot of different ways. There's work underway to say what's the minimum number of operations a center needs to do to be considered at the top of their game, but we don't really have it yet. You have to do a little research on the size of the program, the experience of the valve team to get to the right place.





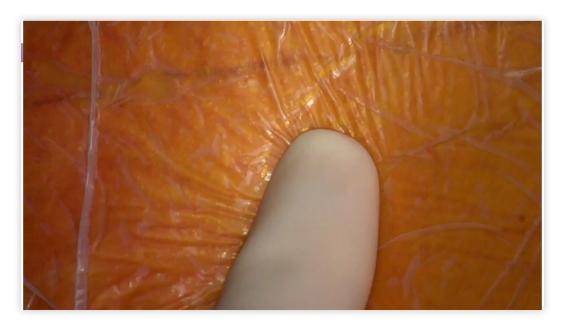
Research Update: Tissue vs. Mechanical Heart Valve Replacement



Dr. Doug Johnston: On tissue versus mechanical... On the left side, this is a big study that one of our fellows, Tamer Attia, who's now a great surgeon down at Emory did. We did three different ways of comparing how long you live if you get a tissue valve, biological valve versus a mechanical valve. Short story is no difference. In the right hands, right surgeon, and if you have the right follow-up, meaning if your tissue valve wears out or if you take your coumadin if you get a mechanical valve, you stand to an equal chance of living 18, 20 years.



Surgical Procedure Video: Mini-Thoracotomy Aortic Valve Replacement



Dr. Doug Johnston: Okay, I'm going to leave you with just a couple things here and then we want to turn over. Because we're going to talk to Josh in a second, this is not him, but this is a brief video that shows what a mini thoracotomy aortic valve looks like. I don't operate this fast. This is sped up a little bit. It's about two-to-two-and-a-half-inch incision in the right side of the chest in between the ribs. We do put a chest tube in. You'll see what that scar looks like a little bit later. You see nothing through this incision right now. It takes a little while to get things exposed. We put a canula in the femoral vein, which is in the groin, which helps us drain the blood out of the heart.





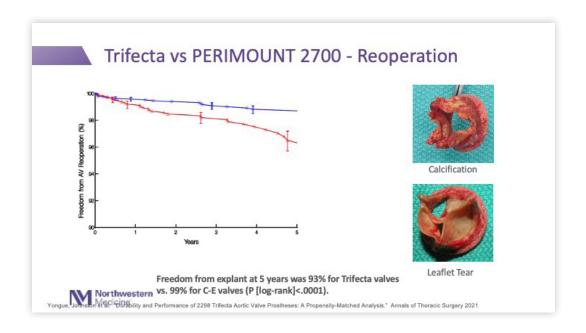
Once we get things exposed, this is the view of the aorta you see. We're putting a tube in the aorta to put the blood back in.

You can see the heart beating on the right-hand side. Then you're going to see this tube going in over a wire. It's a really small incision. It looks like a lot of blood in there. It's like a teaspoon. Then that's the tube going in to help us stop the heart to give cardioplegia. Then believe it or not, through this little tiny incision, once it's open, this is the same view of the heart that you – of the valve that we would get through an eight-inch up and down sternotomy incision.

The stitches sometimes look like they're in the way because of the camera, but that's really just the camera. It's still a very good view of the valve. It's really the same operation we would do. The one difference I would say is you can see those instruments that I was using are not quite as slick as the robot. Then this is tying in the valve.



Heart Valve Replacement: Device Durability



Dr. Doug Johnston: One brief word before we go on because people are asking questions about valve durability, this is a huge moving target. I don't want to give you the idea that we have a magic solution to understand for the current valves where we're going to be in ten years. The valves that we have right now are much, much better than we had 15 years ago, but occasionally, a new valve will come out that looks very good in the animal studies and the in vitro studies. When it goes in patients, it's not as good as its competitors. A perfect example is the Trifecta valve. It looked amazing in the in vitro studies. It looks a little worse than its competitors in patients. It's not dramatically different, but this is an example of why we need to follow patients for many years to figure this out. As we get to the Q&A and I know there are some questions about valve in valve, this is one of the big unknowns about TAVR, especially valve-in-valve.



Preparation for Reoperation Begins With The First Operation



Dr. Doug Johnston: I'll leave you with this one, which is if you choose to get a tissue valve and you're a young patient, it's likely you're going to need at least one more intervention in your lifetime. Whether you get a TAVR first or a SAVR first or potentially if you get a Ross or an Ozaki, there's a potential for another operation. **How that first operation is done has a major impact on everything that happens down the road.** The discussion you have with your team the first time around and what decisions we make have to take into account your next 50 years of life and everything that's going to happen there.



Patient Success Story: Dr. Josh Logan



Adam Pick: Dr. Logan, thanks so much for being with us today from Anchorage, Alaska. Maybe to help all the great members in our community learn about your story, can you tell us a little bit about yourself, what do you do, where do you live, are you married, children?

Dr. Josh Logan: Yeah, thank you. I just want to start by just telling Dr. Johnston thank you so much for your care for me and my heart, and of course, Adam, thank you for the invitation to participate today. Like you said, my name's Josh Logan. I'm a urologist in Anchorage, Alaska. I grew up in Atlanta, Georgia. Through different circumstances in training, I ended up here in pursuing my dreams in the great white north. I'm married to another physician, my beautiful wife Stacy. We have four sons together. Noah is my oldest and then my ten-year-old twin boys. You see us there in the hot tub. Then my youngest is Ari. He's seven.



Very active lifestyle, in the winter there's a lot of skiing, a lot of backcountry skiing, a lot of snowshoeing, snow machining. Summer time, a lot of time on the lake wakeboarding, stand up paddle boarding, lots of time in Tahoe, lots of time in Hawaii, just very active lifestyle. Like I said, I'm a physician. I'm a urologist. I got my first stethoscope in my first year of medical school, which would I guess have been 2002, and of course, like every good medical student, auscultated my heart and I said, I believe that's a heart murmur. A couple inquiries about it and just was, hey, do you have any exercise limitations, no, I feel fine. I don't have any difficulties with anything. It was, I guess, pretty much dismissed as "benign murmur".

When I was a fellow in urologic oncology at UCLA, my wife was over at Cedars-Sinai and I decided I would be a good patient and go have a history and physical exam just to get a check-up. An astute internalist auscultated my heart. She took off the stethoscope and she says, "You know you have a pretty substantial murmur?" I said, "Oh, I know. It's fine." She said, "No, I think we should get an echo." I agreed to get an echo. She subsequentially called me with the results and she said, "You have a bicuspid aortic valve," which of course, I really had no idea what that meant. She said, "You're probably going to need heart surgery at some point." That was a pretty big moment.

Had me see a cardiologist and spent a lot of time talking with him and was basically told I had mild aortic stenosis and that there was really not much to do. The things that were suggested to me was that I needed to get regular echocardiograms. I think we were getting them about every one to two years at that point. He suggested I also keep a log of – I run quite a bit. He suggested I keep a log of my times. I trucked on like that for a decade, just symptom free, getting echos every so often. They were just stable.



Then in I guess it would've been spring of 2022, my neighbor and friend who's a cardiologist was kind enough. He came in there and we were just talking about this, that, and the other thing while the tech was capturing the images. All of a sudden, he stopped talking and I knew it was probably not a good result. That's when he informed me that I had progressed from a mild aortic stenosis to severe. That's when we started looking for a surgeon. My wife, as I mentioned, she's also a physician. She kicked it into high gear and found Dr. Johnston. I've, of course, talked to – I did talk to several surgeons. I think before I talked to Dr. Johnston I was pretty settled on getting a mechanical valve.

The big hump for me to get over was taking Coumadin. Like I said, if I'm not working, I'm outside somewhere doing something fun and spent a fair amount of time in the backcountry. Just trying to reconcile being an anticoagulated on the backside of a mountain somewhere. As I mentioned, I had pretty much come to terms with it, but it just didn't sit perfectly. Then as Dr. Johnston mentioned earlier, he was kind enough to meet with me via telemedicine appointment. He took some time to hear about me and what I do. He said, "I think you should get a tissue valve. I don't think you should be on anticoagulation." It was, I think, just a relief to hear that. There's tradeoffs and I understood that that meant that I was going to be having another procedure at some point in the future, but it was just – I think Dr. Johnston was the first person, a heart surgeon, that said, hey, I think this is probably a better idea for you given what I know about you.

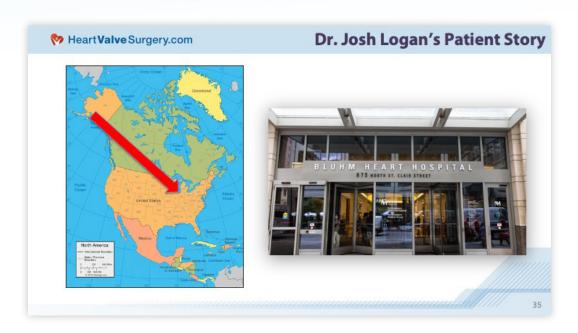
I think from that point on, we didn't look back. Of course, with his expertise – and the biggest thing I would point out is his surgical volume is just through the roof and that makes all the difference in the world. I think we left that appointment with, as I recall, you saying, "I think we're still on a watch and wait position. Let's repeat an echo in six months." I moved off from once every one to two years to once every six months, got that six-month one at a follow-up telemedicine visit with Dr. Johnston. As I recall, there were some further degradations in some of the parameters that were seen on the echo.



He said, we can – and let me just point out, at that point, I was still active running. If I had any symptoms at all, there was a particular hill that I'd run up on a regular basis and maybe I was a little more short of breath by the time I got to that hill, but I was still a very active guy. I think, again, he said the echo parameters had gotten a little worse. He said, look, I think you could continue to monitor, but we all know where this is going. I think it felt right for my wife and I to just preemptively make a move, get the aortic valve replacement and do it in just a controlled fashion where we had the ability to schedule everything. It felt right. The whole process of preparation for that, Dr. Johnston mentioned getting the CT in order to make a decision about if there's a need for a procedure for the aorta.

Then of course, I've got a significant family history for coronary artery disease. I appreciated the fact that he also wanted a coronary geography so he had a thorough evaluation of my coronary arteries.





Adam Pick: Dr. Logan, I'm sure the patients are maybe wondering, because when you're living this active lifestyle but it's time for you to really going in for surgery. You find Dr. Johnston. He's got the minimally invasive capability. He has shown you a little bit of life with a tissue valve to help you avoid being on Coumadin. There's still this big process for you to go – I looked at this map, to go from Alaska to Illinois in the time you're talking about these tests, the CT, everything. How is this done at Northwestern?

Dr. Josh Logan: I'm glad you asked that, Adam. Being a physician, I can appreciate that Dr. Johnston wanted it done there locally at Northwestern. Also, getting at what I was saying about – in terms of being able to do it in a scheduled fashion, there's no emergent nature to it, this was all very – his team was great. They communicated with me everything. All the ducks were in a row from the moment I landed. I knew where I needed to – I think I flew in on – I took the overnight on a Saturday and landed Sunday morning. Monday morning, I got the CT there at Northwestern. Tuesday morning, I got the cardiac cath. Wednesday, I had a pre-op



with him. Thursday, we had surgery. I mean, this was clockwork, which is the way you like these things to work. Dr. Johnston and his team have done a wonderful job of getting a well-oiled machine. The left hand definitely knew what the right hand was doing.

Adam Pick: I've got to ask you this. Just in terms of how did it go for you in the early recovery meeting when you're in Northwestern at Chicago? I'll just start with this. How was your pain managed? How did you experience pain?

Dr. Josh Logan: So very well managed. Like I said, they've got a program in place. I think that's a big part of it is that Dr. Johnston could be as skilled as he is, but if he doesn't have good people and good programs around him, it's not a complete picture, but it is there. I went to the ICU. Pain was well controlled. I think I was in the hospital for two and a half days. I was on narcotics for two of those days but it was a minimal amount. It wasn't a tremendous amount. I have to say I went into this with a mindset of my goal is to get myself onto Tylenol and ibuprofen as quick as possible. I want to separate from narcotics for cognitive reasons for valve issues and just quite frankly wanted to move on. I wasn't grimacing, taking Tylenol or anything like that. It was a tolerable transition.

Dr. Doug Johnston: I will say Josh is tough. I wouldn't encourage patients to try to get off narcotics in two days. These incisions tend to be pretty well tolerated. I mean, I think in particular for aortic valve the mini thoracotomy because the ribs are – the rib is put back together and everything, it's a relatively small incision, but the key thing with post-operative pain is that people can take deep breaths and cough and do the walking that they need to do. Every patient is different. I could tell pre-op that Josh was not going to stay on pain medicine very long. It's quite individual. I think sometimes people come into this with an expectation and a timeline.



I never want people to be discouraged when they hear a story like this and then they have surgery and they're on Day 7 or 8 and they're in doldrums and they're still having pain. Usually, it's the third week when it's you get a rush of energy. The new valve is working and people will write or call me and go, wow, all of a sudden, I feel it. I think Josh was ahead of the curve there.

Dr. Josh Logan: Yeah, he prepped me ahead of time. He said, look – and I think you mentioned the three-week mark of, hey, it's okay if you're taking narcotics after three weeks. Don't push it. Like I said, I wasn't grimacing. I definitely had discomfort. I don't want to mislead anybody, but it was controlled with Tylenol and ibuprofen. I tried to go into it openminded, because of course, I didn't know what to expect, but I also had a mindset going into it that I didn't want to languish. I wanted to push forward.

Adam Pick: I love those points about the mindset, not only the physical side of healing. For everybody on the line, I just want to make sure everybody knows, this didn't happen a year ago. Josh, when did you have your procedure?

Dr. Josh Logan: It's 14 weeks ago today.

Adam Pick: Fourteen weeks ago today, this is you – I'm guessing you have your buoyancy vest. Are you wakeboarding here?

Dr. Josh Logan: I think that was wakeboarding last weekend. We knew we were going to participate in the webinar with you, Adam. I wanted to give you some pictures of me doing some of the activities we do. I had the life vest zipped up. My wife said, "No, no, unzip that thing. They need to see that scar."





Adam Pick: If you can't see it on the screen, Dr. Johnston, that's what you see, the horizontal scar, that's the primary access point, correct?

Dr. Doug Johnston: That's the incision we do the operation through. That's right.

Adam Pick: Okay, and that's about three, four inches?

Dr. Doug Johnston: It's usually two to three.

Adam Pick: Then some patients are thinking, I'm wondering, what's that down there?

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Dr. Doug Johnston: That's the chest tube incision. Any time we go into the chest for any reason, lung surgery, heart surgery, because it's a fixed cavity and fluid can collect, in essence. Much like when you cut your finger, when it stops bleeding, it oozes that clear fluid, same thing happens inside your body as it's healing. The chest tube is designed to drain out that stuff so it doesn't collect around the heart or the lung. Typically, for these incisions, they come out the day after surgery, sometimes two days, but that's where the chest tube goes in.

Adam Pick: Wow, and so I can't tell you how happy I am for your results here, Josh. Thank you, Dr. Johnston and your team, for helping Josh get back in the wakeboard with his four kids. I've just got to ask you both. The whole webinar is about the lifetime management of heart valve disease. Strategically, when you guys came together and collaborated and you went through the shared decision-making process. Can maybe Josh, you talk about, and Dr. Johnston please, jump in here, how did you go about planning the lifetime management? What did you do on this first procedure to tee up Josh for maybe another procedure down the road?

Dr. Doug Johnston: We had this discussion, as Josh said. He came in thinking, "I'm going to need a mechanical valve. I'm uncertain about the coumadin and the lifestyle implications." The discussion we had goes back to that slide that I showed that says, look, your longevity is going to be the same. There's a difference in lifestyle. This gets back to the importance of lifestyle. When we started to talk about what was important to Josh, I said, look, you can get a tissue valve. You're a young guy. We know that they don't last as long in younger people as they do in older people, but they still do last a long time. We have very good data that even in a prior generation of cow valve has a very good chance of lasting 15 years or more. I expect a very active, busy urologist who's maybe running around after grandkids at that point. We have to say what are we going to do in that 15-year timeframe.



The discussion we had was here are the two options. At least in 2023, if you have a cow valve that wears out, you can possibly have a valve in valve TAVR and so we should be planning for that. The unknowns are we don't know how long valve in valve TAVR lasts. That's a relatively new intervention, mostly done on high-risk patients now, but it's pretty safe and time will tell. We'll know a lot more in 15 years. What we know a lot about is if you needed to have a re-operative valve operation. I know there's a question in the chat about this. We know that in a center that does a lot of reoperations, a re-op valve surgery, so second or third time, is as safe as the first time around. It could be done with very low risk. Maybe valve in valve will turn out to be great and that's what you'll have down the road. If not, our current standard is really good. This is the kind of discussion we had so that we've got a plan.

I always tell this story. I operate on this physician who's a marathon runner. I didn't do his first two operations but I did his third operation at 75. He got a cow valve in his 40s and another cow valve in his late 50s. He was 75 and he said, "You know what? This has lasted me really well. I'm still running half marathons. Give me the third one." He essentially got three generations of the same valve. In between, this is one of the most active guys I've ever met. That's the kind of story that we want to be able to support. If you don't want to take blood thinners, and that's very much a personal choice, it's not your surgeon's choice, in between whatever procedure we're going to do, we want you to forget about us.

You talk to us once a year, send your echo, we'll get a CT scan, whatever we need to do. In between, you should be wakeboarding with your kids and not be thinking about your heart. That's my goal when I talk with somebody who has those lifestyle goals. You live your life the way you want to live it. Come see us when it's necessary. That's the end goal.



Adam Pick: Got it. To get that valve in valve in there, I've heard, and I think, Josh, you may have brought it up, that it was something in your discussion, the size of the valve. Is it accurate that you went for a bigger sized valve to prepare for a potential valve in valve down the road?

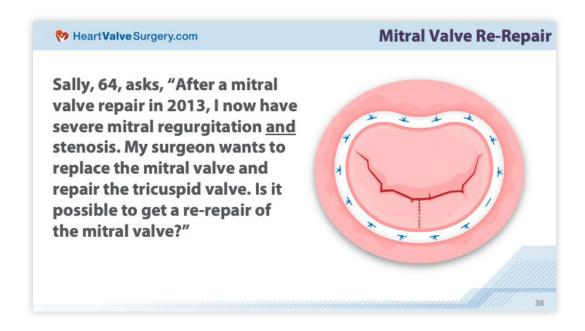
Dr. Josh Logan: I'll let Dr. Johnston weigh in, but he told me he gave me the biggest valve they make. Effectively, my understanding of that is I'm set up for a TAVR if that's, like he said, at whatever point that's necessary and the data looks good, then it sounds like I'm pre-prepared for that. There's more thought that went into it.

Dr. Doug Johnston: Yeah, for a lot of reasons, bigger valves are better if they fit. That's the caveat. There's some enthusiasm now for doing some very extensive procedures to enlarge the root of the aorta to put a bigger valve in. I think the jury is still out on that. If the patient's anatomy will take it, bigger is definitely better. Both right off the bat because bigger valves are more efficient. They're a little more durable, but in particular when we're thinking about valve in valve in the future because we're going to put a new valve inside this old one, that's the nesting dolls question, then we want as big a valve as possible to allow for the future valve in valve.





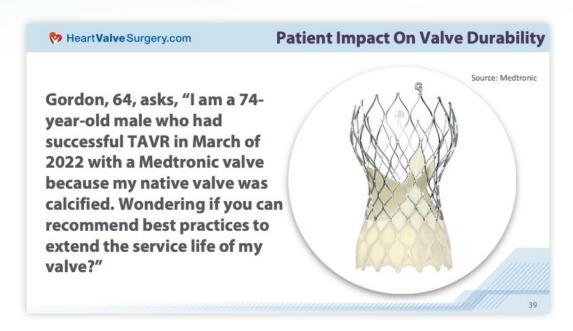
Questions & Answers



Adam Pick: Josh, again, congratulations on your results. As we move from this section to the Q&A, we have got already 41 questions submitted. We're going to go into what we call "Rapid Fire Q&A" with you, We only have about ten minutes left here so let's get going here. Sally says, "After a mitral valve repair in 2013, I now unfortunately have severe mitral regurg and stenosis. My surgeon wants to replace the mitral valve and repair the tricuspid valve. Is it possible to get a rerepair of the mitral valve?"

Dr. Doug Johnston: In the spirit of rapid fire, I'll keep it short. If you have stenosis, probably not. That would be like taking your shoe to the tailor and saying can you change the size. If it's too stiff, we really can't re-repair it and get a good result. You're probably going to end up more stenotic. Patients who have isolated regurgitation after a repair often can have re-repair.

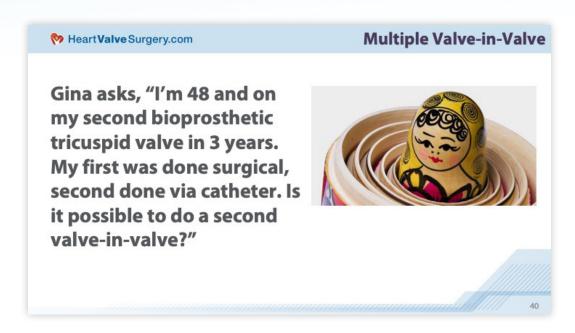




Adam Pick: Got it. Hope that helped you, "I'm a 74-year-old male who had successful TAVR in March of 2022 with a Medtronic valve because my native valve was calcified. I'm wondering if you can recommend best practices to extend the service life of my valve?" We get this question a lot. What can I do as just a living human to make my valve work longer?

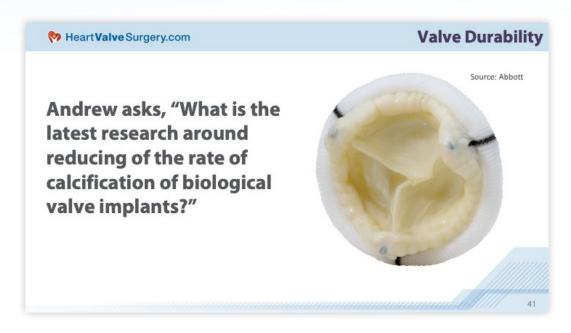
Dr. Doug Johnston: There's one thing that you don't want to do and that is to take really high doses of calcium supplements. Other than that, there's nothing you can do to make it last more or less, which is good news. You live your life and don't think about your valve.





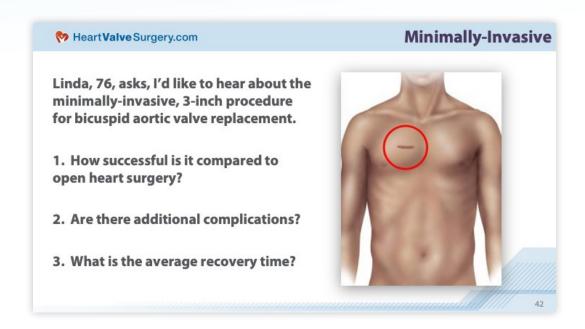
Adam Pick: Right, hope that helped you, Gordon. Gina, we exchanged emails today, she says, "I'm 48 and on my second bioprosthetic tricuspid valve in three years. My first was done surgical, second done via catheter. Is it possible to do a second valve in valve?"

Dr. Doug Johnston: It's definitely possible, especially in the tricuspid, assuming they put a big surgical valve in there, which usually is possible for tricuspid valve surgery. Hopefully this valve in valve is going to last you a long time, but it is certainly possible to do a second valve in valve in that situation.



Adam Pick: This is a question from Andrew. We get this several times a week. "What is the latest research around reducing the rate of calcium of biological valve implants?"

Dr. Doug Johnston: Andrew, that is a great question we could spend a couple hours on. Every company is in a moonshot race to create a biological valve that doesn't calcify. They're getting better and better and better. Each generation of valve, at least based on the animal data, is significantly better than the last one. The trouble is that our valves are so good now that we're going to have to wait 10 to 15 years to see whether each new one is any better. Lots and lots of stuff going on in this area.

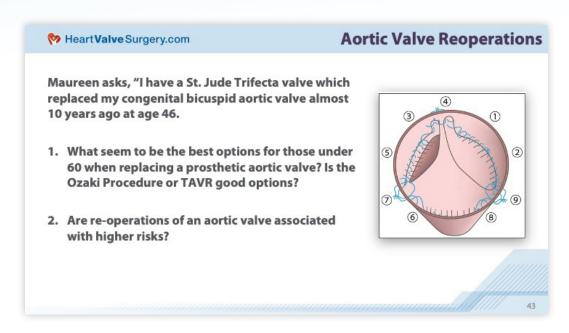


Adam Pick: Linda, 76, asks, "I'd like to hear about the minimally invasive three-inch procedure for bicuspid aortic valve replacement. How successful is it compared to open heart surgery?"

Dr. Doug Johnston: That is a great question. You've heard a success story today, but we don't want to pretend that any operation is without potential complications. The good news is – and there are now multiple studies to show this. I always come back to this. I'm sorry if it seems like a cop out. In an experienced center, or a center of excellence, minimally invasive surgery is as safe in terms of survival and risk of mortality as standard incision open heart surgery. The recovery time is a little shorter.

The need for a blood transfusion is less. The pain is less. You can look at it either way. If you need to have a standard incision operation, probably by six or eight weeks after surgery, you're not going to be able to tell the difference, but there are some benefits in the early recovery to a small incision procedure and it's been shown to be as safe with the caveat in selected patients where all the studies line up to show us that it's going to be safe.



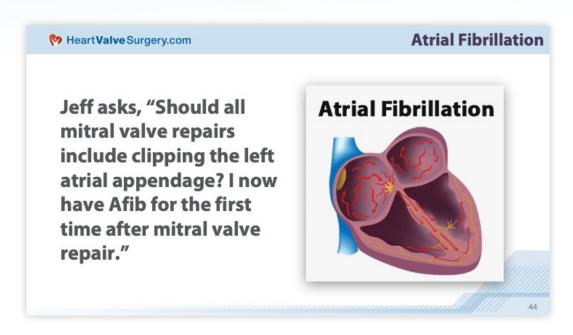


Adam Pick: Maureen asks, "I have a St. Jude Trifecta valve which replaced my congenital bicuspid valve almost ten years ago at age 46. What seems to be the best options for those under 60 when replacing a prosthetic aortic valve? Is the Ozaki procedure or TAVR good options?"

Dr. Doug Johnston: The short answer is it totally depends on what valve you have and the anatomy of your root. The Trifecta, Number 1, it's great that you got ten years out of it. It shows that this valve, even though we're a little concerned about it, it's not that much worse than other valves. It's just not quite as durable. It is constructed a little differently than some other valves. That can make TAVR a little challenging. It is possible to do a TAVR and a Trifecta if the root size and shape are right.

Ozaki can be a good option, again, if the root size and shape is right. The general question really is you have to have a picture of the whole thing. You and your surgeon need to look at the echo and the CT scan to make that decision. The good news is that we have shown very thoroughly that reoperation, patient for patient, is not a risk factor. It should not be higher risk than your first operation.





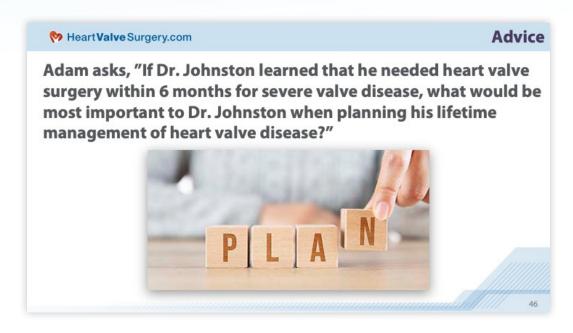
Adam Pick: Thanks, Jeff asks, "Should all mitral valve repairs include clipping the left atrial appendage?" Obviously, this one's about afib after surgery. Josh, real quick, did you have afib after your surgery?

Dr. Josh Logan: I did not.

Adam Pick: Fantastic, getting back to the question. Jeff struggled with it. He now has afib for the first time after mitral valve repair, but getting to his question, Dr. Johnston, should everybody get a clip?

Dr. Doug Johnston: We don't know. There is a study going on right now called the leaps trial which is looking at this particular question. It's patients who've never had afib but who have some risk factors for afib, like a dilated atrium. There's some other things on the list. Essentially, those patients are being randomized to a clip or no clip at the time of surgery. We will know in probably three or four years if this is the right thing to do. A clip is not – it's very safe. It's not 100% benign intervention to do. Because most afib after surgery is self-limited, the jury is still out on whether everybody should have a clip, but great question.





Adam Pick: We are going to end on a question that I had to ask myself, Dr. Johnston, as I've got you on the line. I will just ask it to you personally, which is, "If you've learned that you needed heart valve surgery within the next six months for severe valve heart disease, you can pick whatever one you like, what would be most important to you when planning your lifetime management of heart valve disease?"

Dr. Doug Johnston: The most important thing to me, and I've got a little leg up on this because I know so many people on my field, would be having a team that is willing to talk to me about all the options. I think that's what I would recommend to anybody who is in this position now is, as I said, surgeons have preferences. Surgeons have things they are more comfortable with or less comfortable with or they don't do at all. The same is true of cardiologists, things they lean towards or lean away from, but you deserve a discussion of all of the available options.

If somebody tells me "This is not right for you," they ought to be able to explain to you what it is. I would work with people that I know that I know are very openminded about all the interventions and we would look at the data together and look at the studies together and say, okay, what's right for me? Like Josh, I know I don't want to take coumadin. That would be off the table from the beginning. That leaves a lot of options. I'd want to work with a team that's willing to run through all those with me.

Adam Pick: Great point. Great advice. On that note, we are going to wind up the webinar, but please don't hang up. I'm going to ask you to do the survey as this webinar comes to a close. I want to thank everybody on the call. I am amazed by your registration for this event with over 975 people, your attendance. We are a community coming together to help one another. It is very special to have all of you on the line.

I also want to thank, of course, Dr. Johnston. Thank you so much and your entire team at Northwestern for participating in this event. It was great to have a patient who is also a physician on the line. Dr. Logan, thank you so much for being with us today. On behalf of the entire community, as we always say here, keep on ticking. The survey is going to be coming up on your screen right now. Thanks so much, Dr. Johnston. Thanks, Dr. Logan.

Dr. Josh Logan: Thank you, Adam.

Dr. Doug Johnston: Thanks, Adam. Thanks, Josh.





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

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

- Adam's Free Patient eBooks Download 10+ free eBooks about heart valve dis-ease and treatment options for aortic, mitral, pulmonary and tricuspid valves.
- <u>Heart Valve Learning Center</u> Visit the Heart Valve Learning Center to access over 1,000 pages of educational information about valvular disorders.
- <u>Patient Community</u> Meet people just like you in our patient community. There's nothing better than connecting and learning from patients who are sharing their stories in our community.
- <u>Surgeon Finder</u> Find and research patient-recommended heart surgeons that specialize in heart valve repair and heart valve replacement procedures.
- 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.
- <u>Educational Videos</u> Watch over 100 educational videos filmed by the Heart-ValveSurgery.com film crew about heart valve surgery.

