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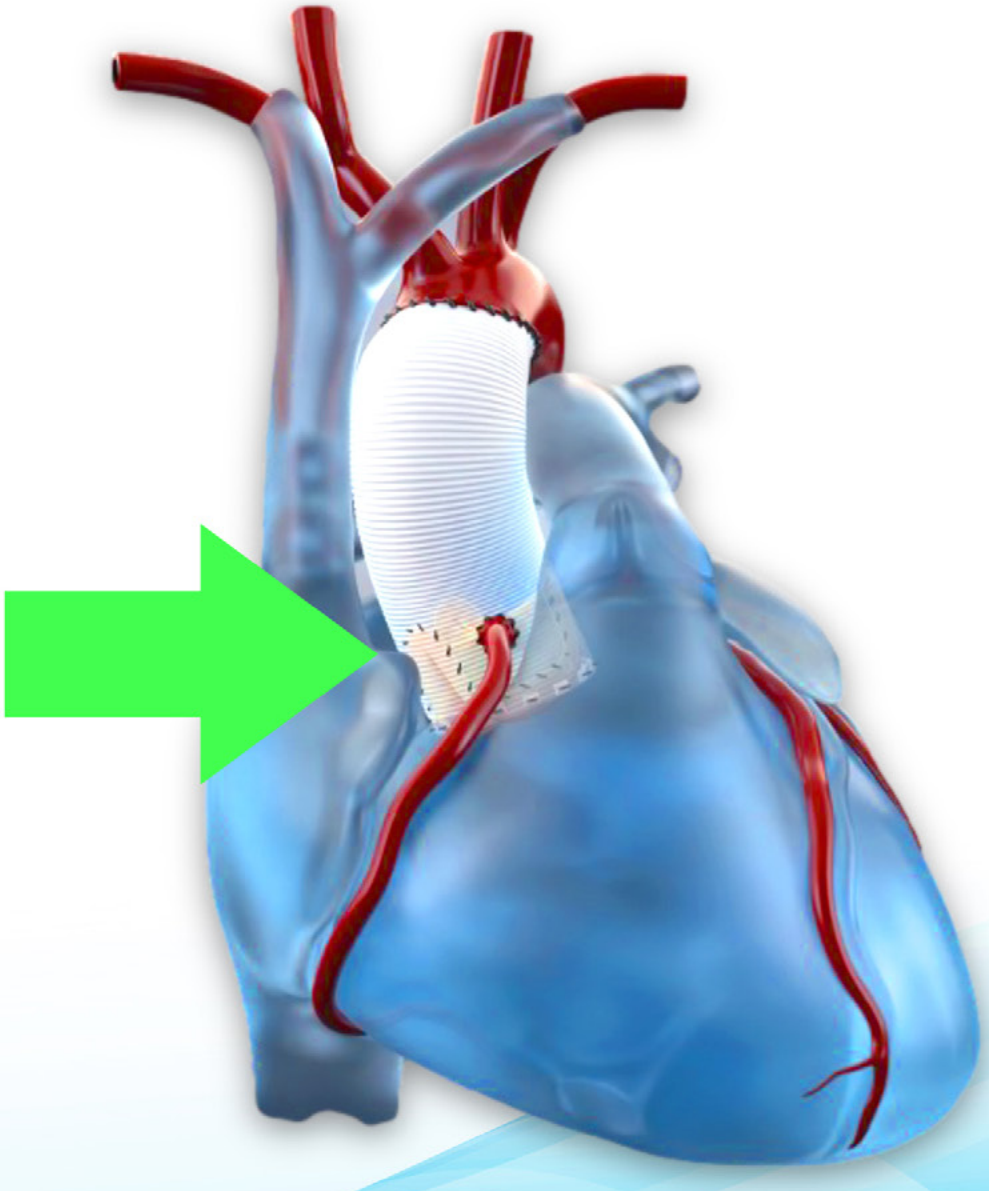
ADVANCES IN AORTIC VALVE RECONSTRUCTION



Cleveland Clinic

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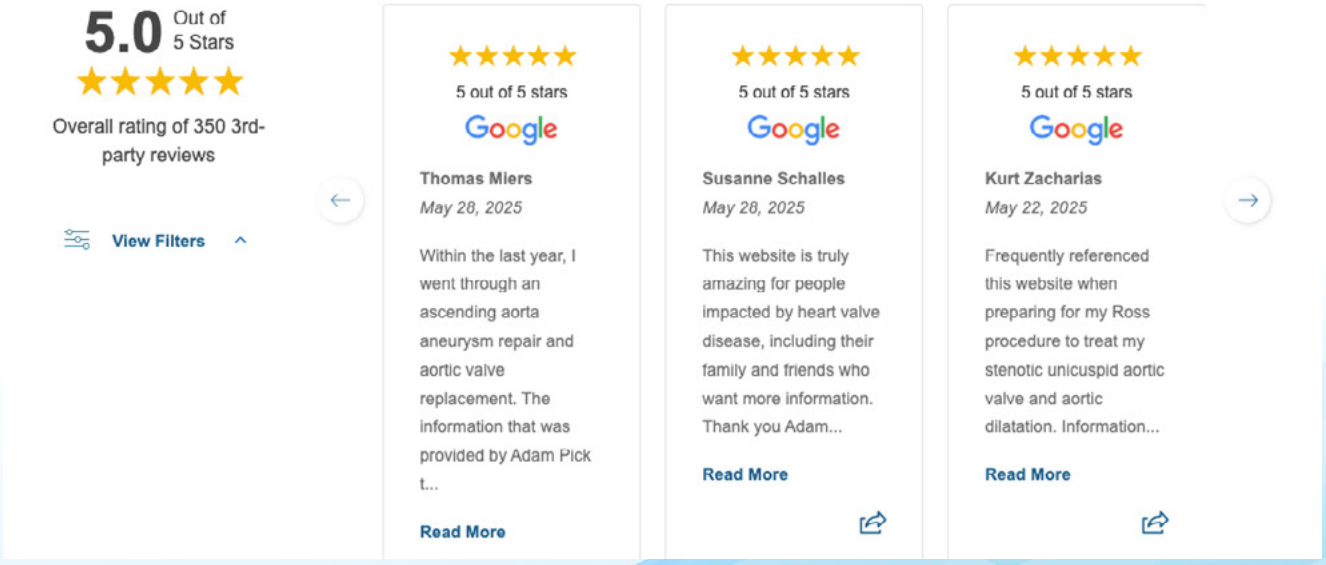

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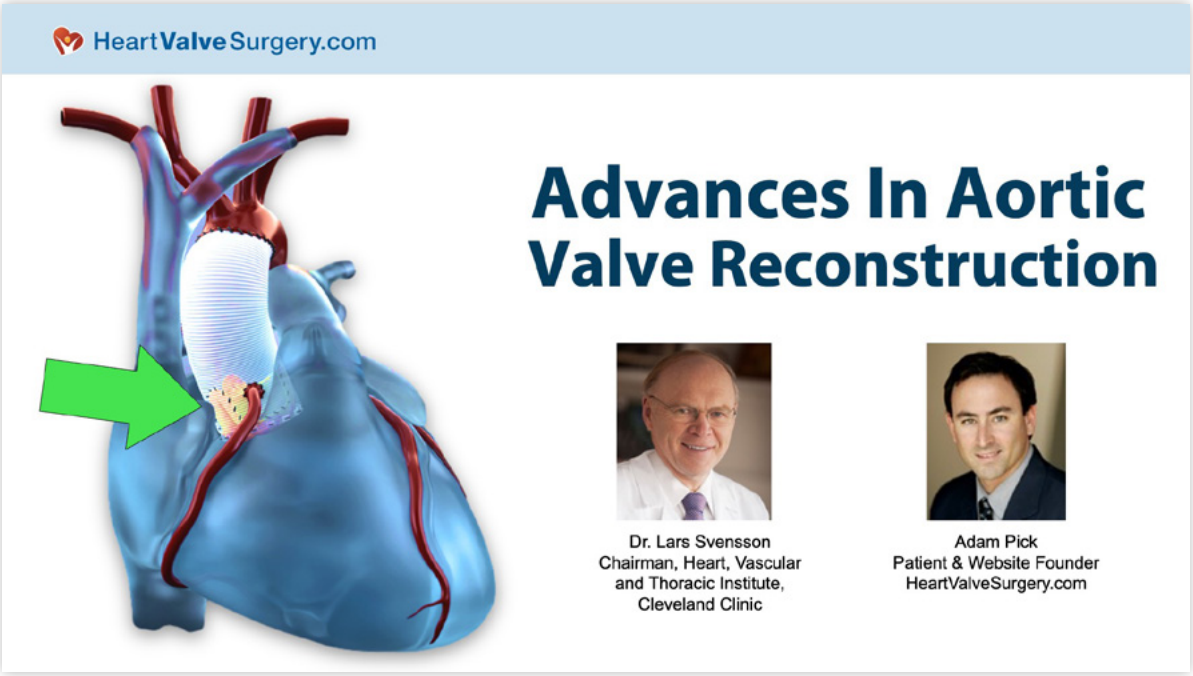
Please note: A complimentary video playback of this eBook is now available on YouTube at this link.

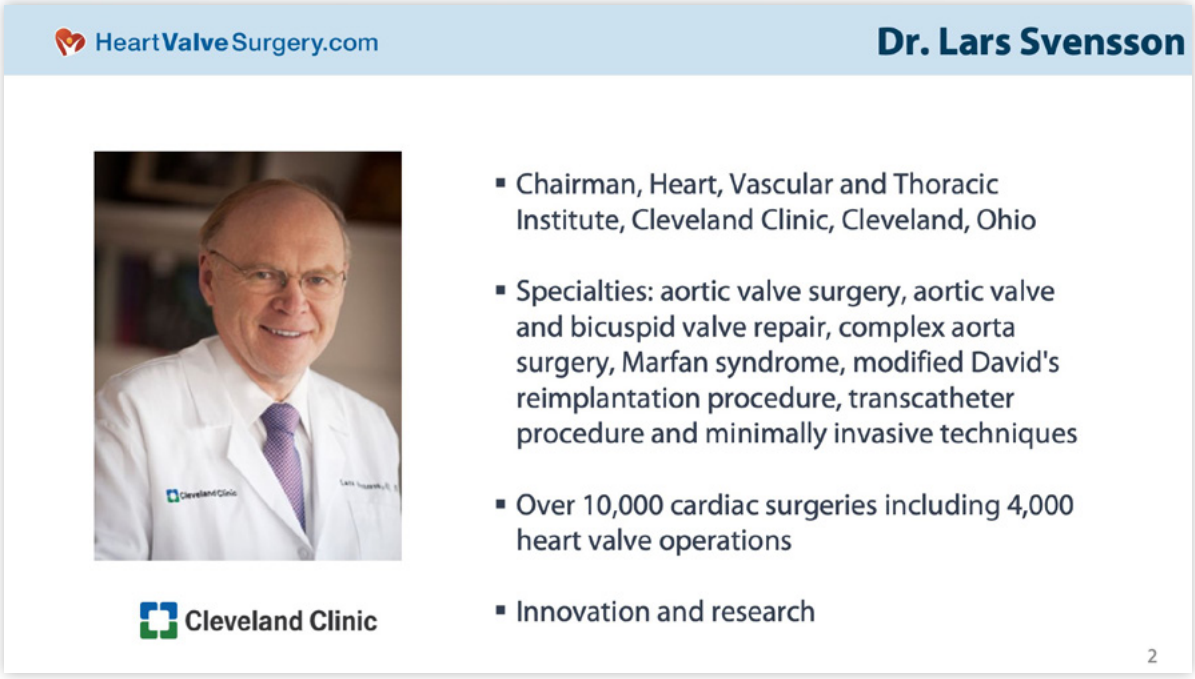
Table of Contents

Introduction



Adam Pick: Hi, everybody, my name is Adam Pick, and I'd like to welcome you to the webinar titled, "Advances in Aortic Valve Reconstruction". If I have yet to meet you, I'm the patient, the aortic valve patient, who started HeartValveSurgery.com nearly 20 years ago in 2006. The mission of our website is very simple. We want to educate and empower patients just like you. And this webinar, which has had over 400 registrations from patients in countries all over the world, was designed to support that mission.

Now, throughout the webinar, you're going to be in "listen-only" mode, but I'd encourage you to submit your questions in the control panel on your screen and as we look at the agenda. To start, I'm going to introduce our featured speaker. We're then going to look at the aortic valve. We're going to get clear understandings about what aortic valve reconstruction techniques are. We're going to look at the outcomes. Then we're going to get right into that Q &A session. Lastly, I'm going to ask you to complete a very quick five-question survey.

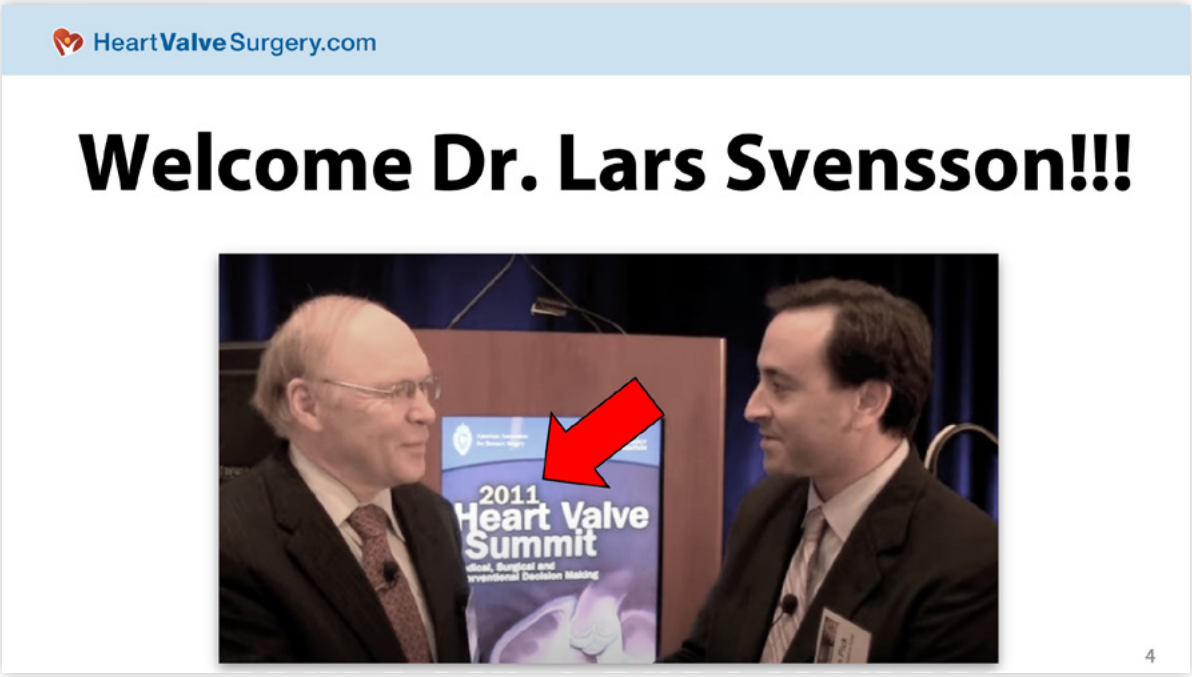


Now, as for our featured speaker today, I am humbled and I'm honored that he's taking time away from his very busy practice. And who is he? Well, Dr. Lars Svensson is the chairman of the Heart, Vascular and Thoracic Institute at the Cleveland Clinic in Cleveland, Ohio. And let's look at his specialties, which are aortic valve surgery, aortic valve and bicuspid valve repair, complex aorta surgery, Marfan syndrome, modified David's reimplantation procedure, transcatheter approaches, and minimally invasive techniques.

Now, it's one thing to have all these specialties, but to put them into practice is something different. Let me just share this with you. Dr. Svensson hasn't performed just 100, or 1,000, or 3,000, or 5,000. He's performed over 10,000 cardiac surgeries of which 4,000 have included some type of valve operation. And it's not just the incredible volume and the lives that he has changed over the years, but he is also very deep into the innovation and the research that may have already impacted the people on this call or those who will need some type of operation in the future.

Dr. Svensson's Patient Success Stories

Adam Pick: When it comes to his impact on our community, I do want to share this with you. I looked in our database and I looked at some of the patients that he's helped over the years and here they are, whether it's Sean Adkins or Daniel Conrad or Alan Neff. These are all patients from the HeartValveSurgery.com community that have gone to Dr. Svensson and are living great lives as evident by some of the smiling faces that you see here. He's helped, for example, Robert on the left with an aortic valve repair. He's also helped professional athletes get back to playing the sports that they love.



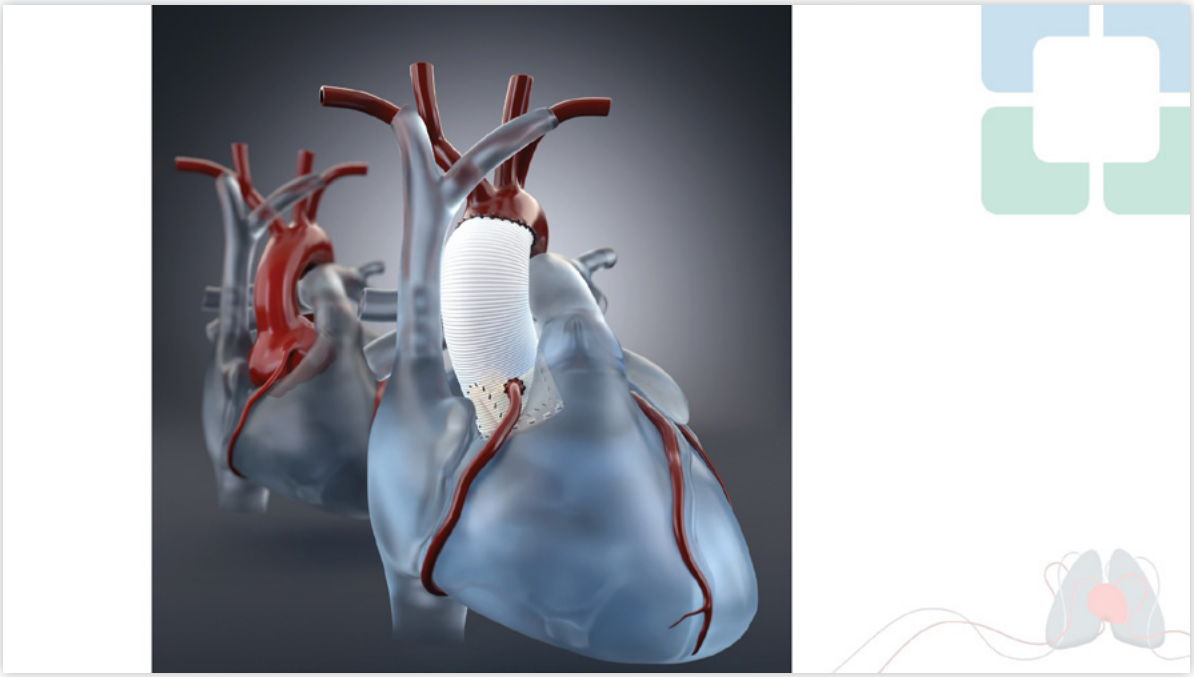
I'm going to welcome Dr. Svensson, but I also want to share with you a personal note. Dr. Svensson was one of the first physicians who agreed to film a video with me at a conference. And at the time, I don't know if you remember this, Dr. Svensson. At the time I only had a Flip camera and everybody looks right there. You'll notice the year; it's 2011. Dr. Svensson, you and I have been going at this now for over 14 years. And from the bottom of my heart, I can't thank you enough for being here with us today, helping all the patients that you have in the past and the present and in the future. And with that, thanks for being with us, Dr. Svensson, and I'll turn it over to you, and I'll give you the controls.

Understanding The Aortic Valve

Dr. Svensson: Well, thank you so much. It's really my pleasure and privilege and honor to talk to you. I've had a long interest in this, as you mentioned, Marfan Syndrome, because one of my friends had it. And this has been a long journey, and you've been very much part of it, Adam. So I appreciate the opportunity to talk to you and everybody who's on this website and been very grateful for the many patients over the years who've entrusted their care, both with myself and my colleagues here at the clinic. And so it's a privilege to chat to you. I still operate every day and do one or two cases every day, and a lot of what I do is aortic valve repairs so that's why we're going to concentrate on - both isolated bicuspid valve repairs, 3D valve repairs, and talk about the connective tissue disorders.

Just to set the scene... Last year, we did some 3,970 valve operations here at main campus at the Cleveland Clinic and about 770 of those were root operations and we did over 200 reimplantation operations last year. My personal series is over 600 reimplantation operations. We'll talk a bit about the outcomes of that a bit later.

The aortic valve, obviously as you know, is at the top of the heart where the coronary artery is coming off the sides of the aorta just above that and the reimplantation operation, therefore, involves freeing up the aortic valve and putting a graft around it and reimplanting the valve within that tube and then hooking up the coronary arteries



There were also the remodeling operations that we don't do as much of now because we've noted that the reimplantation operation is a better operation when it's required for patients with root dilatation.

Aortic Valve Disease and Not Repairable

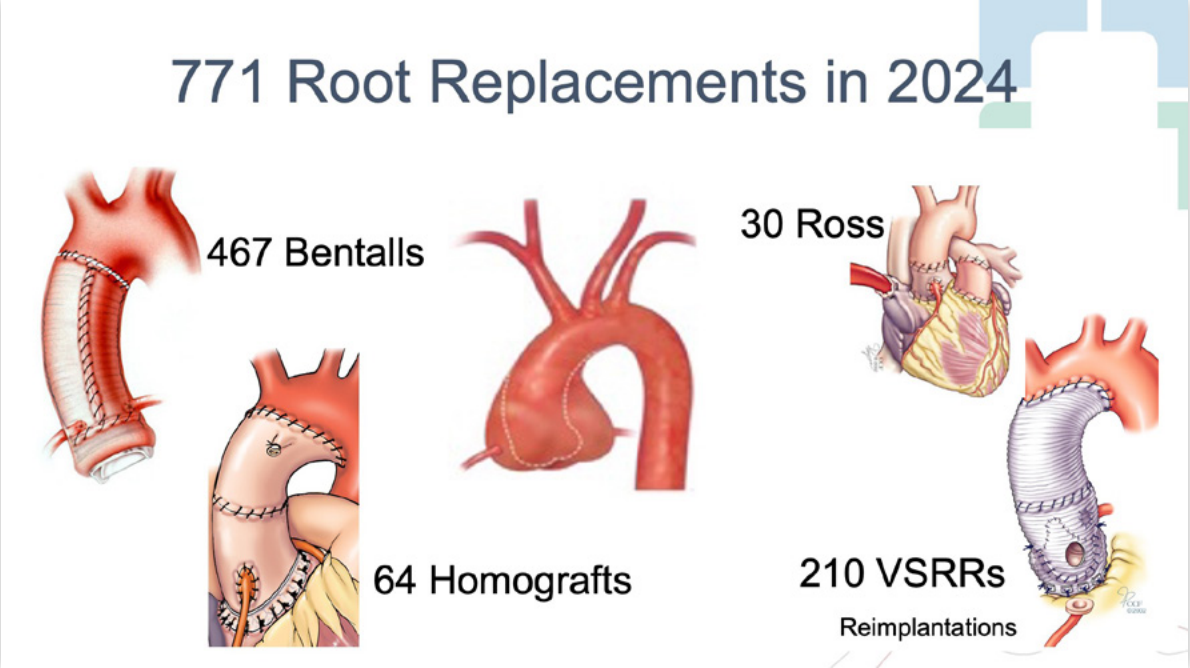
Dr. Svensson: So here are some things to keep in mind that we think of as surgeons, as far as whether a repair is possible or not, and that's all repairs, not just reimplantations, how bad are the leaflets torn, and there's a dilatation that's causing the leaking valve. Calcification usually means we're not able to do a repair, but we do sometimes do that with bicuspid valves. The usual presenting symptoms are fatigue, dizziness, occasionally chest pain, but leaking valves typically take longer to present with symptoms as opposed to the narrowed down valve, aortic valve stenosis.

If it's not treated, regurgitant valves, leaking valves cause heart failure, not as often sudden death, but that happens more with the stenotic valves, and that's about 1 % per year. At this time, there's no medication that cures progression of aortic valve stenosis. We certainly can see some medications like lisinopril slowing down heart failure with a regurgitation.

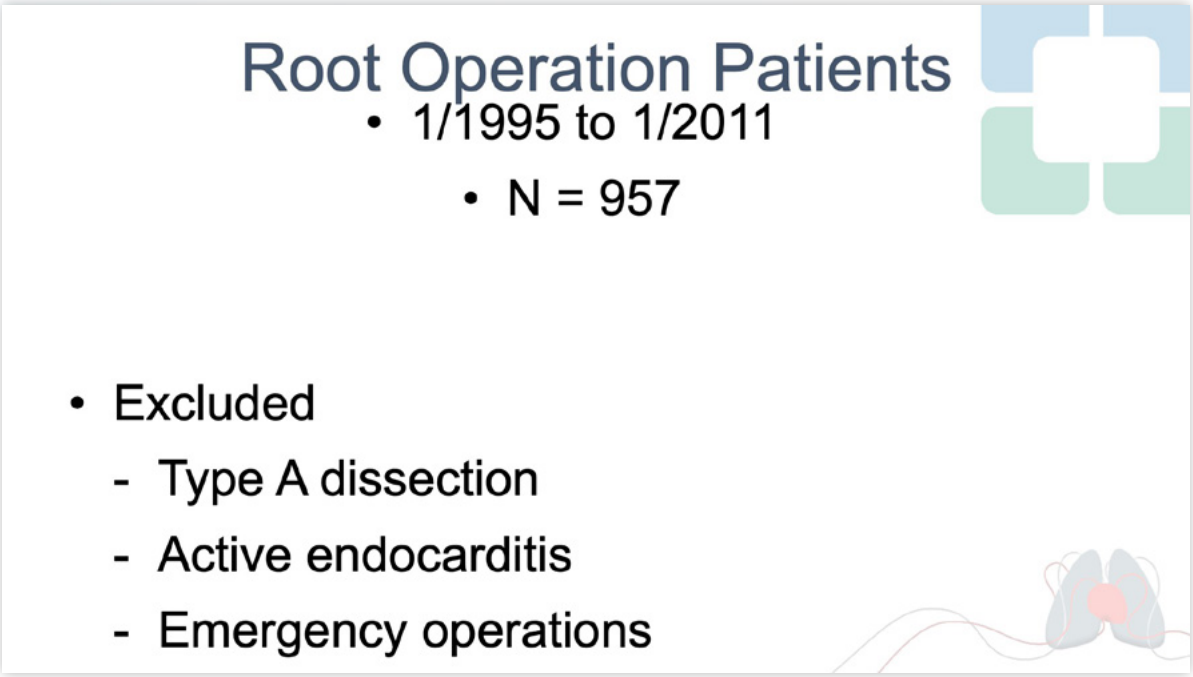
Then as far as incisions and operations, the majority of my bicuspid valve repairs or ascending bicuspid valves or three-leafed valves plus ascending aortas, I do with a minimally invasive J-incision that I described many years ago and was the standard operation for Toby Cosgrove that he adopted for mitral valve repairs, too. I still use that for mitral valve repairs when robotic approach is not feasible. We'll talk about valves and aneurysms, but basically when it comes to stenotic valves, the options that you have to consider with your surgeons are replacement with a biological valve versus mechanical valve. And in patients without aneurysms, the Ross procedure, and then one of our surgeons does a lot of these so-called Ozaki procedures.

So this is the kind of valve that unfortunately we cannot preserve because of those perforations in the leaflets. And here's the calcific valve. So this is the aorta side of a bicuspid valve, and this is what it looks like on the undersurface. That's why we have to replace those.

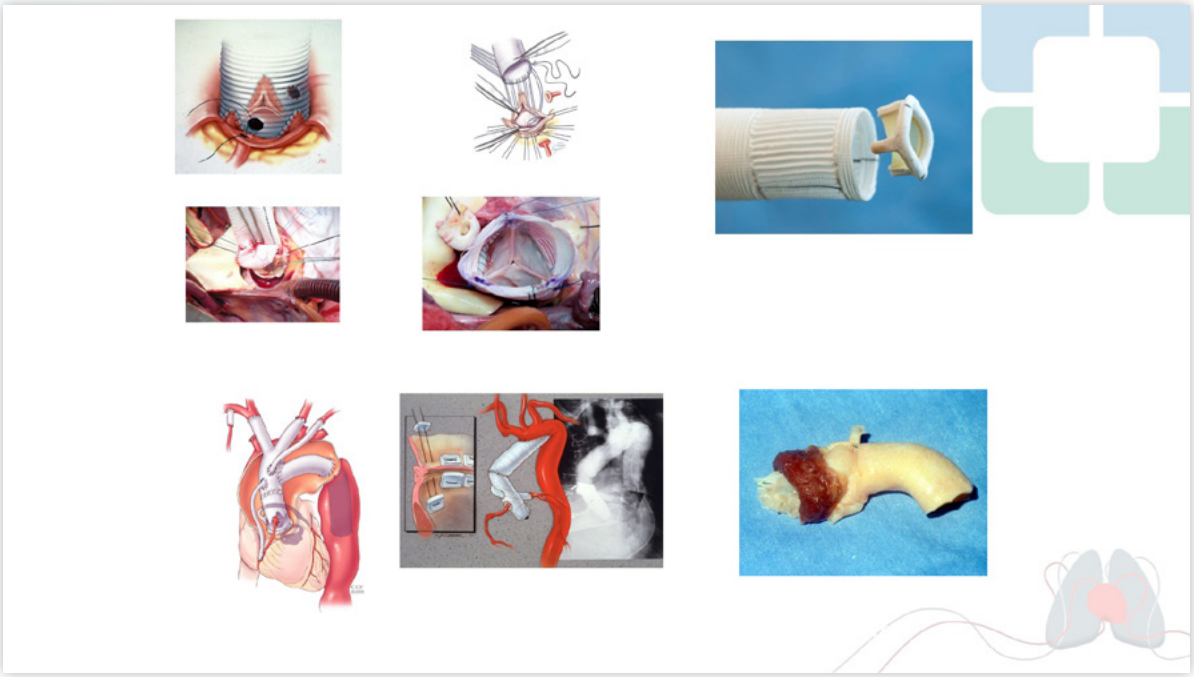
Root Replacement Techniques and Survival



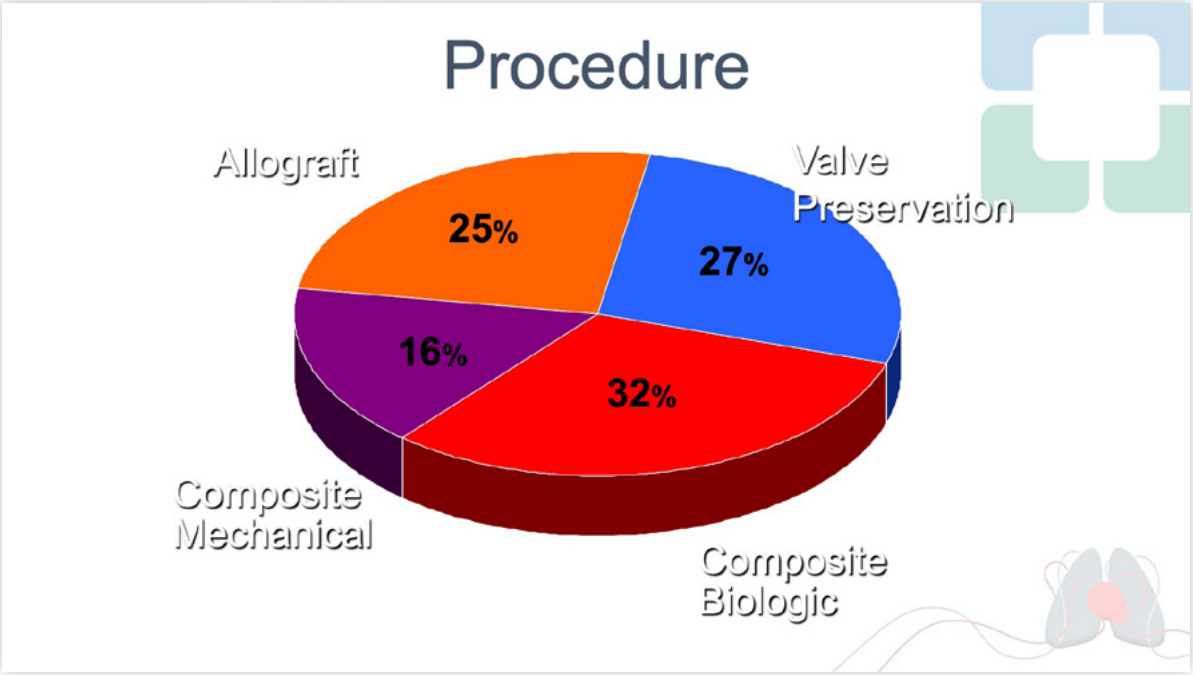
So 771 root replacements in 2024. 467 of those were so-called Bentalls; 64 were homographs, so human transplant valves; and 210 valve-sparing operations with reimplantations, and then the 30 Ross procedures. So let's just talk about root operations and outcomes.



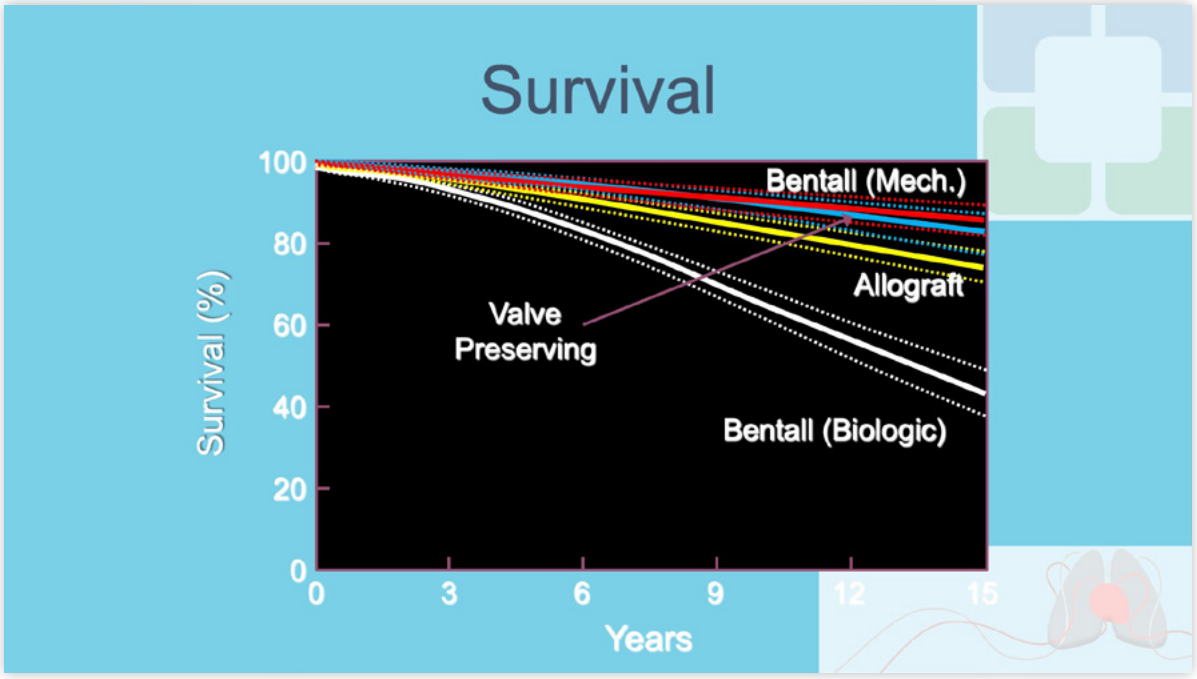
This is a study from a number of years ago that looked at 957 patients. This was maybe elective surgical patients with either the remodeling operation, which would be this operation where we cut a slit into a graph and sew that to the annulus. Then the reimplantation operation where the valve is freed up and put inside a graft. You mentioned Jeff Green just moments ago. He's been open and they have done a number of interviews. This actually is his valve after reimplantation, so I've had six NBA players as patients for these kind of issues.



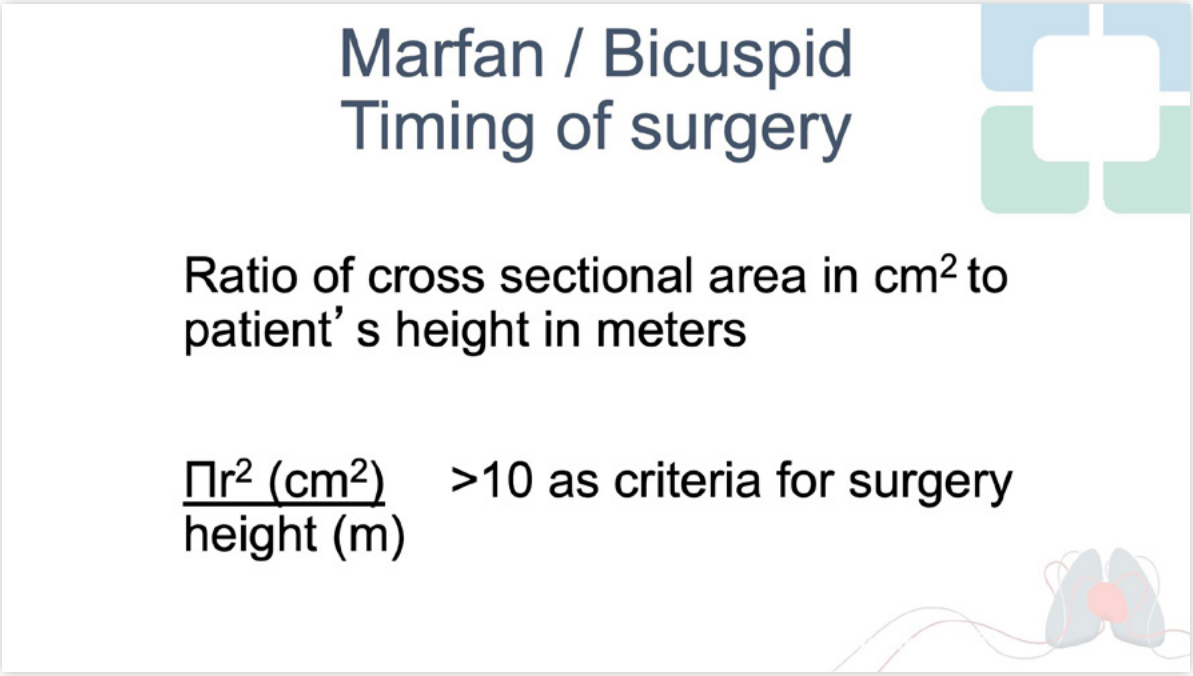
The biological composite valve graphs, we put a biological valve into a tube. Joe Bavaria and I were involved in working with Edwards and designing what's now called the Connect valve, which is a composite valve graft, and the results look pretty good on that. And then you have the other composite valve graft techniques. This is a technique I described many ago for complex repairs with a tube graft to the left main, with a mechanical valve and homographs.



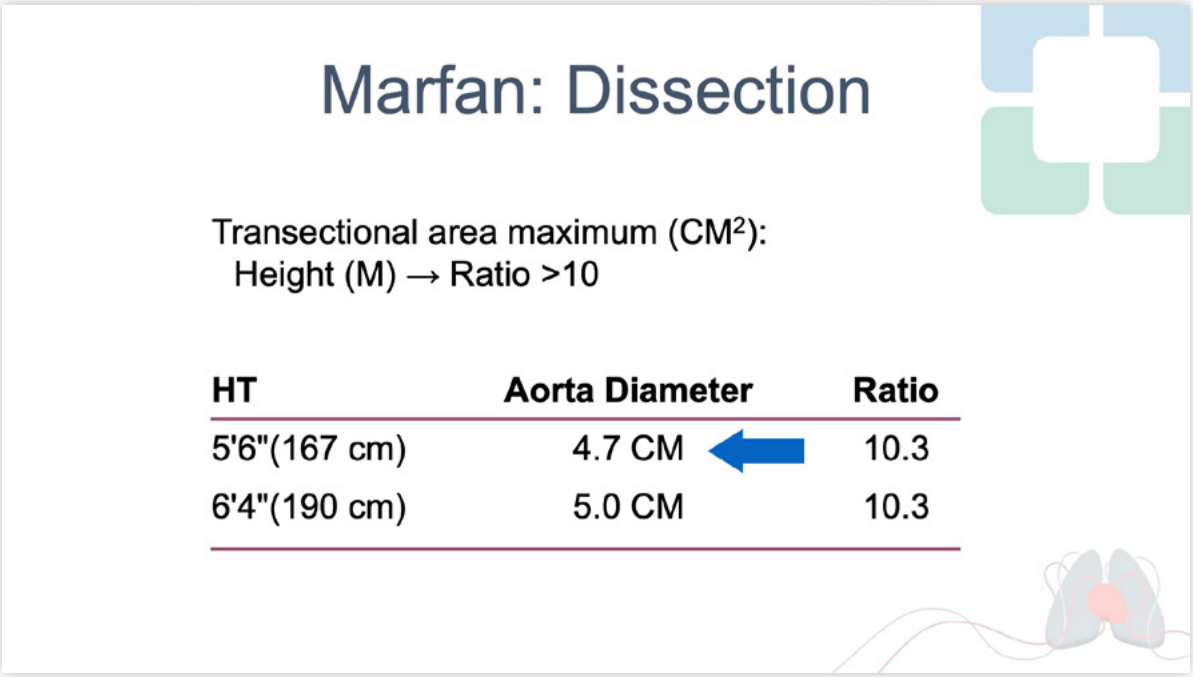
In this study, the numbers were about equally divided. From a survival point of view, Bentalls and valve-preserving operations had the best but remember, these are younger patients. Bentalls were biologic, which are typically older patients, didn't have as good a survival.


Survival
100
80
60
40
20
0
Survival (%)
0
3
6
9
12
15
Years
Bentall (Mech.)
Allograft
Valve
Preserving
Bentall (Biologic)

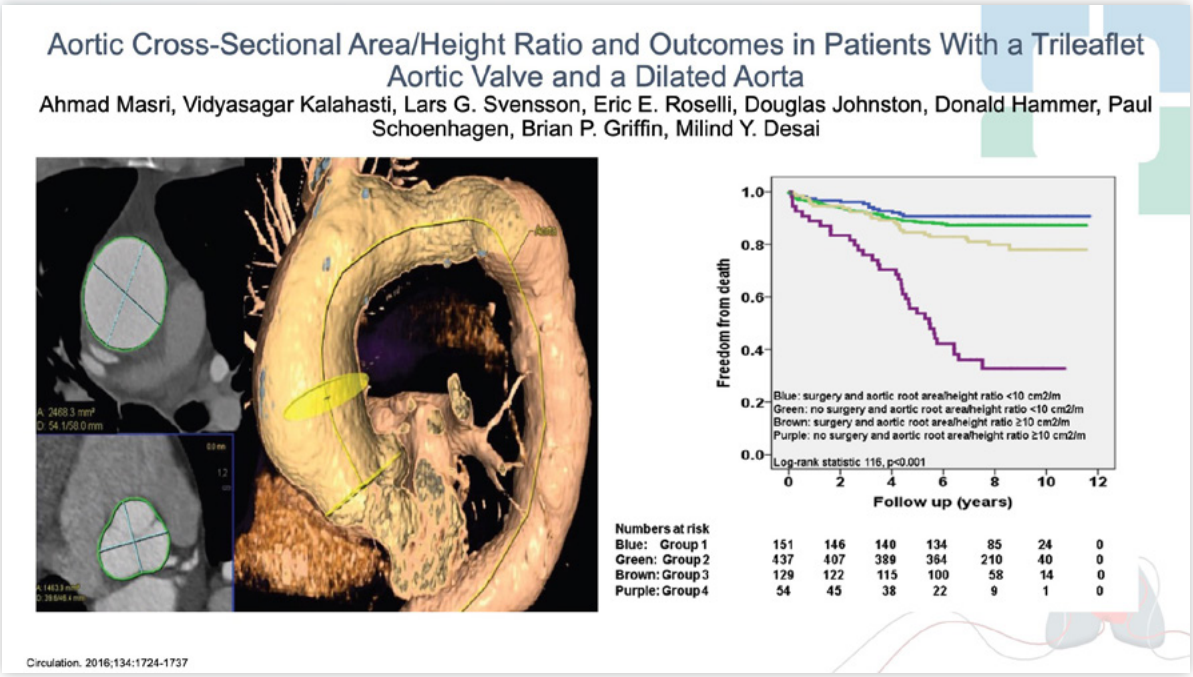
Timing Marfan and Bicuspid Surgery



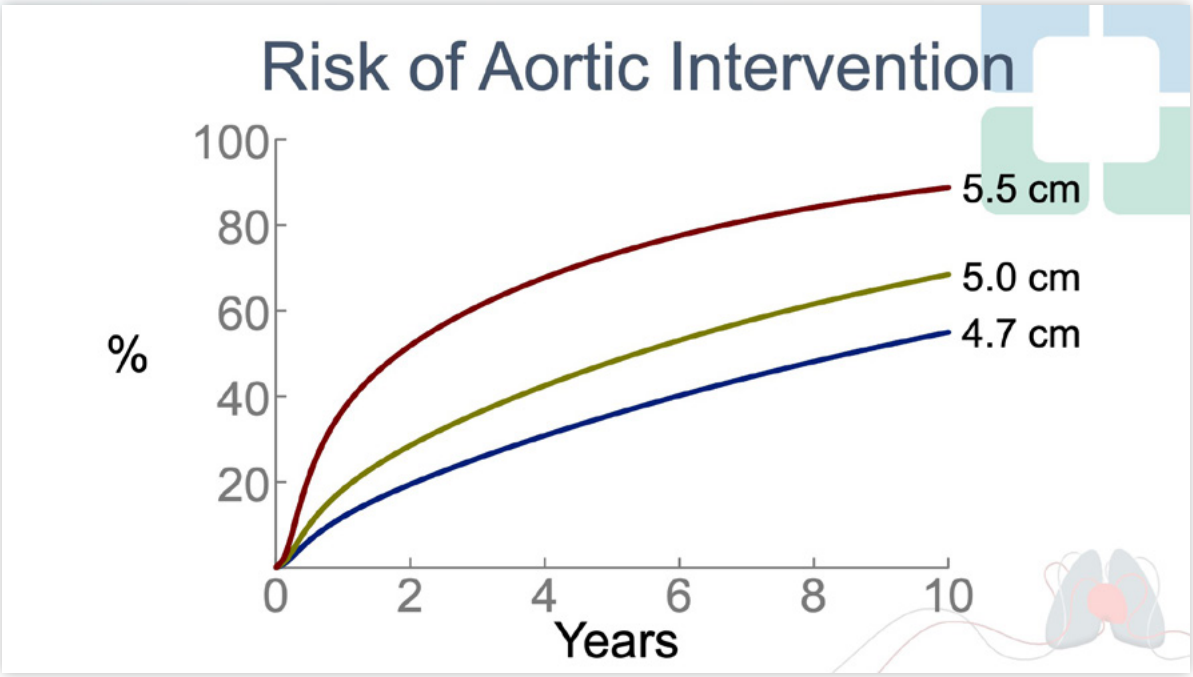
Dr. Lars Svensson: So what about timing of surgery? This is based on a study I did when I was in Boston with Marfan patients. And we found that when the cross-sectional area of the aortic root divided by the height of the patient is more than 10, that is an indication for surgery. So in a shorter person, that might be at 4.7 centimeters and for taller person, 5 centimeters. One of our cardiologists together with some residents then looked at this using CT and cross-sectional area and when that ratio is less than 10 the long-term survival is not good and it's particularly so for patients with root aneurysms as opposed to the ascending aorta. So this is now in the guidelines as one of the measures used to deciding when to operate.



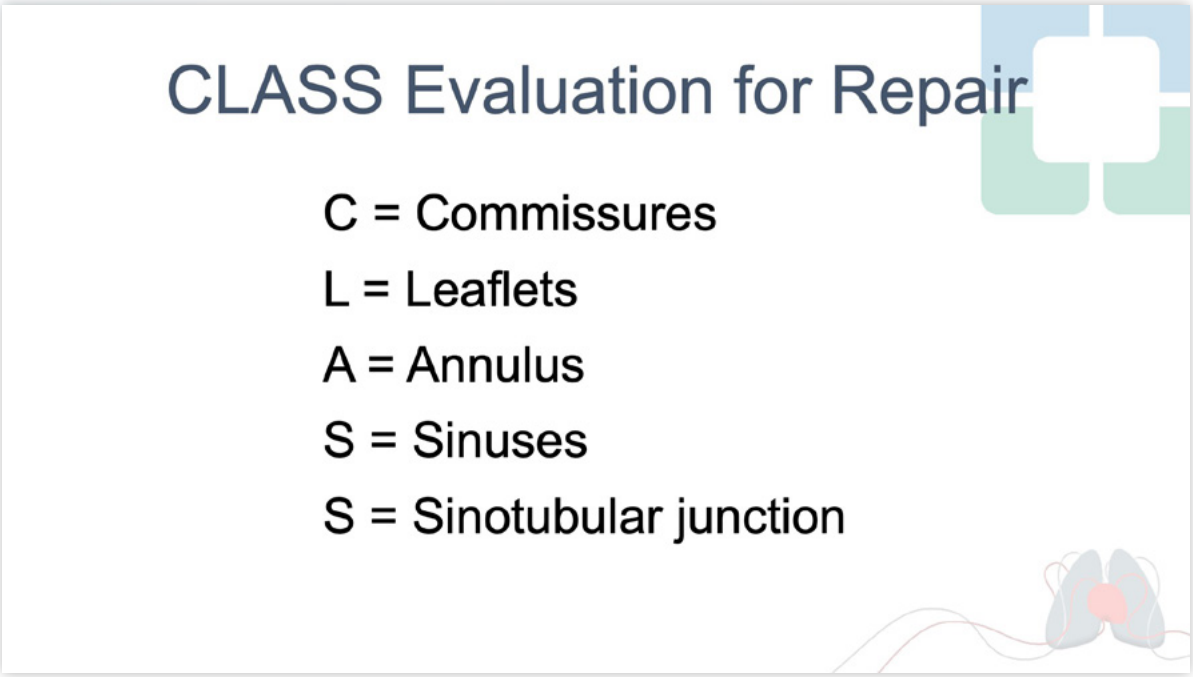
This is another study looking also at size and the risk and the inflection point is somewhere about 4.7 centimeters in this case for the increasing risk of dissectional problems. So we looked at four patients with bicuspid valves and aorta more than 4.7 centimeters over time. We had 1 ,000 patients; 801 had surgery. In those patients who had the combination of valve and ascending aorta, the risk of death was 0.25%. In the surveillance patients, we've followed a number of those patients over 10 years. The inflection point for dissection was at about 5.2 centimeters. Obviously you want to operate before dissection happens. And so that's why we recommend 5 centimeters or that size ratio of 10.



When we looked at this more specifically or all the indications or parameters to use for timing or surgery, the cross-sectional area to height is the best one. Over time, people started it off at 4.7 centimeters.

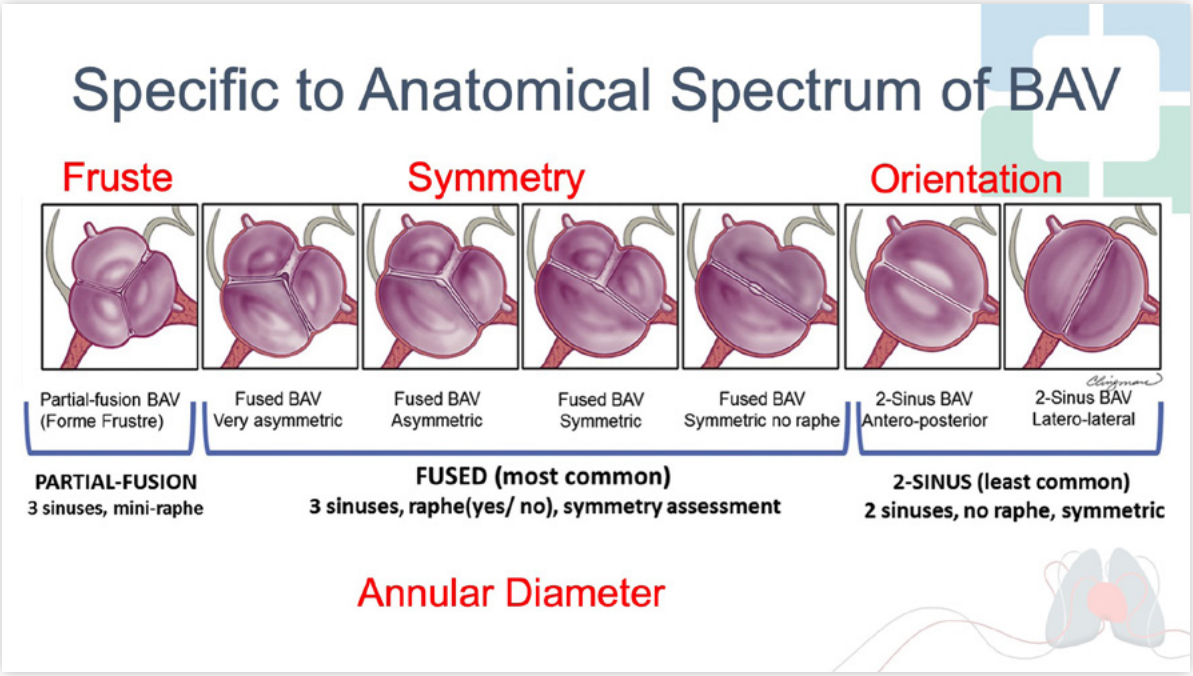


Fifty percent needed surgery within 10 years, and the larger the size, the more risk of needing surgery.



These are the things I look at, a schema I use to decide how to repair a valve and what's needed. You look at the commissures, the leaflets, the annulus, the sinuses, and the sinotubular junction and all of those need to work together for a successful and long-term durable repair.

Bicuspid Aortic Valve Classification

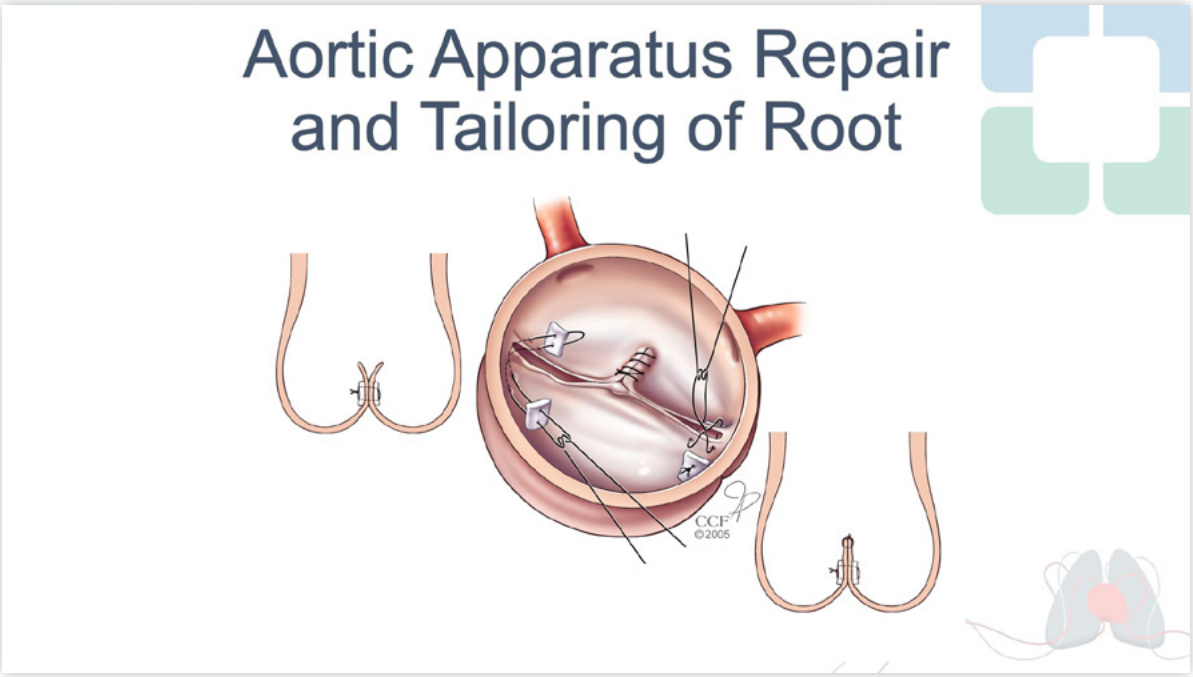


Dr. Lars Svensson: I'll just mention a bit about the classification of bicuspid valves. This is something that we worked on. And essentially, we looked at is this just a minimal bicuspid valve, a narrowing at one of the commissures? Then we look at symmetry, not that important from the point of view repair. And then the orientation, most patients have the fusion of the left and right leaflets, less so the right and non-coronary. And pretty rare is the fusion between the left and the non-coronary. Then annular diameter gives us a lot of information about how likely we are going to be able to repair a bicuspid valve. The raphe, we look at that too, and as I mentioned, if there's a lot of calcification there, that usually is an indication that the valve repair is probably not going to hold up long term.

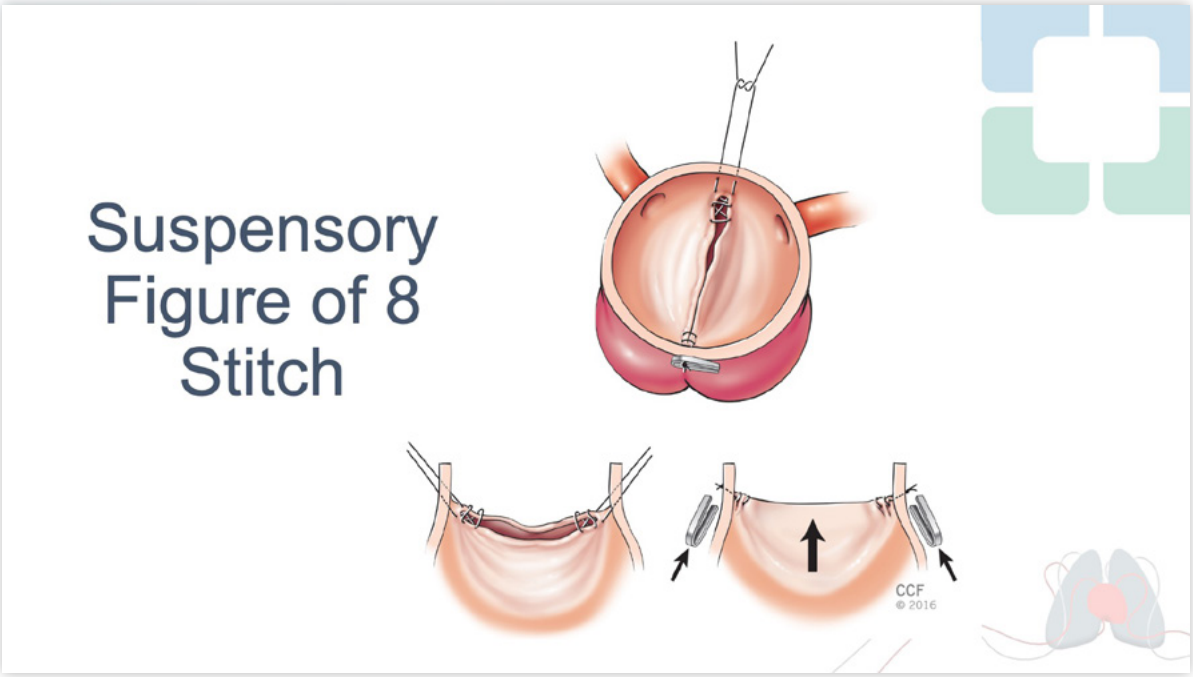
Bicuspid Aortic Valve Surgery: How Is It Done?

Dr. Lars Svensson: The basic steps for a simple bicuspid valve repair that is regurgitant is divide the raphe that frees up the conjoined leaflet and Cabrol sutures at the commissures to narrow the inter-commissure or angle, close any incomplete fusions, and then something that I started using, goodness it's about 20 years ago, is a figure-eight stitch at the commissures to hitch up the leaflets.

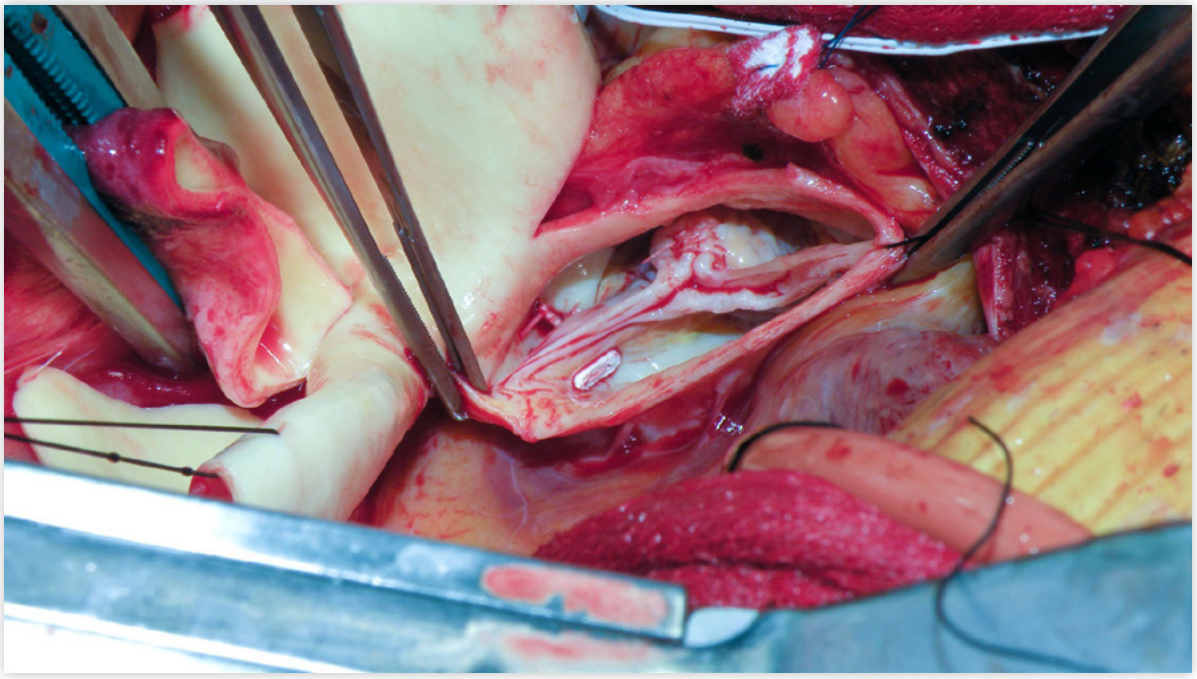
Adam Pick: Dr. Svensson, can I ask you real quick? We might have some patients who, they may have been diagnosed yesterday with some form of aortic valve disease. And there's some language here they might not know. And I don't want to turn this into just a vocabulary session, but can you quickly -- what you're describing in terms of how you go through the criteria for the possibility of a repair is fascinating. And if you could describe maybe just those, maybe the raphe and the commissures, what those are going through this in the planning process?



Sure. So the raphe usually is over here where there's a fusion. Here you have an incomplete fusion of the leaflets. And then the commissures are over here and the inter-commissural angle is this angle here. The Cabrol sutures bring that together to narrow that angle which improves the apposition of the leaflets and then the figure of eight sutures does that also but it also hitches the commissure higher up so here, I tried to show that. It brings it up so you have our position of the leaflets which improves the ability to control the regurgitation of the valve.



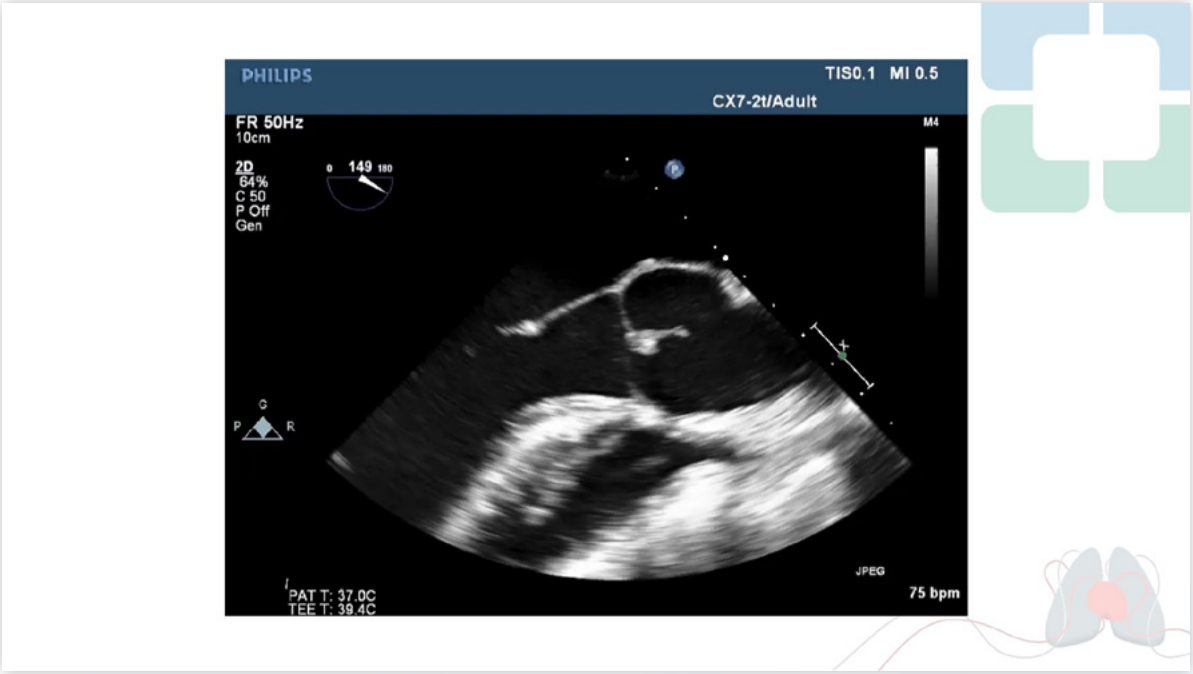
I'll show some of the anatomical features as we go through here. Here's another figure of eight suture on a bicuspid valve and just hitching those leaflets up to a higher level.



And here's the actual operation. So here's an incomplete fusion. And here's the plication of the leaflets. The raphe has already been cut. You don't see it, but it's up here. So that frees up that body of the leaflet. Then you have these Cabrol sutures, which narrow into a commissural angle. And then here you have the figure of eight suture that hitches up those leaflets to a higher level to improve the appositional leaflets. Here you can see a bit more towards the raphe, which is that little left over from the malformation.

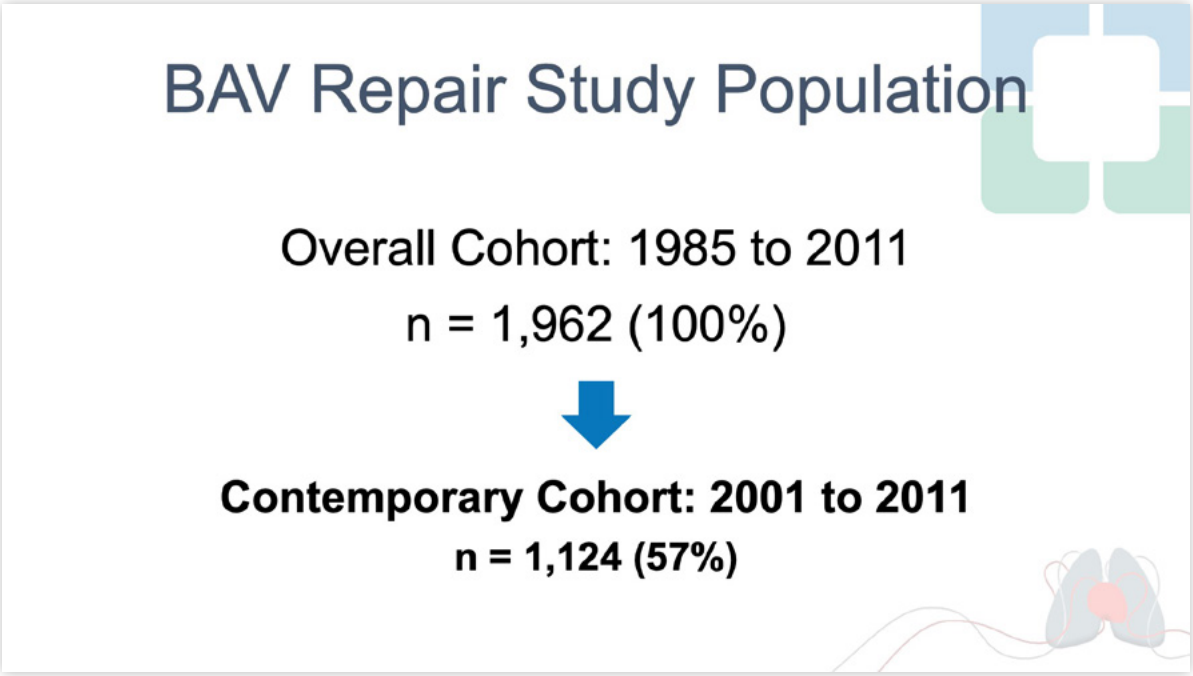
Here's another patient. There you actually can see the raphe has been divided to free up that leaflet. This is a remodeling operation, so the annulus is over here. We've put in the figure of eight, and so we're now ready to sew the cut graft to that annulus. Here's another patient or same patient, but here the graft has been beveled, so this is the remodeling operation and sewing to the annulus of the aortic valve.

Here's a patient with floppy leaflets but a bicuspid valve, and we put a running suture on the edge of the leaflets to try and make that a more durable operation long-term. Here are the two coronary artery osteo coming off to supply blood to the heart and here's where the raphe sits that we divide to improve the freedom of that leaflet. There's how we stretch those leaflets to make sure they're nice and symmetrical before we know we can reimplant or remodel that valve. And here's the finished operation of that particular patient.

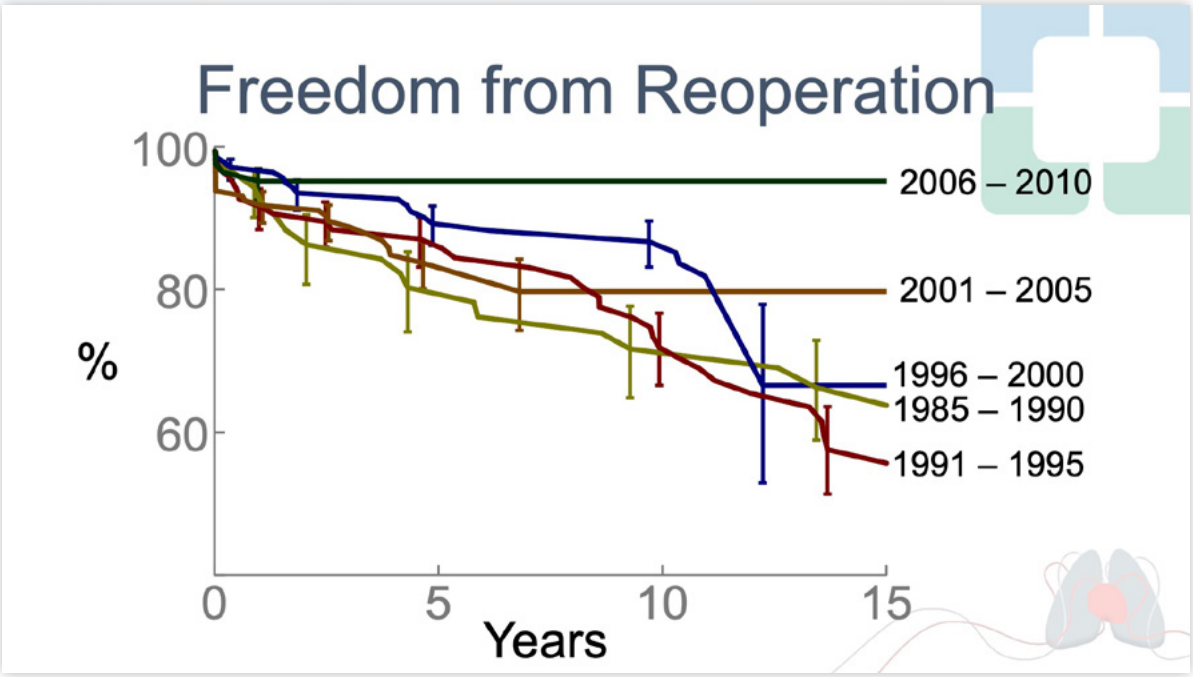


Here's the echo. As you see this great apposition of the leaflet's here as far as height, and that's as important for the long-term durability of these valves. There we go, and there you just have the echo showing that.

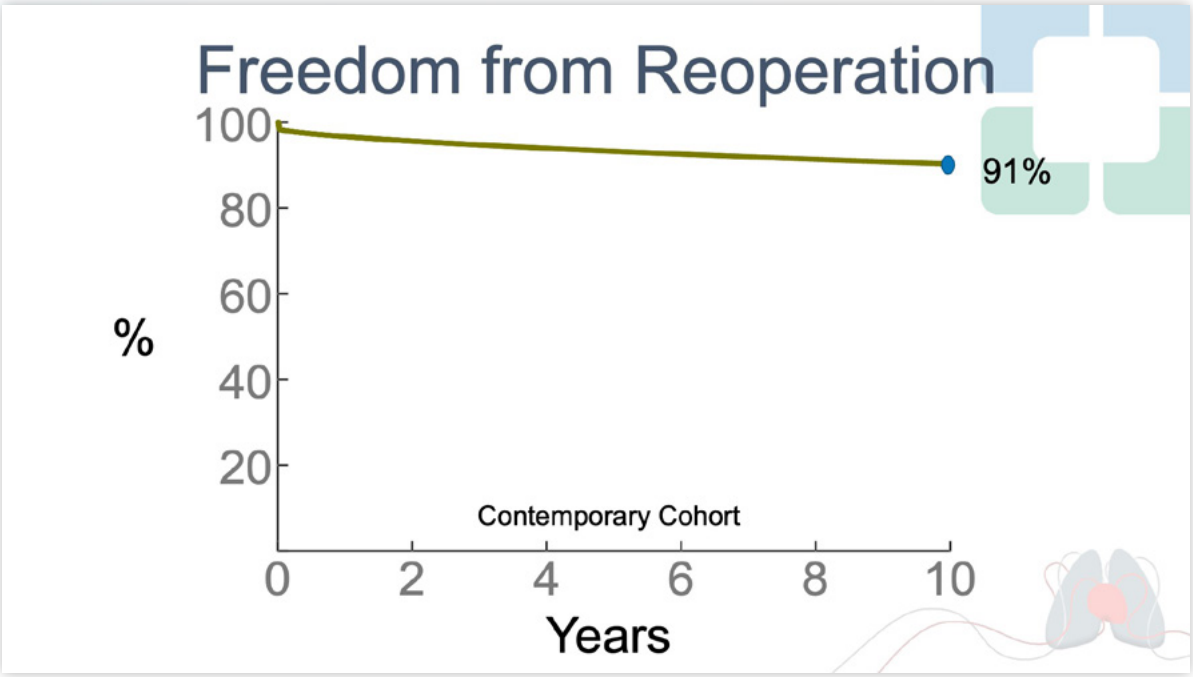
Bicuspid Aortic Valve Repair: Outcomes



Dr. Lars Svensson: Wwhat about bicuspid valve repairs? Between 1985 in 2011, we've done about 2,000 bicuspid valve repairs and we looked at the more recent population up to the end of 2011. We're about to do another study of this, but in the more recent operation patients with more better techniques, the durability was better. Now obviously we don't have 15-year follow-up for all of those patients. So just make that point.

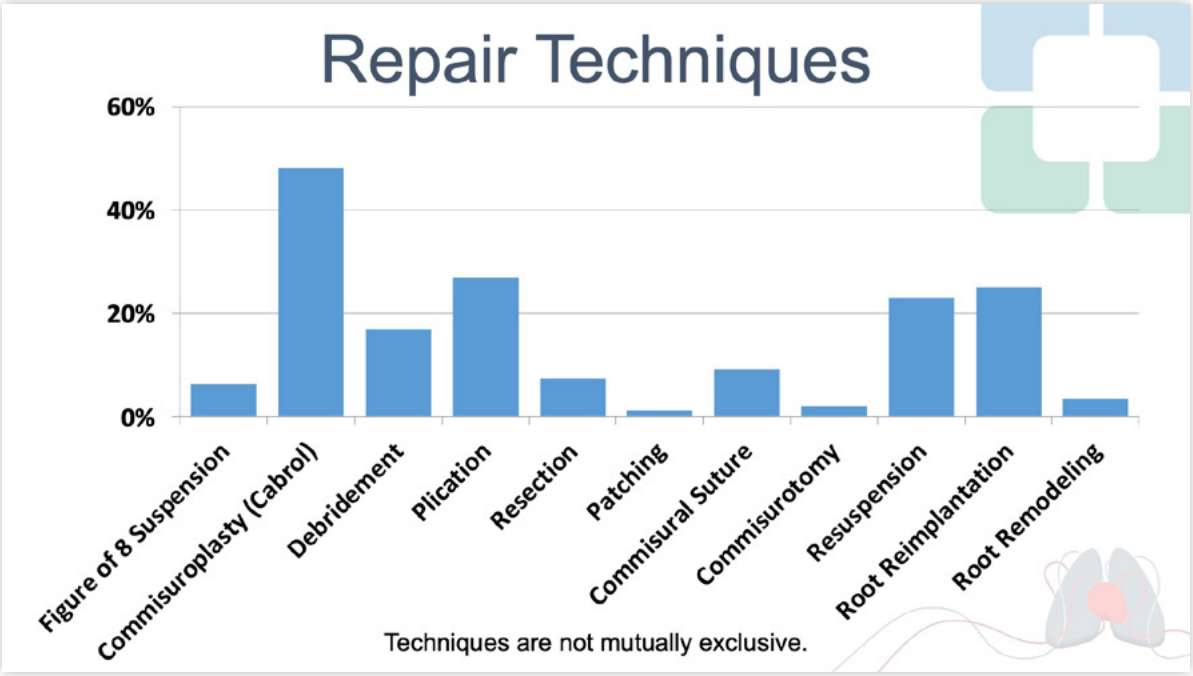


What about the contemporary repair techniques? A lot of different operations and techniques, but I mentioned the Cabrol and the figure of eight technique.



And the freedom from reoperation at that series was 91% at 10 years. So these are patients who otherwise would have had their valves replaced, either biological valve or a mechanical valve. And we've got data to show that if patients have a successful repair, they are much better off than having a biological valve replacement over time.

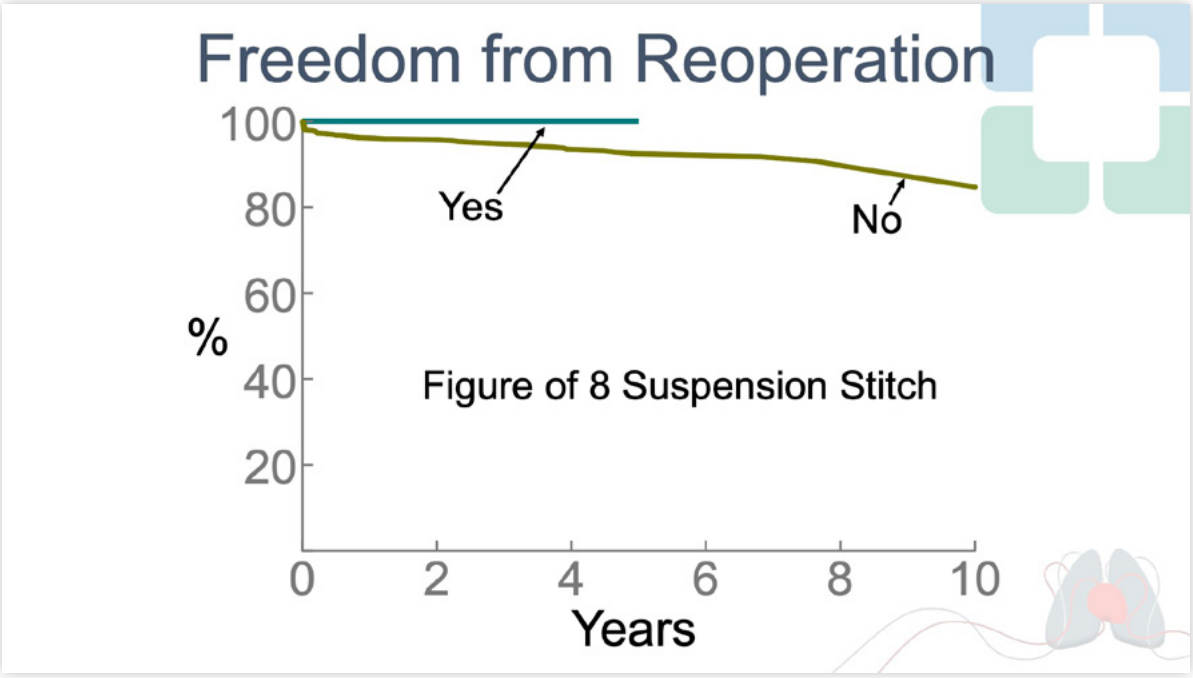
Bicuspid Aortic Valve Repair: Techniques



Adam Pick: Dr. Svensson, just to add in a really quick question for you, we've learned that sometimes when patients choose a tissue valve, one of the factors for them might be because they don't want to go onto blood thinners, like Coumadin. Are there ever situations when you do some kind of reconstruction technique and the patient also needs to go on some form of blood thinners? Or when you say freedom from reoperation, they have no medication. They are just living a normal life without any medication.

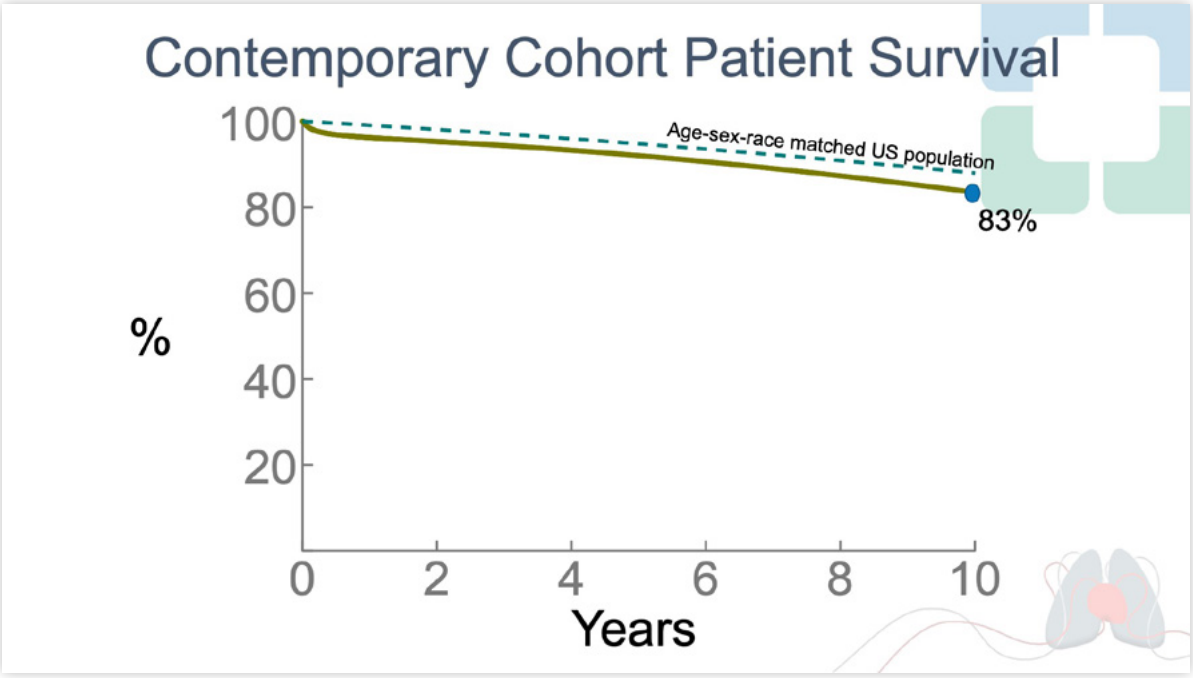
Dr. Svensson: That's correct. So the only thing I recommend is they take a baby aspirin a day. I think that's always wise in this population, but they don't need to be on blood thinners. The only reason for a blood thinner would be if they've got atrial fibrillation or some other reason and then one of the newer types of medications that don't need blood testing. like INR, is the usual way that that's treated.

Figure of 8 Suspension Stitch



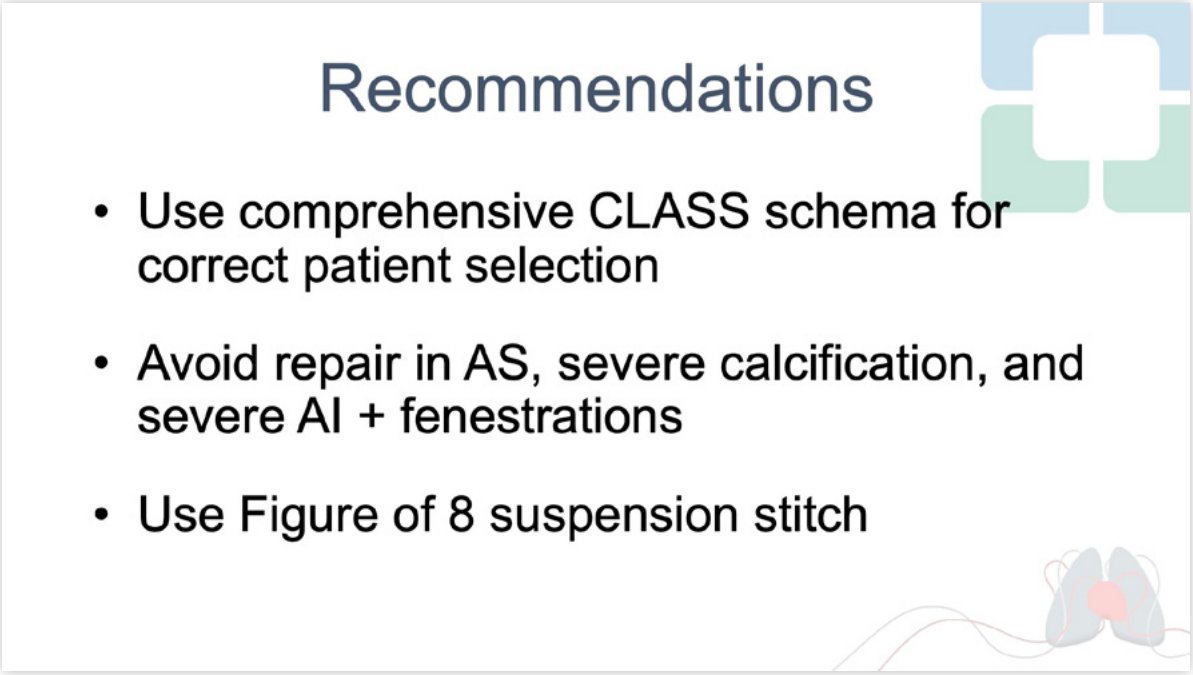
Dr. Svensson: So the figure of eight stitch seems to result in better results long-term in patients that we use it. And also when we do a root repair with bracing of the root just from the technical point of view, that seems to result in a better repair over time.

Bicuspid Aortic Valve Repair: Long-Term Survival



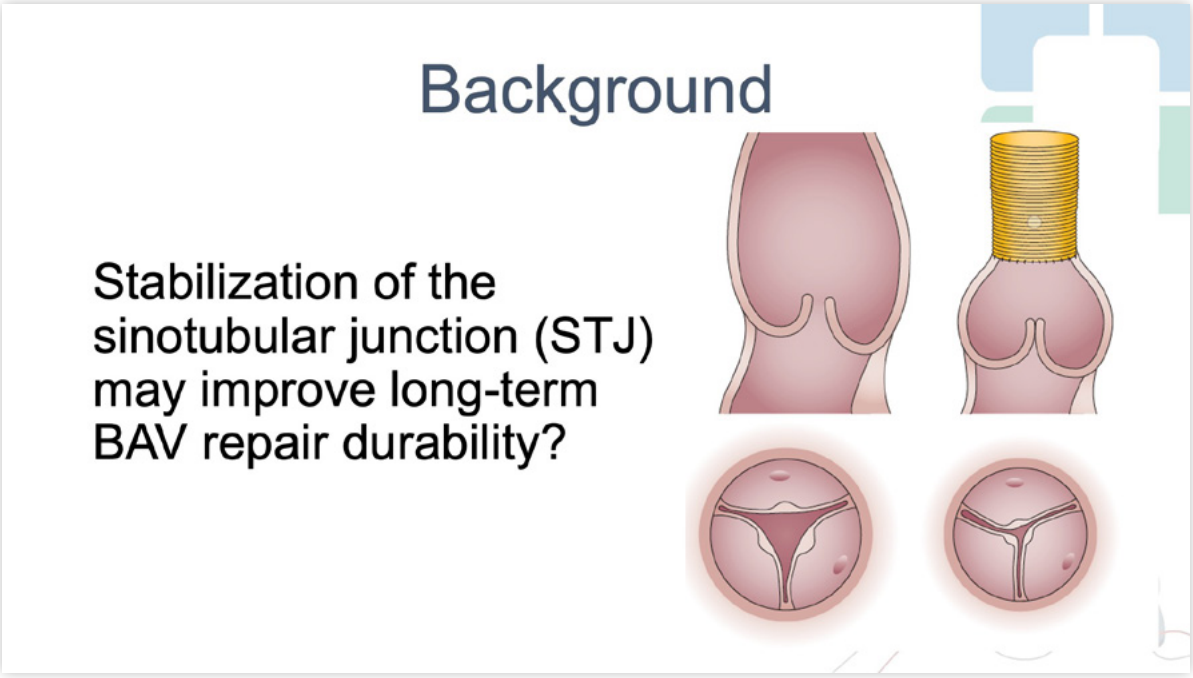
Dr. Svensson: One question that people ask, "How's my long -term survival?" So we matched survival with age and sex and race for the United States population. And once people get over the initial operation, the long-term survival is the same as the general population. And for example, this year, we've had no deaths for any aortic valve replacement or aortic valve repair, isolated valves that is, and we do about 400 a year. So I often say to patients, I haven't had a death after an aortic valve replacement for the last 10 years. So the results here at the Cleveland Clinic are already good with the replacements and the repairs, and your life expectancy should match the rest of the United States.

Bicuspid Aortic Valve Repair: Recommendations

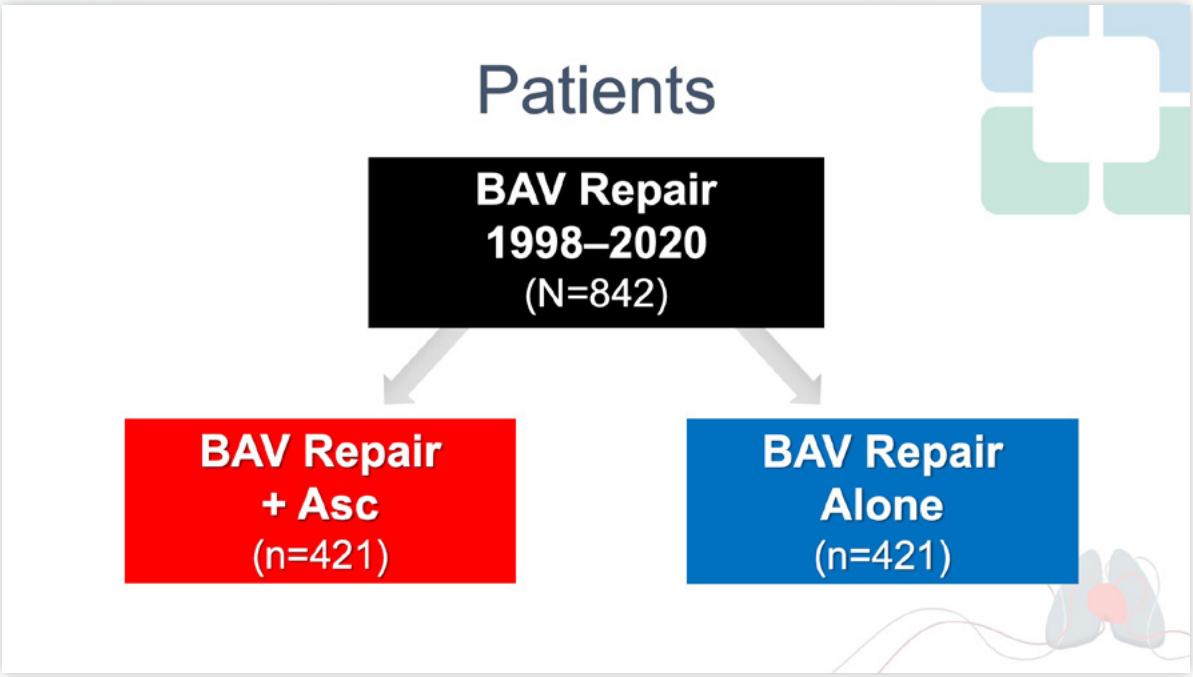


Dr. Svensson: So from a recommendation point of view, when it comes to repairs and talking to your surgeon, I recommend they follow the schema I mentioned, avoid repair in patients with aortic valve stenosis and fenestrations, and the figure of eight stitch really makes the repair more durable.

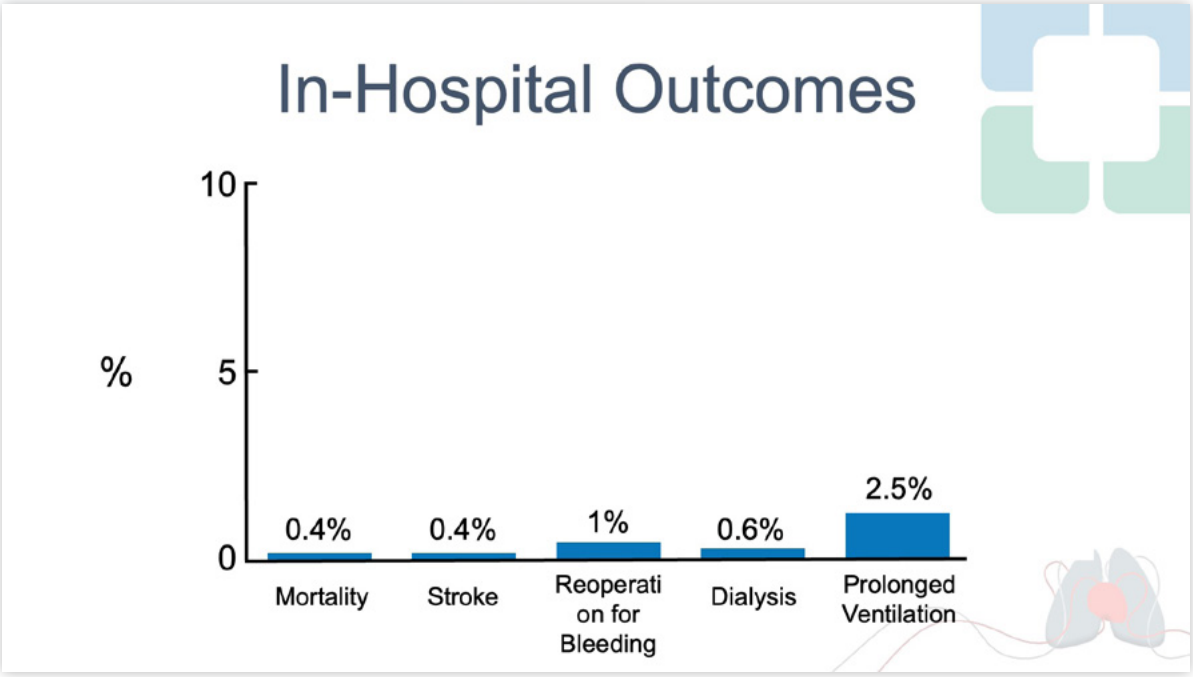
Ascending Aorta Considerations



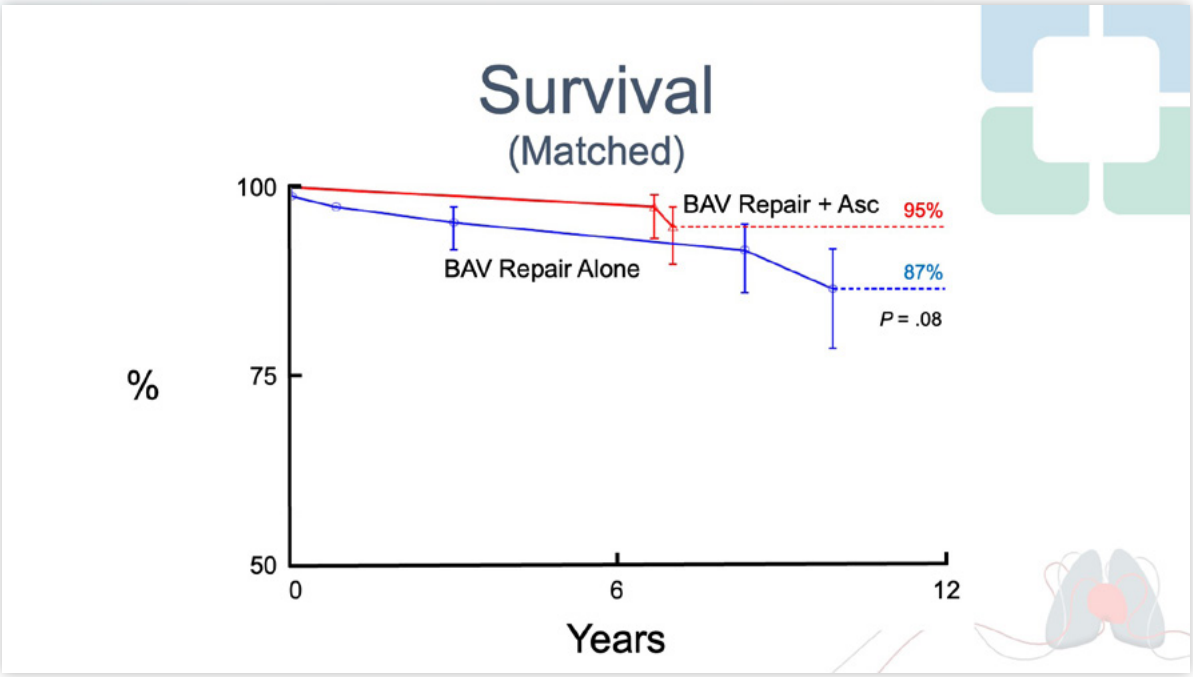
Dr. Svensson: So one of the questions we had for patients who came to see us was should we be more aggressive in replacing the ascending aorta above the aortic valve to improve the durability of repairs. One of my trainees looked at that, looking at the outcomes over time.



We had 842 patients that we matched in comparison; 421 in patients who had repair plus ascending aorta plus repair alone. And when we matched outcomes, overall mortality in that series was 0.4%.

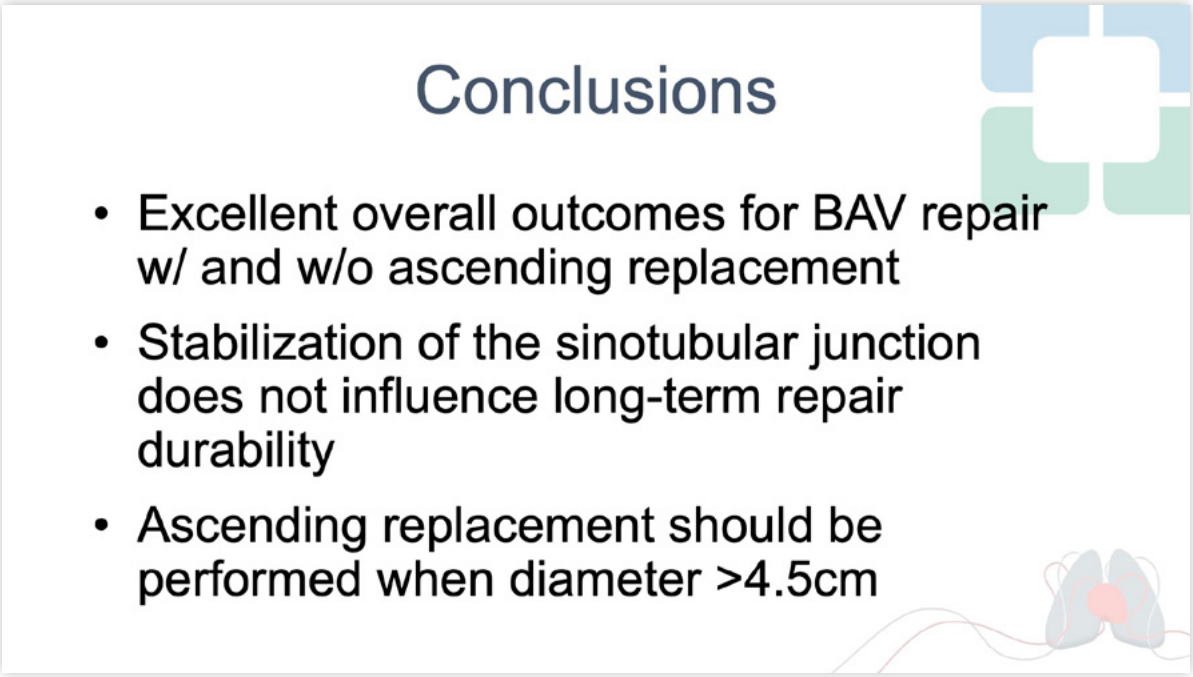


And late outcomes basically showed when it comes to survival, no difference in the significant survival over time, out to 12 years, no difference in regurgitation from the valve, leaking valves over time, no difference in dilatation of the aortic root or the hastening aorta afterwards. And reoperation for aortic valve stenosis development was the same in that population and no difference in reoperations for aortic valve regurgitation



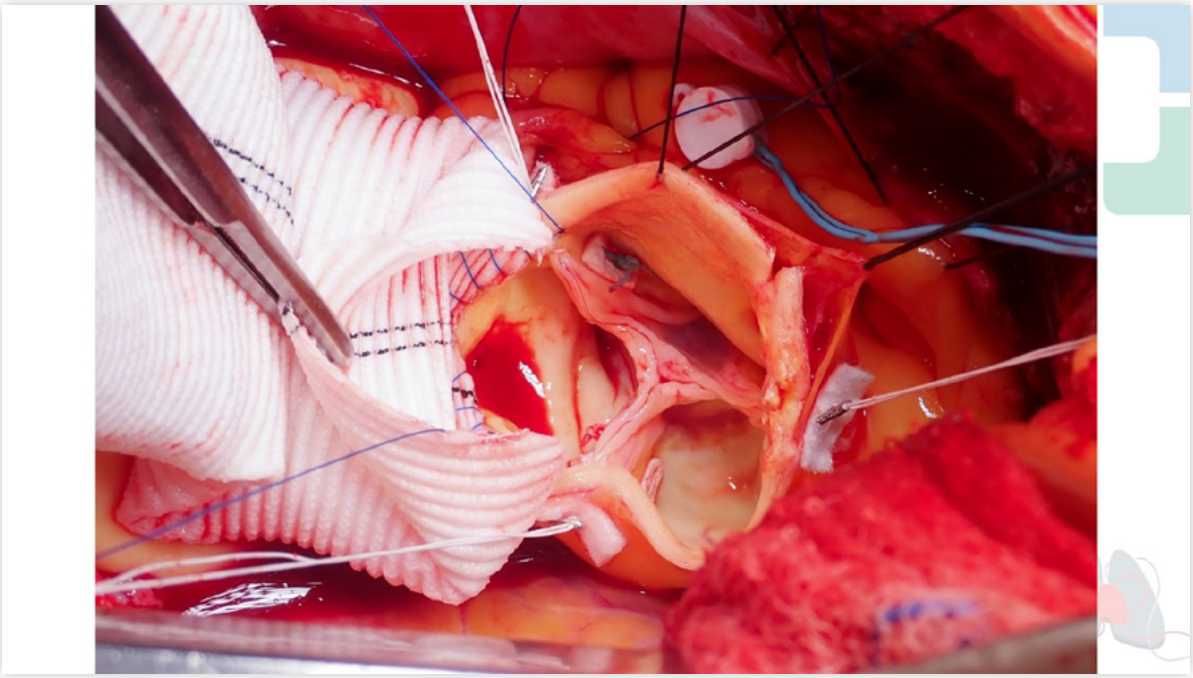
So this one point is important because I thought maybe if we replace the ascending aorta, the repair freedom from reoperation would be even better. But on the other hand, here you have again that number of 91% freedom from reoperation at 10 years. So that's about the standard for these patients. And risk of root dilatation, as long as the root is replaced if it's more than 4.5 centimeters, no difference in outcomes. So that's basically the keys from that study. But I think it's important that if the aortic root is more than 4.5 centimeters, it usually needs to be replaced. But a lot of things come into that decision-making, including whether reimplantation is feasible or not.

Bicuspid Aortic Valve Repair: Conclusions

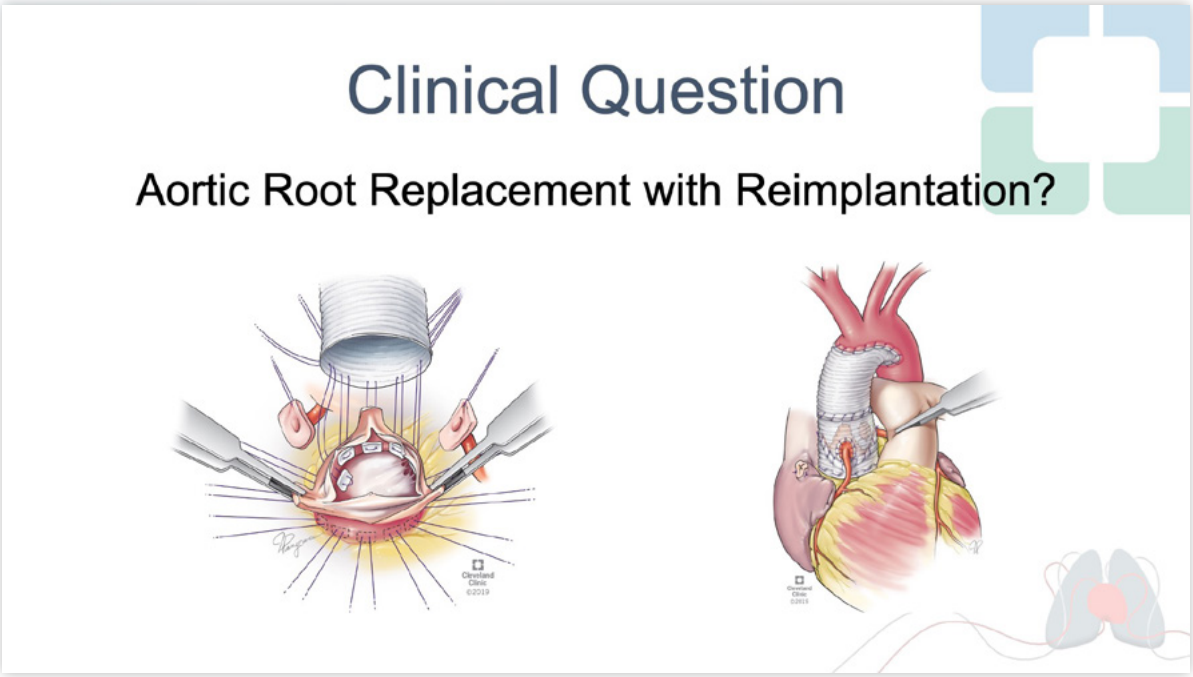


Dr. Lars Svensson: I think it's important that if the aortic root is more than 4.5 centimeters, it usually needs to be replaced. But a lot of things come into that decision-making, including whether reimplantation is feasible or not.

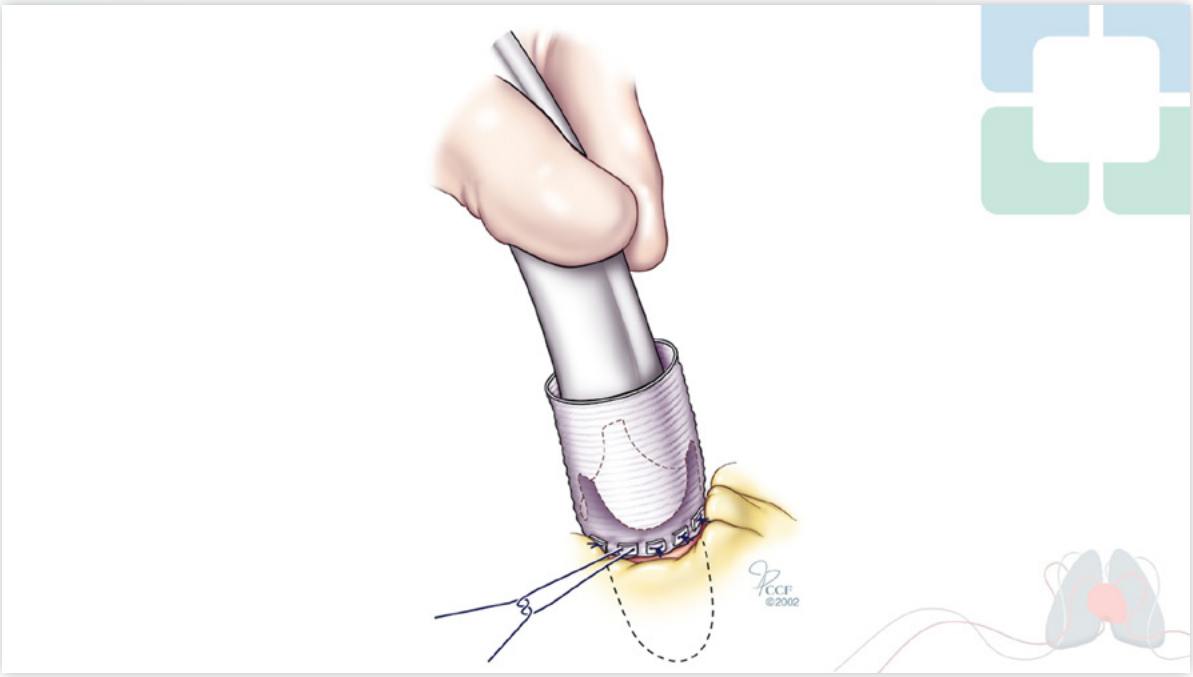
Aortic Valve Reimplantation Operations



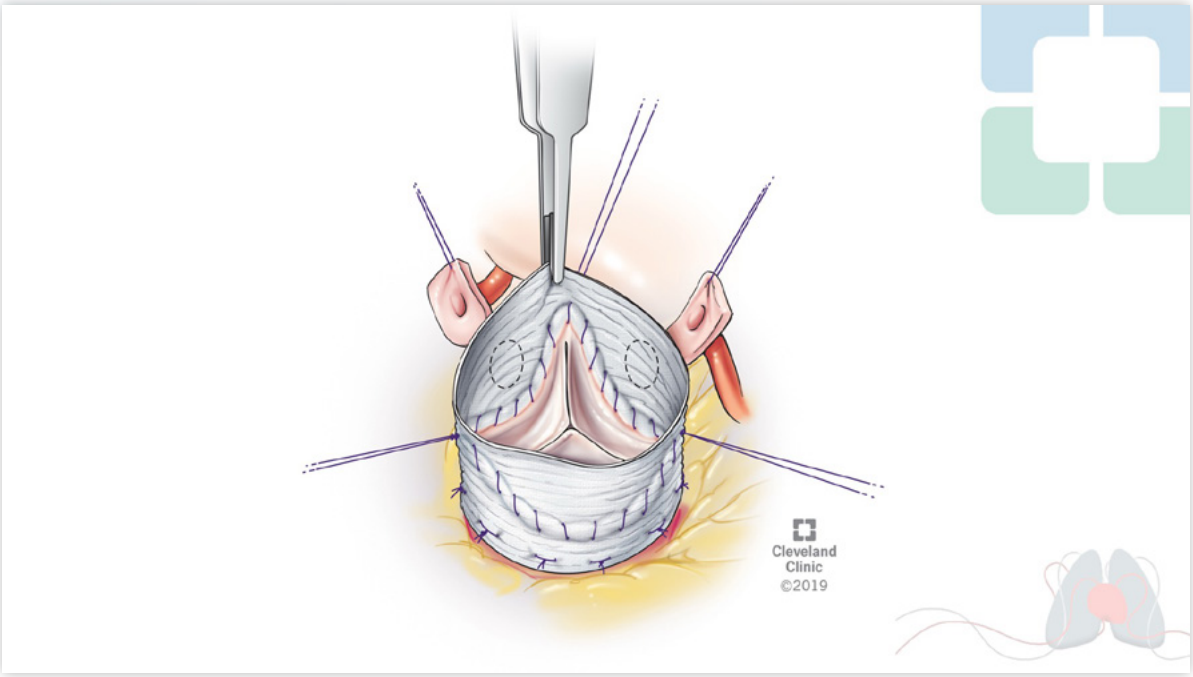
Dr. Lars Svensson: What about now the reimplantation operations? I will make one comment about an operation we used to do a lot of, we don't do as much now, which is a three-leaflet valve that's leaking severely but the aortic root is not enlarged. In that population, we put in those Cabrol sutures I showed you, and then I put in these figure of eight sutures to hitch up the leaflets, to hitch them up to a higher level, and then often we can repair those three leaflet valves and preserve the valve for the patient. And the results of that, I don't go into that in this talk, but the results have actually been very good long-term.



So let's talk now about the modifications for the reimplantation operation. The key ones are putting pledgets in the left ventricular outflow tract. So the aortic valve here has been freed up and pledgets have been put through the pumping chamber underneath the valve and those are going to be put into the new tube graft and then the valve gets reimplanted.



The other thing that's key to this is using what we call a Hagar's dilator. So this is a measured size that we use to tie down those stitches I showed you and that ensures that we don't over-tighten these sutures and narrow the aortic valve excessively. It's the aortic valve annulus in particular and also that we bring down the size to a normal size. So some patients, for example, with Marfan syndrome may have a 4 centimeter aortic valve annulus. That also affects the long-term durability of these valves. So that's the reason why we use the Hagar's for a reimplantation of the valve.



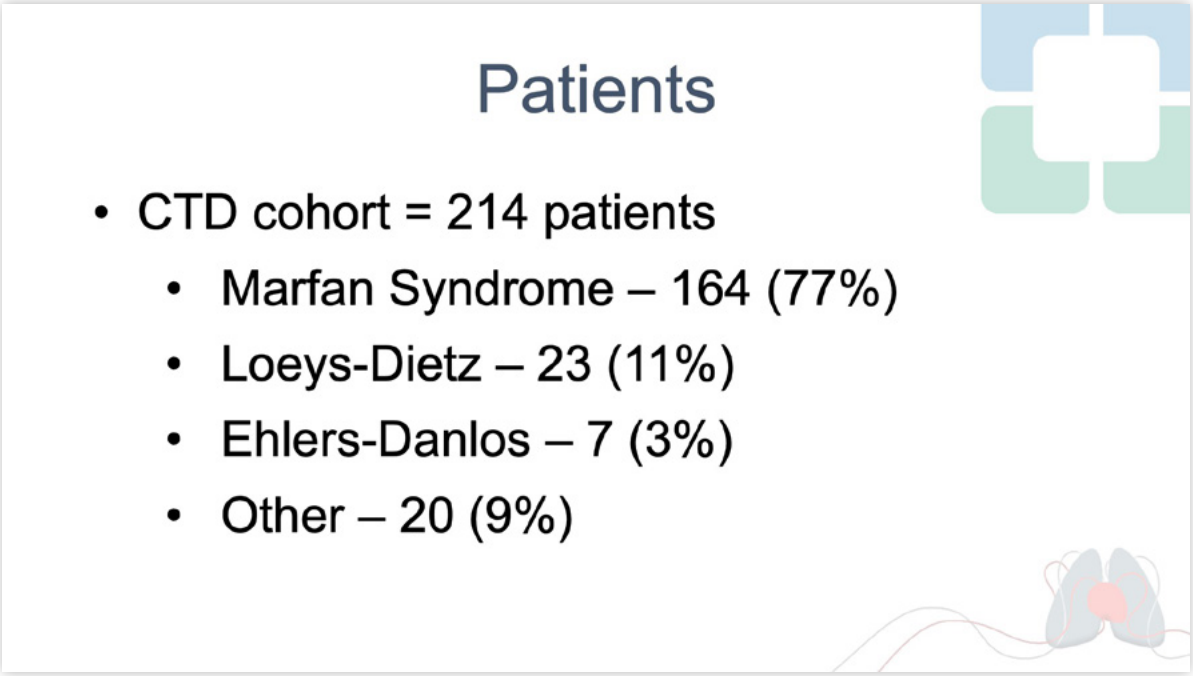
Here's the valve just then sewn in position with the coronary artery buttons that are going to sew onto the sides of that glute.

Adam Pick: Dr. Svensson, can I ask you a real quick question? I don't know if you can see me. I'm shaking my head up and down and side to side in amazement by all of this and getting back to the reimplementation. I'm curious to know, when I saw you describe how you use the pledgets for the annulus and keep maintaining the structure, it kind of reminded me of a mitral valve repair ring to some extent But that's not what it is. I'm curious for the folks on the line, how then did you come up with that innovation to use pledgets? Do you remember what caused you to think hey, we can use pledgets here to help out the annulus?

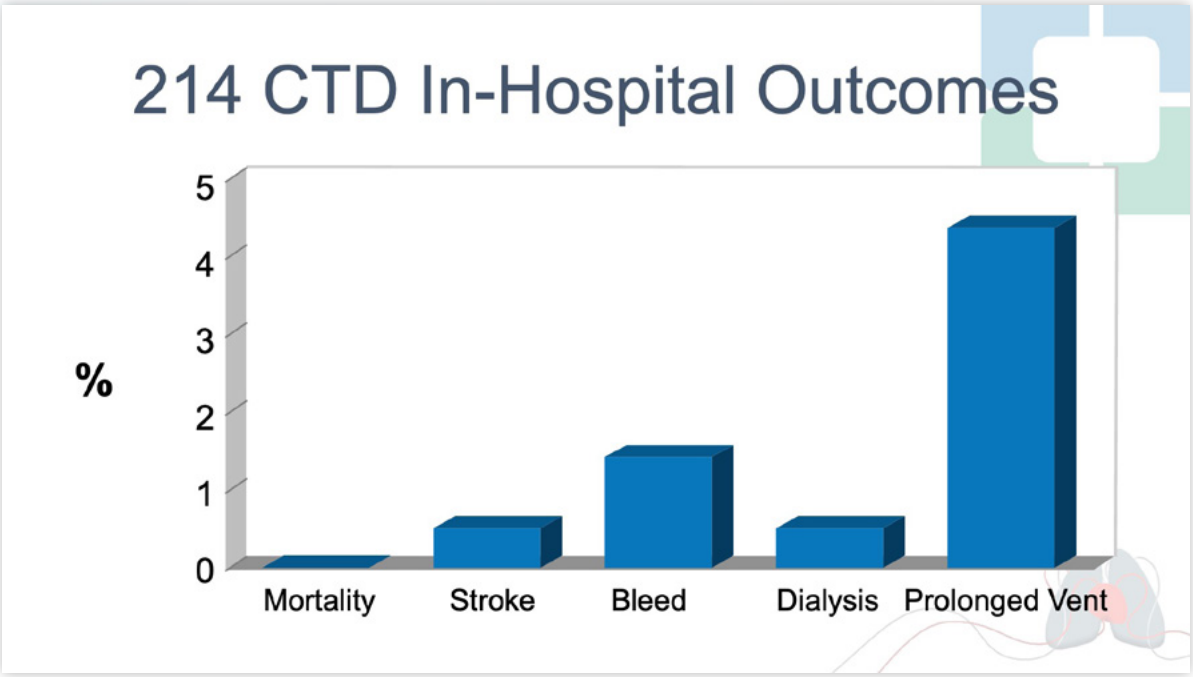
Dr. Svensson: Well, what I discovered in looking at what people were doing was that the sutures were pulling through and people were ending up with so-called fistula, which means a communication between two chambers in the body. So there were holes being made in the mitral valve. There were ventricular septal defects being created, holes in the right ventricle and causing leaks between the chambers of the heart. And particularly in patients with Marfan syndrome and Loeys-Dietz, their tissues are much more fragile. And so the obvious to me thing was to put pledgets on those so the stitches did not tear out. And that's a basic principle we use in a lot of aortic and valve surgery is to use pledgets.

Over time, pledgets have become the way that most valve replacements are done now with both mitral valve and aortic valve. We use pledgets for that. So that was the key from that point of view. And when it came to using the Hagar's, that was because I was seeing Marfan patients with these very big annuli. And part of the reason the valves were leaking was because the annulus was very big. And so I thought it was important from a durability point of view, long-term to bring down that size. And we'll talk some more about it, but that I think is one of the key reasons why the freedom from reoperation is 95% at 15 years with these modifications of the reimplantation operation, which means the results so just as good, getting back to your comment, as a mitral valve repair. So a good done reimplantation operation should have the same durability as a mitral valve repair for a posterior leaflet that has ruptured.

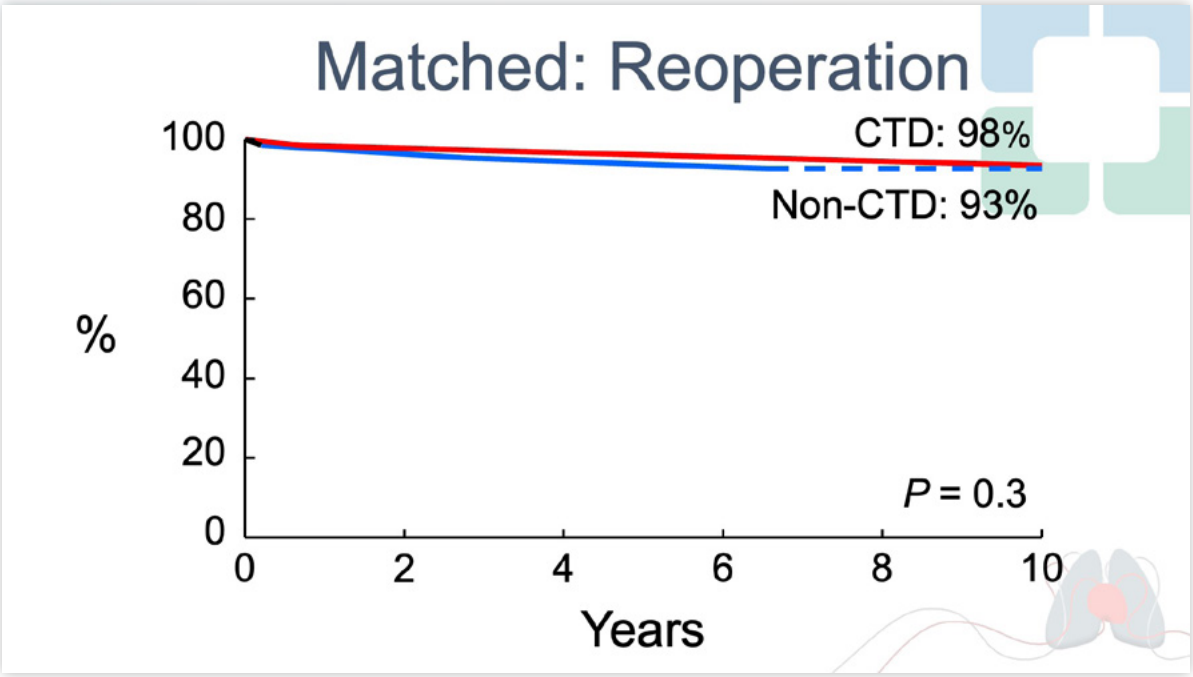
Connective Tissue Disorders



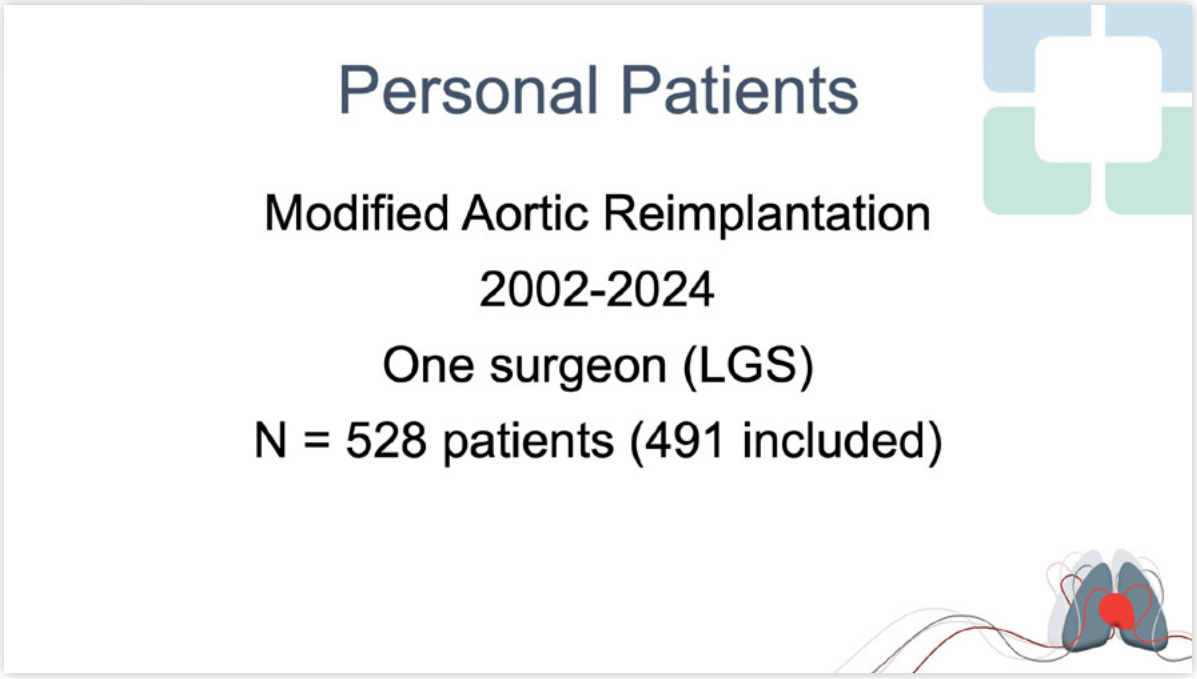
Dr. Svensson: Let's talk about the connective tissue disorders. As I mentioned this has been a long interest of mine since a friend of mine had it, played rugby with him, and if I can interject a personal note, I pushed on his butt and so I always had a good relationship with him and we were great friends. Then when I worked for Dr Crawford in Houston and trained with him, he gave me the privilege of reviewing all his Marfan syndrome patients, the biggest series at that time of 151 patients. And in that group of patients were patients who clearly had a connective tissue disorder but did not meet the GENT criteria for Marfan. And in retrospect, those were patients with Loeys-Dietz. And so I called the Marfanoid in that series. And then obviously Ehlers-Danlos has been known for long term.



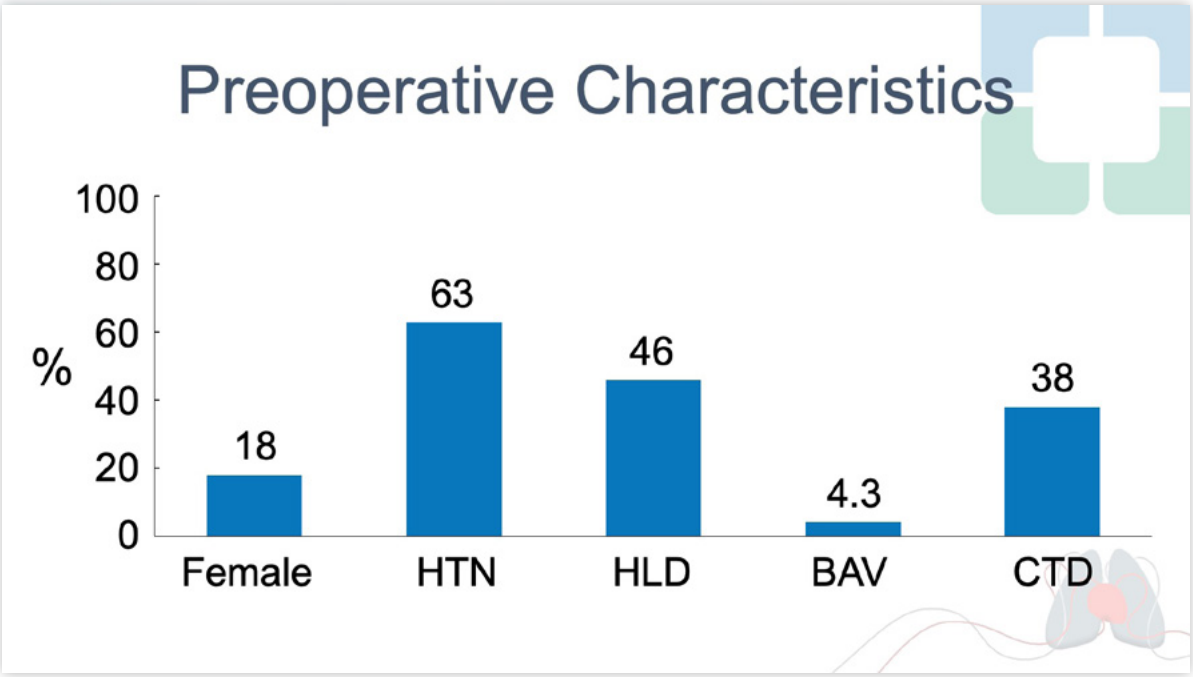
So this is our 214 patients we studied a few years ago with connective tissue disorders. And in that series, there were no operative deaths for the 214, small risk of stroke in that group of patients. So what about risk of reoperation over time? In that series, the freedom from reoperation at 10 years was essentially exactly the same, slightly better with the patients with connective tissue disorders, so really great results.



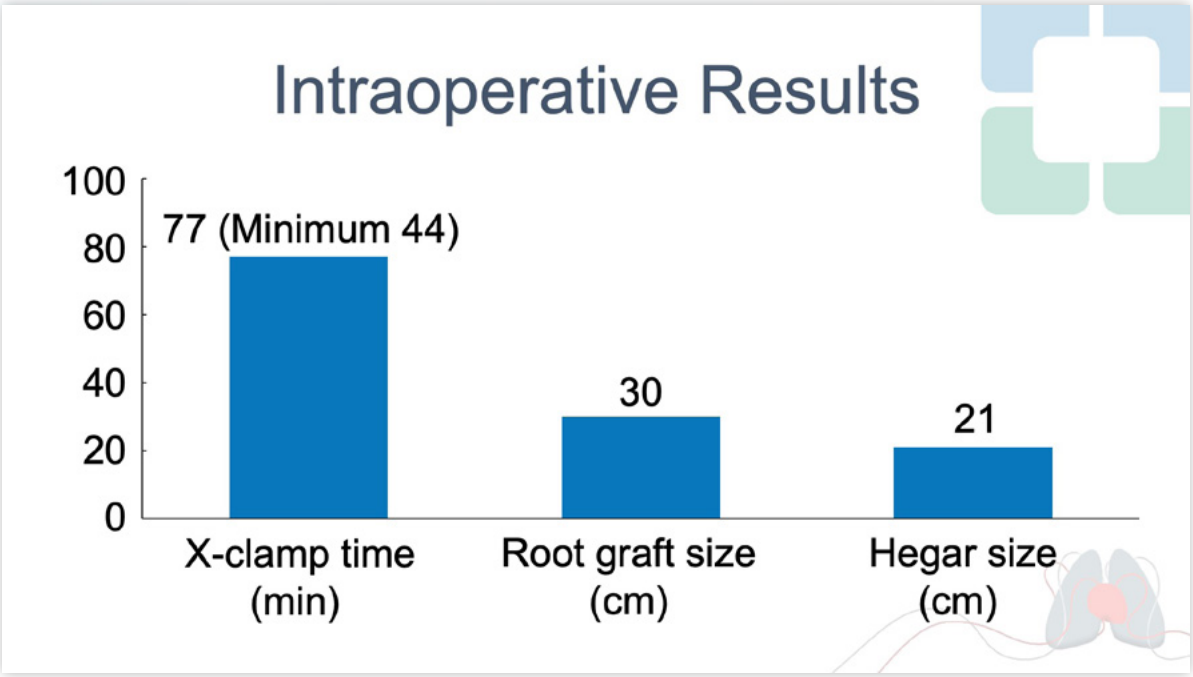
The fear we had when we started doing reimplantation operations for connective tissue disorders was that the leaflets weren't normal; they'd fail over time but that has not been the case and so we are actually very happy with the four patients in the long-term outcomes. Last year at AATS, you mentioned this, one of my trainees presented my personal series of 528 patients up until 2024 for re-implantation operation using the modified reimplantation operation.



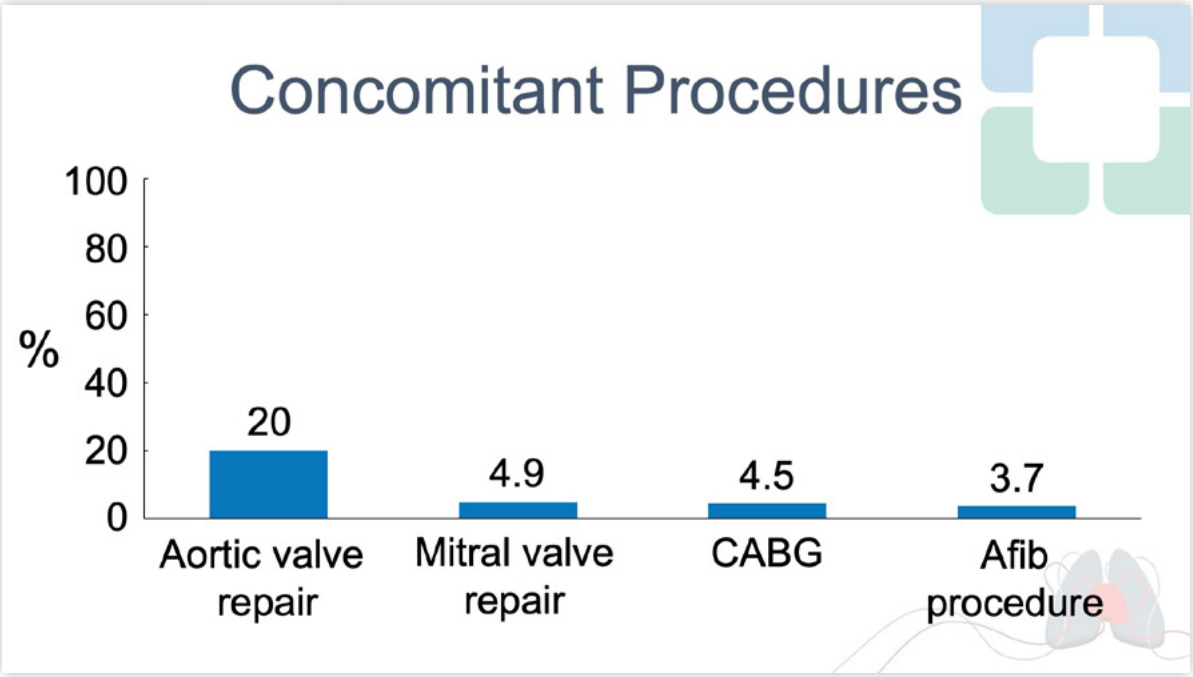
Thirty-eight percent of those patients had connective tissue disorder and various grades of regurgitation and ages. My oldest patient is 81 years old and still doing well when she had her reimplantation operation.



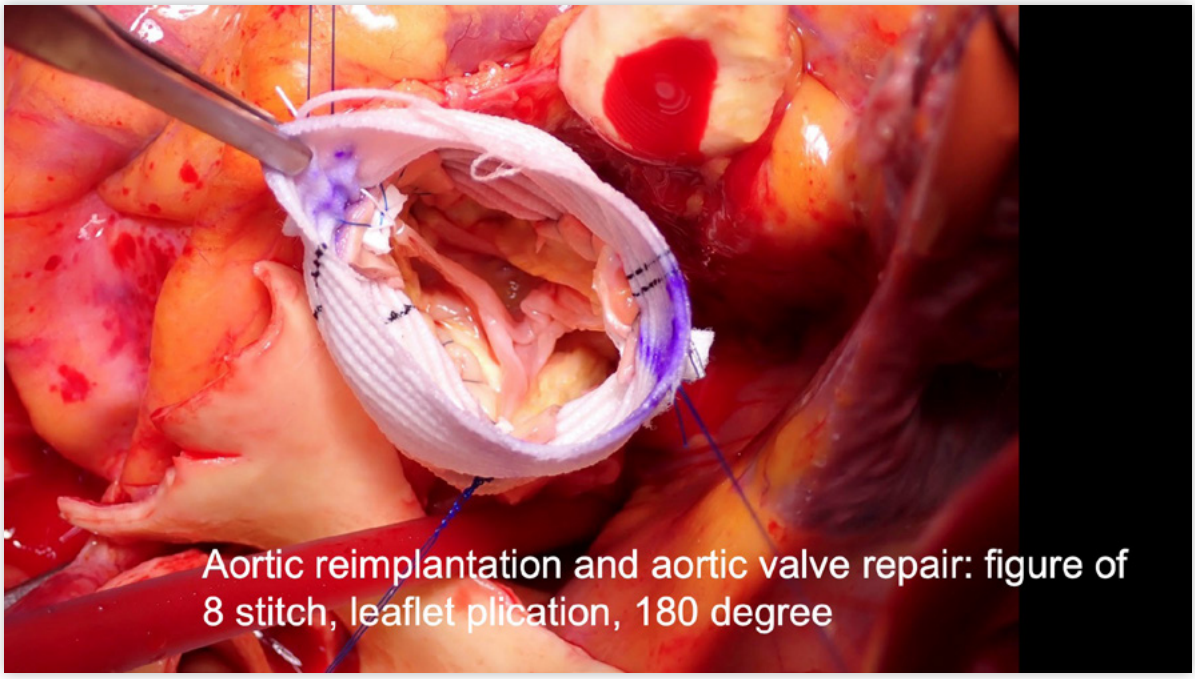
Some of the intraoperative results, typically the clamp time is less than an hour, so that's the time that the heart needs to be stopped for the operation and do the valve reimplantation.



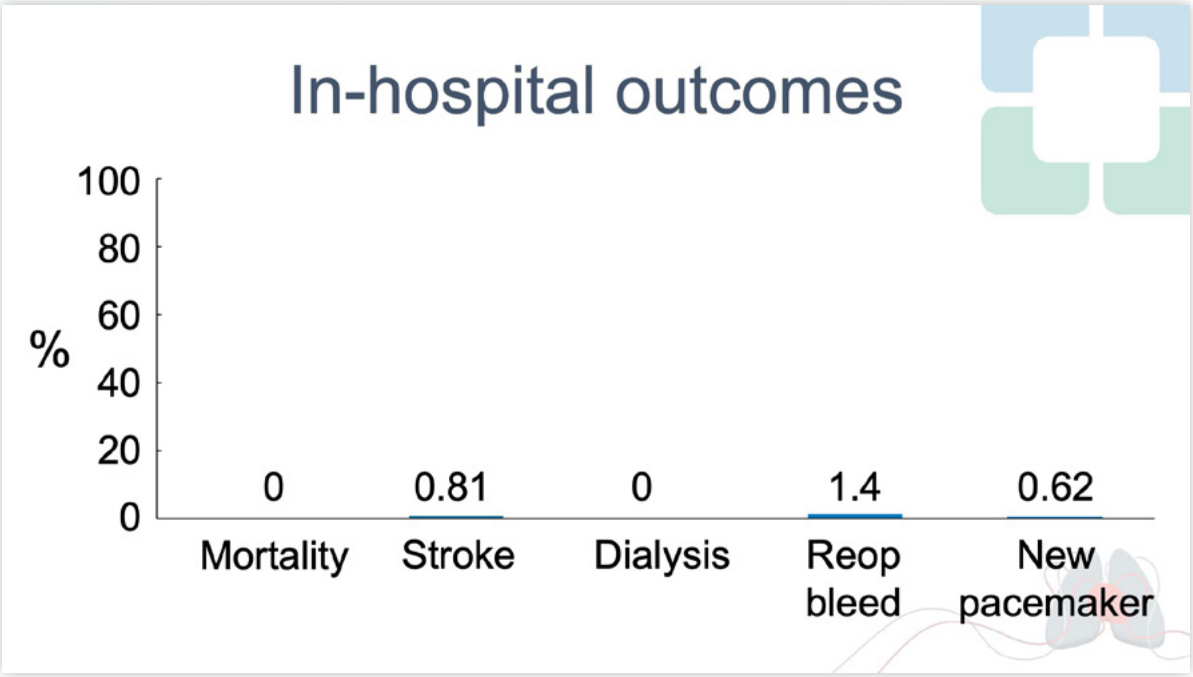
If additional things need to be done like coronary artery bypasses or mitral valve repairs, that adds to the length of the operation and concomitant procedures, as I mentioned, the mitral valves, coronary bypass, and quite often patients need atrial fibrillation operations too.



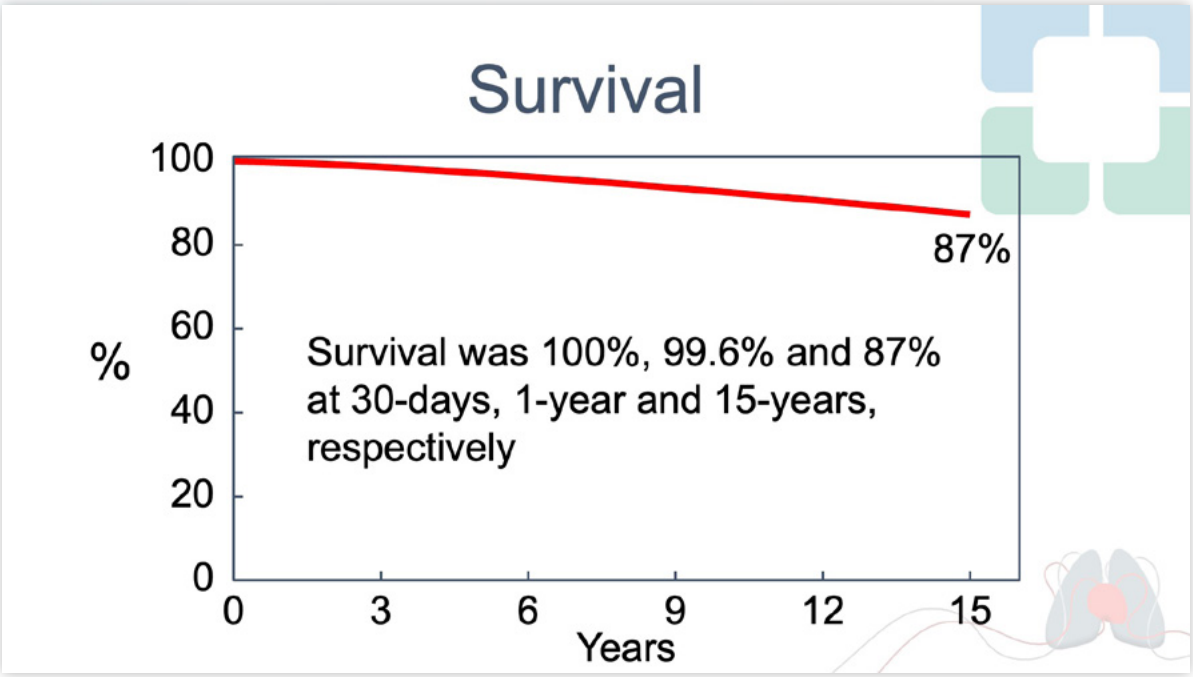
Sometimes things can get a lot more complicated. This is not what I'd recommend your surgeon to start off doing, but this is a patient with a figure of eight sutures and a plication of the leaflets to make a successful repair.

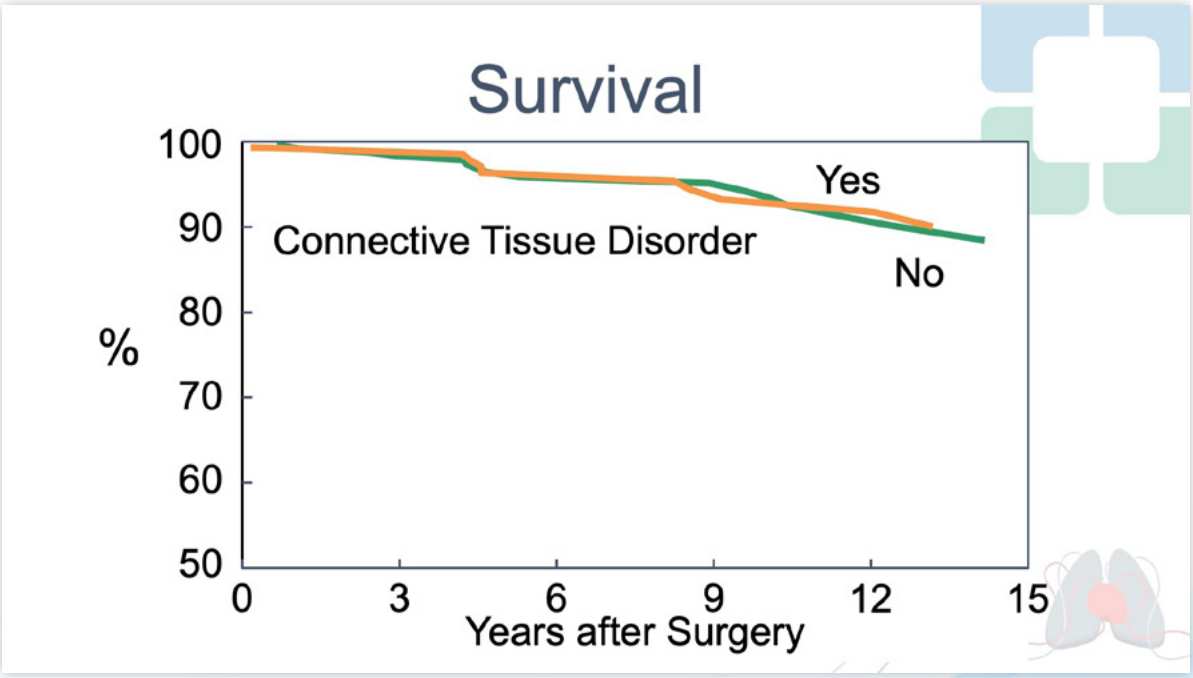


And that outcomes, a series of mine, there were no deaths, and new pacemaker rate is 0.62. So if you compare that with patients who have Bentall operations, in other words, have the valve replaced, that usually is about 2% to 3% and a low stroke risk in this series.



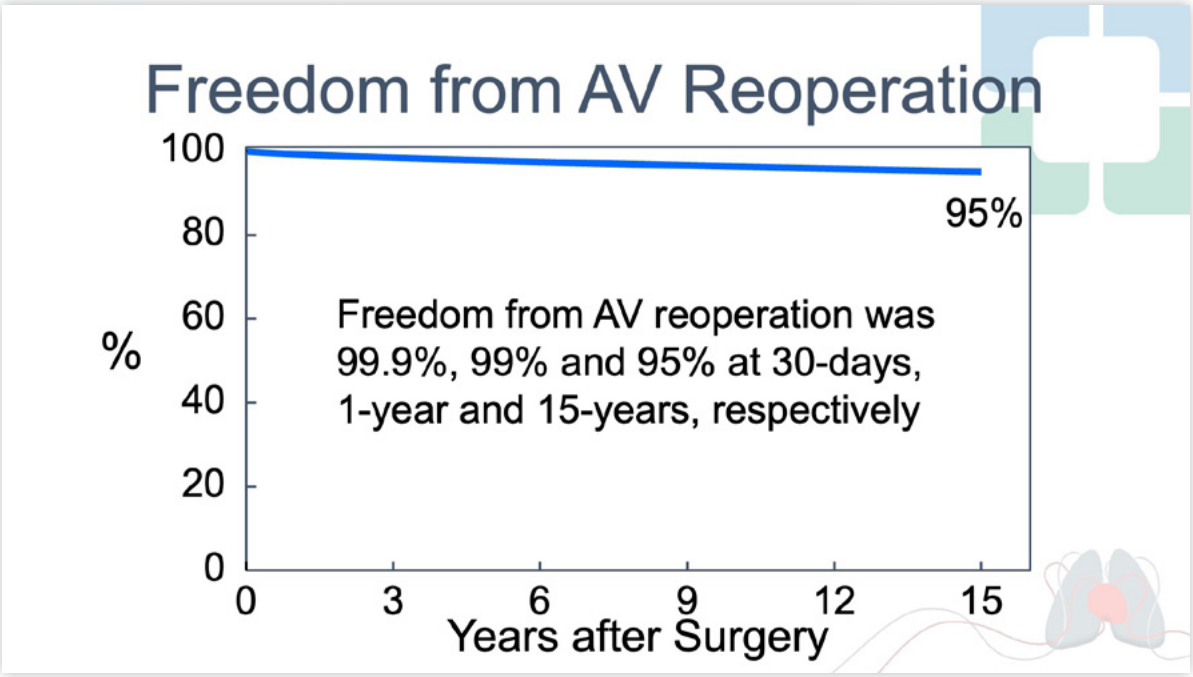
Survival at 15 years is 87% of patients are alive. No difference with survival with connective tissue disorders. And look, this is one of the great successes in cardiac surgery.


Survival
100
80
60
40
20
0
%
87%
Survival was 100%, 99.6% and 87%
at 30-days, 1-year and 15-years,
respectively
0
3
6
9
12
15
Years

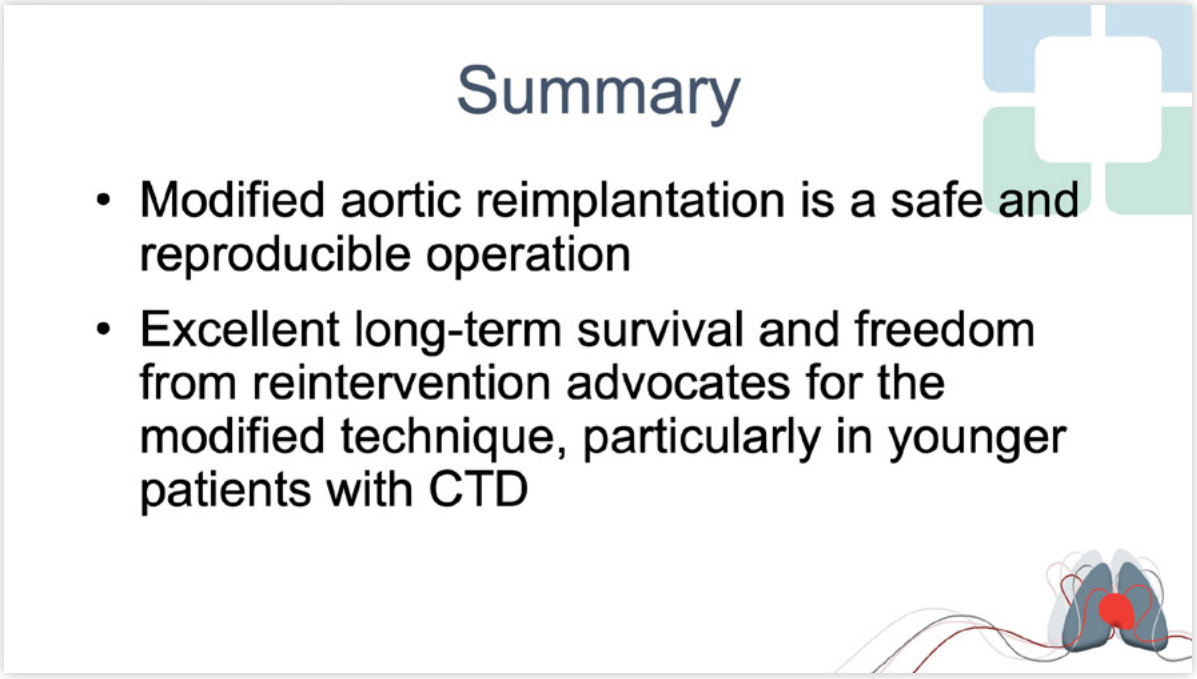

Survival
100
90
80
70
60
50
%
Yes
Connective Tissue Disorder
No
0
3
6
9
12
15
Years after Surgery

The life expectancy for patients with Marfan used to be 32 years. Now patients are living well into their 70s and I get notes from patients and it's just one of the great successes in heart surgery. So for those of you who have the unfortunate connective tissue disorders, once you have the valve and the root fixed, the long term prognosis really looks good.

What about freedom from reoperation overall?



In my series 95% freedom from reoperation at 15 years and disorder is slightly better results than the non-connective, but that's probably influenced a bit by bicuspid valves in that series. So here's the bicuspid valves, no significant difference in outcomes with reimplantation in patients with either tricuspid or bicuspid valves. And this is a survival; survival is excellent in both categories of patients. And the risk of regurgitation over time moderate is about 10% over time, but typically moderate regurgitation does not need an intervention and doesn't need any further treatment.

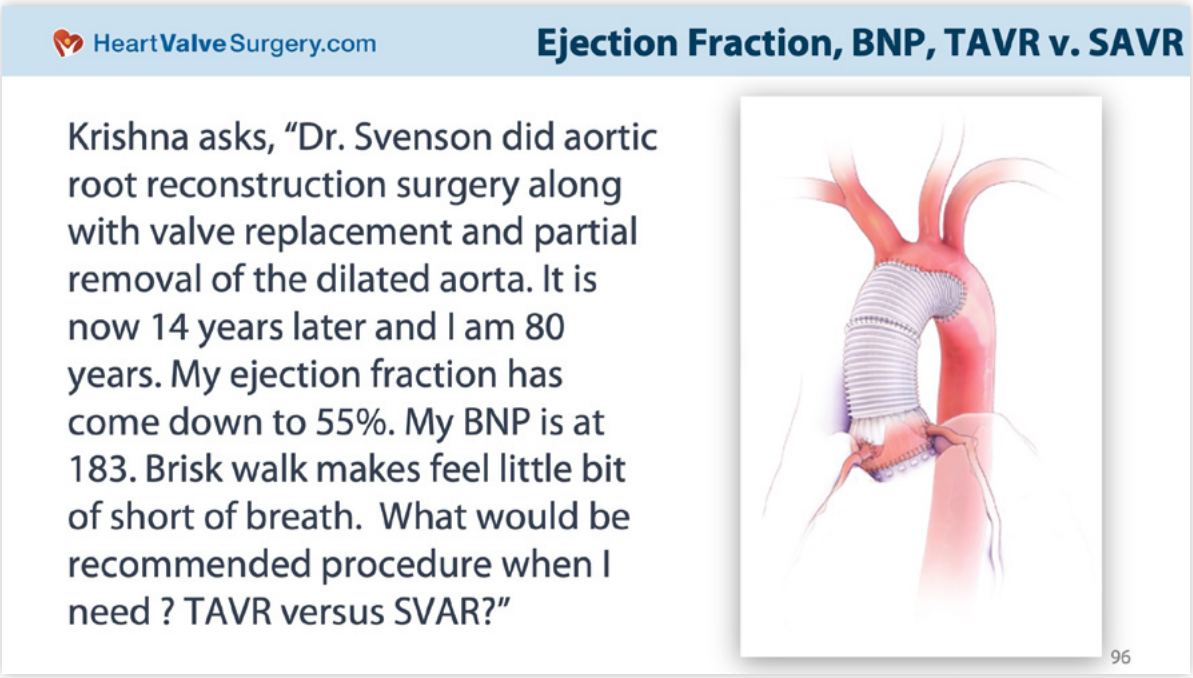


So the modified aortic root reimplantation is a reproducible operation and a lot of surgeons are doing it. If you look up on YouTube, there's one that I did on Loeys-Dietz. So if you look up Loeys-Dietz reimplantation, by my name you'll see some description of that. And the great thing is the outcomes in connective tissue disorders are really good.

This is, as I can reveal this obviously because Jeff Green has given us permission, this is – and discuss his operation. This is obviously somebody who's very tall. He was in the championships recently. One other comment for those of you are concerned about biological valves, there is a lot of controversy at the moment within the surgical community and patients basically are given the option of choosing between mechanical and biological valves. Since 2010, the risk of having a reoperation aortic valve replacement at the Cleveland Clinic is no higher risk than the first operation. And that particularly is important when you think how you may need to manage a reoperation for a biological valve. This is a very safe operation here at the Cleveland Clinic.

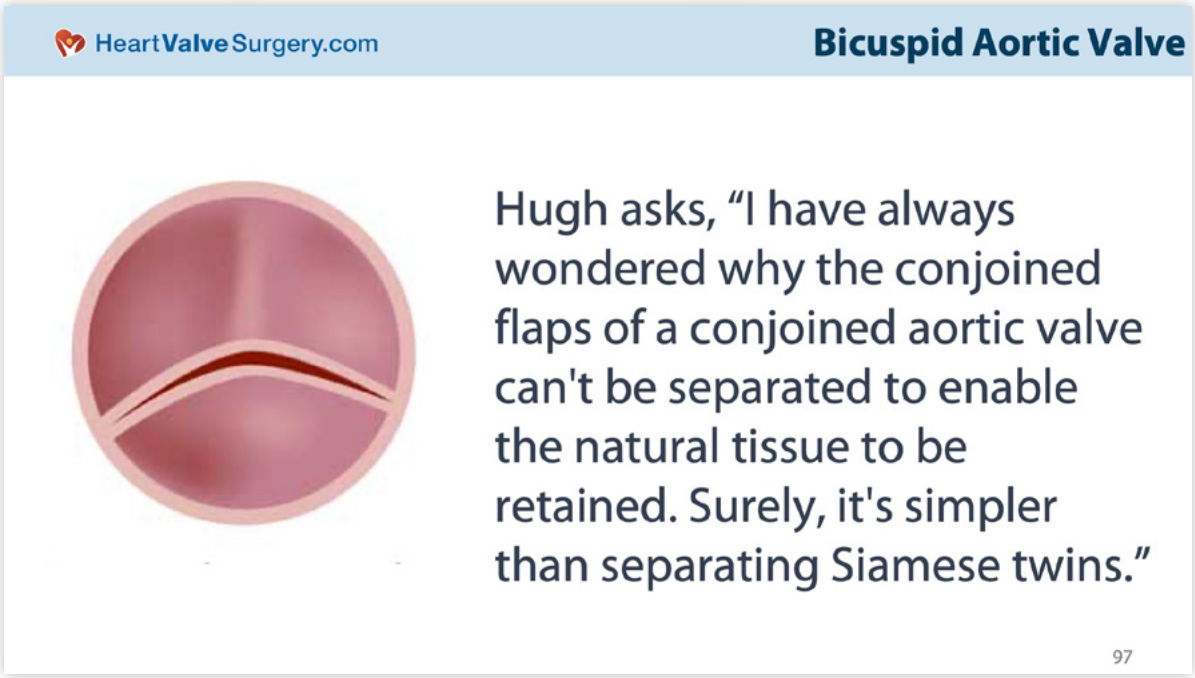
So with that, I'm open to questions and answers and again, it's my privilege to chat to you. Delighted so many of my patients have come from your forum and it's our pleasure to help you in any way we can. I didn't put my phone number up there, but my office number is (888) 801-7462 and my secretary, Rhonda, is fantastic at answering the phone and Lindsay Hackney is my nurse practice manager and she chaperones you through everything, presents your studies to me. I review them and usually within a couple of days, I can get back to you on what my recommendations are. So thank you very much for the time and opportunity to speak to you.

Questions and Answers



Adam Pick: Let's get into the question and answers. And we've gotten a bunch of them, Dr. Svensson. This one comes from Krishna, who's actually one of your patients. And he says, "Dr. Svensson did a root reconstruction surgery along with valve replacement and partial removal of the dilated aorta. It is now 14 years later and I'm 80 years old. My injection fraction has come down to 55. My BMP is at 183. A brisk walk makes me feel a little bit short of breath. What would be a recommended procedure when I need a reoperation, TAVR or SAVR?"

Dr. Svensson: Alright, so that's a personal choice, but I would think most people who are 80 years of old age would go for a TAVR, but certainly a replacement of the aortic valve is also feasible. A couple of weeks ago. I did I think five or six like that within a week period where I went in to a biological valve composite graft, took out the biological valve, and put in another new valve. So that certainly is feasible, it's safe and it's worked out pretty well in my hands doing it that way. But that becomes a question of personal choice. I think if you're 80 and your valve is still working well, you may very well not need another operation, hopefully not, but those are two very reasonable operations. In our hands here at the Cleveland Clinic, only after the age of 85 for a reoperation does the risk of a reoperation start increasing. So that gives you a sort of baseline number.



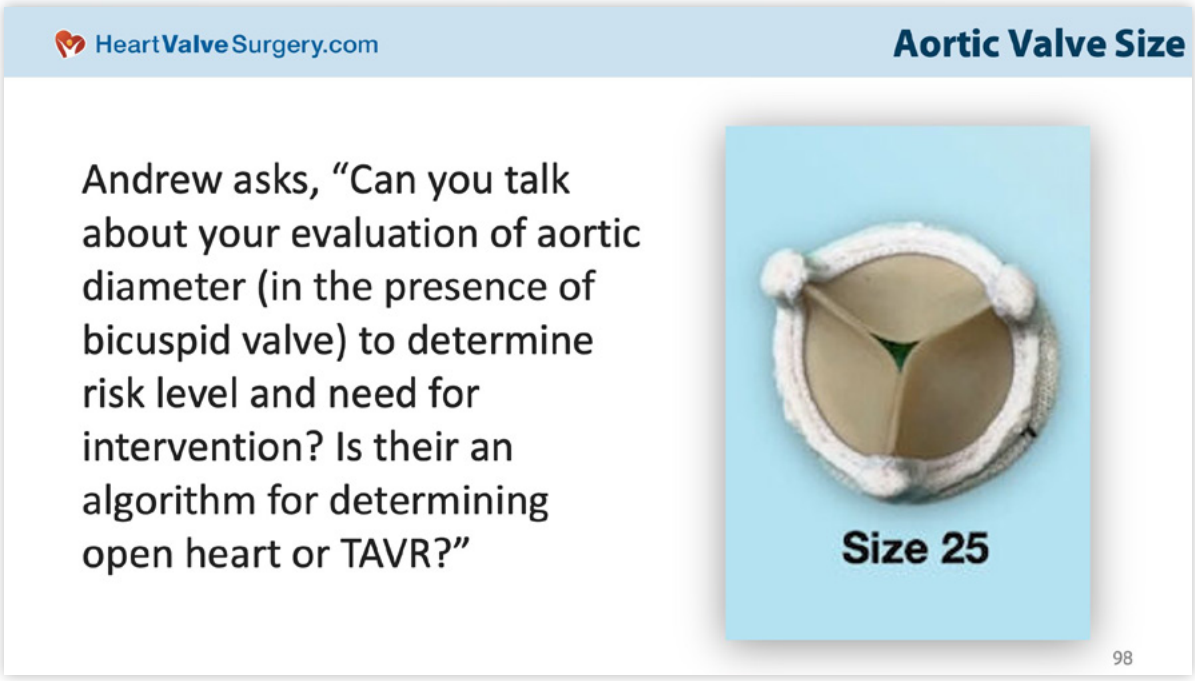
Adam Pick: Great. Thanks so much. And for the folks on the line, feel free to go ahead and use the control panel to ask your questions, because we've got some great time here to answer them live. We have another question that came in from Hugh all about bicuspid aortic valves. And he says, "I've always wondered why the conjoined flaps of a conjoined aortic valve just can't be separated to enable the natural tissue to be retained. Surely it's simpler than separating Siamese twins."

Dr. Svensson: Well, I like the way you're thinking, but unfortunately, I don't want to get into comparison to Siamese twins, but there's not enough leaflet tissue. And we went through a period where we tried to add tissue in the sense of either native pericardial valve tissue or cow pericardium. And the problem was that there's a high risk of clot formation and usually with clot formation, you get calcification. Apart from pericardium from cows, bovine pericardium has a higher rate of calcification. So we discovered that it's better to keep the leaflets bicuspid. There is typically with bicuspid valves excess tissue, so that means the annulus in a bicuspid valve is big than a three-leafed valve typically. So the bivalve is better accommodated in that situation than one would expect.

Adam Pick: Great. Hugh. I hope that helped you. We're going to go real time to a question from Christine Geiser. And you've referenced this a bit, Dr. Svensson, about atrial fibrillation, an abnormal heartbeat. And she asks, "What is the incident of AFib after open heart surgery, whether a repair or a replacement?"

Dr. Svensson: Yeah, that's an interesting question. So essentially, virtually all patients who have heart surgery with a full sternotomy, the risk of atrial fibrillation is about 25 to 30%. It's higher with, for example, mitral valve surgery than aortic valve surgery, and there's some operations that carry a lower risk. We know the minimum invasive J-incision tends to have a lower risk of atrial fibrillation after surgery, as does robotic operations.

Now, having said that, we just completed a big study on over a thousand patients where we looked looked at genetics inflammatory markers and the risk factors for atrial fibrillation after surgery. So the biggest correlate with the risk of atrial fibrillation is age. The one that was very interesting from a genetic point of view was that patients who are genetically predisposed to developing atrial fibrillation over their lifetimes had a higher risk of atrial fibrillation after heart surgery. In other words, heart surgery brought out that risk of atrial fibrillation at an earlier time. So we haven't solved that problem of atrial fibrillation after surgery. About 95% of patients within two months of heart surgery with atrial fibrillation that is de novo, in other words, the first time, are back in a regular heart rhythm. So most of the time it's not too much of an issue.



Adam Pick: Great. Thanks so much. Christine, I hope that helped you. Here comes in from Andrew all about aortic valve size. Can you talk about your evaluation of aortic diameter in the presence of bicuspid valve to determine risk level and need for intervention? Is there an algorithm for determining open heart or TAVR?

Dr. Svensson: So as I mentioned, the patients with bicuspid valves tend to have a bigger annulus. And so from that point of view, typically the determination of open heart surgery versus TAVR is not a factor in patients with bicuspid valves. I saw a patient today that on transit thoracic echo, they said the annulus is only 1.9. But I know from experience that that annulus is going to be bigger than that because it's a bicuspid valve. And so I probably won't need to do an annular enlargement.

Back to the discussion about bicuspid valves and TAVR, we know the risk of stroke is higher. Dr. McCart from Cedars-Sinai did that study. We also know that the risk of dissection in patients with enlarged aorta is higher. Bicuspid valves usually in younger patients, which we don't recommend TAVR. There are now three peer-reviewed studies, including the New England Journal of Medicine, showing that after three and a half years to five years, depending on the study, the risk of death and stroke have crossed. In other words, after about five years, the risk of death and stroke are higher with TAVR than they are with open surgery. Now there's a statistical analysis that has to be done on that and that really hasn't been done yet, which is a restricted means analysis. So when I say to patients well, how long do you plan to live and that's going to be a factor in determining which you choose. When it comes to durability so far we don't have data to show a separation between the TAVRs and the open biological valve repairs. And we know from history that in the patients who have open biological valve replacements, we only start seeing that separation occurring at about nine or ten years.

Now, we have – and I was the principal investigator for the Resilia Valve, which became the Inspiris Valve for Edwards. And in that study, we had some 689 patients. We've only had two failures with the dry storage leaflets for the Resilia Valve, one at five years and one about seven years. And we've got a paper that we're working on now with the Inspiris valve, which is the FDA-approved version of the Resilia Valve, also showing very good outcomes and better than the old gold standard, which was the Edwards Carpentier, Edwards Pericardial Valve.

So we feel pretty reassured about the durability of the open valves. The other part of this that we don't know the consequences of is that again Dr. Makar, 22% of patients with TAVRs have clot formation on the valves whereas the open valves, it's about 7 or 8%. The long-term consequences are that we don't know yet, at least at this stage. We haven't seen a separation and durability but we are seeing that separation and the risk of stroke and death.

Adam Pick: Well, I thank you for bringing and shining the light on that research. I was not aware of that and very great to hear that you're having seen some extra durability with the Resilia Inspiris tissue from Edwards. You kind of alluded to this in your conversation just now, but we have a question from Anne Fiss. This is going real time, Dr. Svensson, all about echocardiograms. And she asked, "Can an echocardiogram give a false-positive for an aortic valve regurgitation?"

Dr. Svensson: Well, that's a debate that the cardiologists constantly have. What is the best thing to look for with regurgitation? Look, I talk to my expert cardiologists about this on a regular basis, they give about a 10% error rate for regurgitation numbers, and they are derived numbers. The area where I see, particularly since we got into the stenosis problem, an underestimation of the severity of valve disease are the patients who have mixed disease. In other words, they have a combination of a narrowed valve, aortic valve stenosis, and a leaking valve, aortic valve regurgitation. And those patients tend to be underestimated on echo for their severity of disease.

Again, I happened to see a patient today who has severe restriction on his breathing ability, but his breathing tests on FEV1 is superb, yet he is not coping, and there's a big question mark on how severe his aortic valve disease is. And based on my experience of the combination of aortic valves stenosis and leaking valve, he has severe disease and I have no doubt that in six months, he'll be feeling considerably better if not within a few weeks after surgery.

Adam Pick: Thank you. And now we're going to move over. Again, you touched on this too, but a question came in from Jenna all about genetics. She asks, "Is there any update on genetics specific to aortic valve disease and aneurysms that we should know about?"

Dr. Svensson: All right, so let's take aortic valve disease with stenosis. No genetic particular predictors there but on the other hand, there's more evidence of lipoprotein A is a factor in developing stenosis and progression of stenosis and the rate of progression of stenosis. That's why they're now trials looking at medications to reduce lipoprotein A with the idea to slow down the development of aortic valve stenosis.

In bicuspid valves, as common as they are, you'd expect to see more genetic findings associated with bicuspid valves, but that has not been the case and so there's really just one gene that's been associated uncommonly with bicuspid valves, so that is not strong. When it comes to aneurysms and root aneurysms, so about 50% of patients with root aneurysms have a genetic underlying inherited valve problem or genetic disease and obviously more offense in Loeys-Dietz are the ones. We're seeing more and more now of genetic mutations that seem to be associated with root aneurysms. We're working on doing some papers on that. We have a free genetic test here at the Cleveland Clinic for people who wish to have it done. And we're beginning to see some other mutations showing up as potentially associated with aneurysms.

So the list of mutations associated with aneurysms is growing. And we began to understand also much more the subgroups, for example, with Loeys-Dietz.

Adam Pick: Got it. And this is a very interesting question from Helen who says, "I'm an operating room nurse. Is there a better, more efficient, safer, new blood thinner than Coumadin after an aortic valve replacement?"

Dr. Svensson: Well, that's a very good question. And that was top of my mind a few years ago. And so we set up this trial with the mechanical Onyx Valve with the idea of could we choose a population of patients who would be ideal for using one of the new non-Coumadin blood thinners. In this case we chose to use Anarchists and so we randomized patients to either Coumadin or the non-Coumadin, one of the new medications, and unfortunately we had to stop the trial early. Our safety committee found that we had a greater risk or stroke in the patients who did not have Coumadin. That was a trial where we started this three months after starting or having had the patients on Coumadin. So we set up the trial for ideal situation to make it work and unfortunately, it didn't. So I think the feeling of most of us, it does not look like at the moment with the current valves and the current medications is an option other than Coumadin for these valves, mechanical valves.

Adam Pick: Great, well, I hope that helps you, Helen. And on that note, we're coming to the end of the time that we had allotted for the webinar. And what I'd like to do is please don't sign off the webinar just yet. I want to thank you, Dr. Svensson, for again, just all the commitment, dedication of you and your team being with us today and sharing your experiences and research with us. Thanks, Dr. Svensson, for being with us today.

Dr. Svensson: Thank you, my pleasure. And we're always available to help. And thanks, Adam, for a wonderful job. It's a wonderful resource for our patients. And thank you for everybody who participates and shares the information with other patients.

Patient Resources

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

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

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