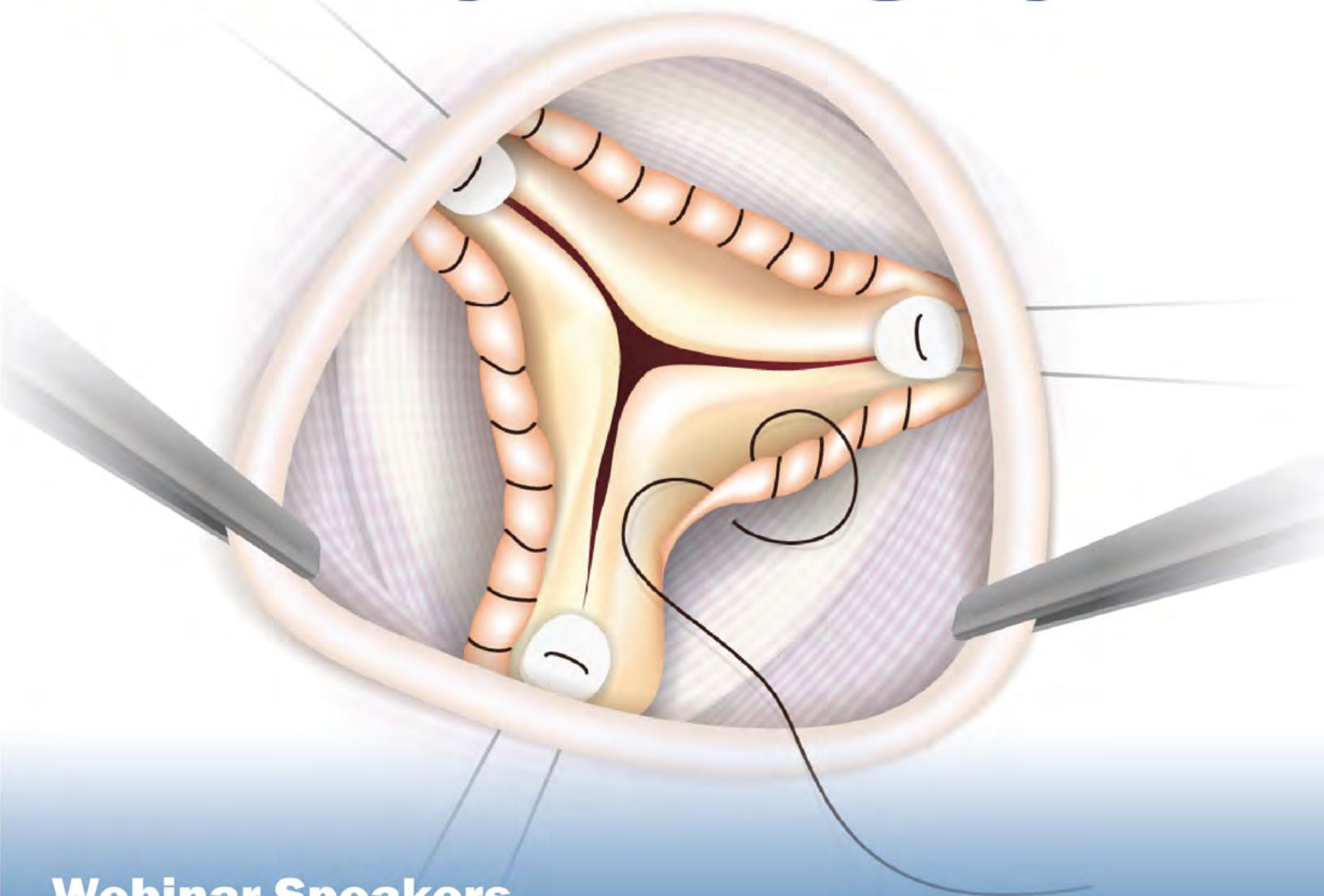


Patient Webinar Transcript

Advances in Aortic Valve & Aneurysm Surgery



Webinar Speakers

Dr. Allan Stewart

Cardiac Surgeon
The Mount Sinai Hospital
(866) 306-8541

Adam Pick

Patient & Website Founder
HeartValveSurgery.com
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I. Introduction from Adam Pick, HeartValveSurgery.com founder

Dear Patients & Caregivers,

As patients with heart valve disease can be confused about the diagnosis and the treatment of aortic valve disease and aortic aneurysm, The Mount Sinai Hospital and HeartValveSurgery.com held a live, online webinar titled, “*Advances in Aortic Valve & Aneurysm Surgery*”, on Thursday, July 17, 2014, to educate patients.

During this live event, [Dr. Allan Stewart](#), the Director of the Aortic Program and Co-Director of the Valve Center at Mount Sinai shared critical information about aortic valve disease and aneurysm therapy.

The webinar was an overwhelming success – with over 300 patient and caregiver registrations from all over the world. For those patients and caregivers who were unable to attend this event, I prepared this eBook to help you learn more about aortic valve disease and treatment.

If you have any questions, please email me at adam@heartvalvesurgery.com.

Keep on tickin!

ADAM

Adam Pick
Patient, Author & HeartValveSurgery.com Founder

P.S. If you would prefer to watch the video playback of this webinar, [click here](#).

II. Featured Webinar Speakers

The featured speakers for the webinar were:



Dr. Allan Stewart

Cardiac Surgeon
The Mount Sinai Hospital
(866) 306-8541

[Learn more.](#)



Adam Pick

Patient, Author & Website Founder
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[Learn more.](#)

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III. Written Transcript & Presentation Slides

In addition to providing you the written transcript of the “*Advances in Aortic Valve & Aneurysm Surgery*” webinar, we will also provide you the presentation slides shared during the online event.

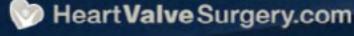
Webinar Introduction

Advances in Aortic Valve and Aortic Aneurysm Surgery

Allan Stewart, MD
Director, Aortic Surgery Program
Co-Director, Valve Reference Center
Department of Cardiovascular Surgery
Mount Sinai Health System

Adam Pick
Double Heart Valve Surgery Patient
Author of *The Patient's Guide To Heart Valve Surgery*
Founder, HeartValveSurgery.com

Adam Pick: Hi, everybody. My name is Adam Pick, and I'd like to welcome you to the webinar titled, Advances in Aortic Valve and Aneurysm Surgery. If I have yet to meet you, I am a former heart valve surgery patient, and I'm also the founder of HeartValveSurgery.com. The mission of our website is simple, we want to educate and empower patients with heart valve disease. This webinar, which has had over 300 registrations from patients in countries all over the world, is designed to support that mission.

So you know, during the webinar, all participants will be in what we call listen-only mode. That being said, and this is important, you may submit questions during the webinar. Simply post your questions in the control panel on the right side of your screen. We will do our best to answer your questions during the Q&A section of the webinar. Lastly, at the

end of the webinar, I'm going to ask you to complete a very quick five-question survey.

Now, I am beyond thrilled to introduce the featured speaker of this webinar. Interestingly, Dr. Allan Stewart really needs no formal introduction to our community. As many of you know, Dr. Stewart has been one of our greatest supporters since I launched this website back in 2006. Yes, he is the director of the aortic program at Mount Sinai Hospital in New York. Yes, he is the co-director of the Valve Center at Mount Sinai. Yes, he has performed over 2,000 heart valve procedures. And yes, many of you have seen him on ABC's hit television show "New York Med." What I really want you to know about Dr. Stewart is that he is what I call a patient's surgeon. He really understands how critical patient education and advocacy is before, during, and after surgery. Most importantly, Dr. Stewart gets incredible surgical results.



To date, Dr. Stewart has successfully treated over 100 patients from our community including the smiling faces that you see here: Mark Lampersberger, Summer Ashe, Anna Thomas, Joan Davenport, and Bill Easton, who traveled across the country to be operated on by Dr. Stewart.

Just how far will Dr. Stewart go to make sure his patients are recovered?

Dr. Stewart & Greg O'Keefe
Complete Nautica Triathlon



As Greg O'Keefe found out, Dr. Stewart will swim 2.4 miles, bike 112 miles, and run 26 miles. That's right, Dr. Stewart has trained and completed over 10 triathlons and marathons with 15 of his patients. I don't know about you, but this is what I call extraordinary.

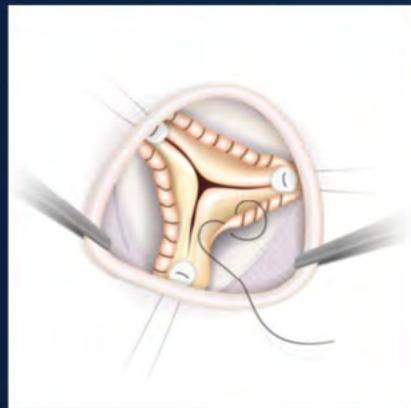
Now I am, again, thrilled to turn the webinar over to Dr. Stewart so we can begin this very special educational session.

Opening Remarks By Dr. Stewart

Advances in Aortic Valve and Aortic Aneurysm Surgery

Allan Stewart, MD

Director, Aortic Surgery Program
Co-Director, Valve Reference Center
Department of Cardiovascular Surgery
Mount Sinai Health System



Dr. Stewart: Welcome everyone. My goal today is to teach you that heart valve and aneurysm surgery is really just a reset point in your life, that in fact, it does not mean that the body's broken afterwards. In some cases, where problems have developed either at birth or over the course of one's life, it allows you to (a) achieve a new sense of heart healthiness and (b) perhaps increase the function and the relationship with your heart in a way that you've never had before to allow you to achieve a better functional and enhanced quality of life.

My goal today is to teach you about the newest procedures that we're doing now in valve repair and in valve replacement to show you that the old days of having a big cut down the center of the chest and a protracted recovery are essentially over. We have a myriad of advances in the past several years that have allowed heart surgery to be performed in a minimally invasive manner with a very brief hospital stay and a very quick return to function. So, I'll take you through a few slides, and then we'll have an informal discussion for a period of time.

When Do When To Intervene?

When Do We Intervene

Valve Issues Alone:

- Symptomatic AI
- LVEDD greater than 6cm

Aneurysmal Root:

- Connective tissue disordered patients with any root dilatation
- Bicuspid patients greater than 5cm
- Trileaflet (no CTD) greater than 5.5cm

Dr. Stewart: When do we fix heart valves? The most common time that we start to fix hearts are when people develop symptoms. There's a period of shortness of breath or fatigue that's really not explained by normal aging or just being out of shape. What we normally do, though, as patients start to convince ourselves that well, even if we took the stairs before and walked up a flight or two of stairs and now we take the elevator, that we feel fine. Sometimes you get tired a little earlier in the day, but you say, "Well, I guess I'm getting older or I'm out of shape."

In fact, it's rare that those are the proper explanations. At times, either a leaky valve or a valve that's not opening properly is causing those symptoms, and it's important to have a relationship with your primary care doctor or your cardiologist to take a look and see if in fact these valves aren't functioning properly. Once those symptoms develop and we find, based on an echocardiogram, for instance, that the valve is not working properly, we start to think about intervening.

There are occasions, though, that you'll be referred by a cardiologist because the function of your heart, even if you say you feel no symptoms, has gotten to a point in time where we recommend surgery. I have a special interest in operating on aneurysms, and aneurysms are what ended the life of John Ritter, of Lucille Ball, and a variety of other equally important but not famous people. In those folks, we have a variety of indications for surgery. Sometimes people have genetic defects such as bicuspid valves or connective-tissue disorders like the Marfan syndrome, that each have a criteria for when we would intervene.

Traditional Surgical Teaching

Traditional Surgical Teaching

- Valve is Replaced Regardless of its Health
- Age Defines Valve Choice
 - 65 years has been the traditional inflection point
- Reproducibility (Ease) has Guided Surgery

Dr. Stewart: Our traditional teaching in the past was that we would put mechanical valves in people. Mechanical valves are carbon-based valves that would last a lifetime, and we used in the infancy of heart surgery, but they require a blood thinner. All of the information that we had was based on studies done about 40 years ago. If you were under 65 years old, we would put a mechanical valve in. As time went on, if you were over 65, we would put in a biological valve. In fact, the reproducibility or the ease of surgery guided people in putting those valves in. Whether you put a biological valve or a mechanical valve in is the same type of operation for the surgeon; it's the same number of stitches, same amount of time. It was just a different valve.

What we found is now we are getting into a phase where valves are being replaced without even surgery by putting them in through the leg, which we'll get into a little later, called transcatheter valves. That's really changed the way we look at who would have a mechanical valve versus who would have a biological valve. Now, as we go along, we're starting to say to ourselves, "Are there other options, though, rather than replacing the valve. Can we, perhaps, repair valves?"

Aortic Valve Repair

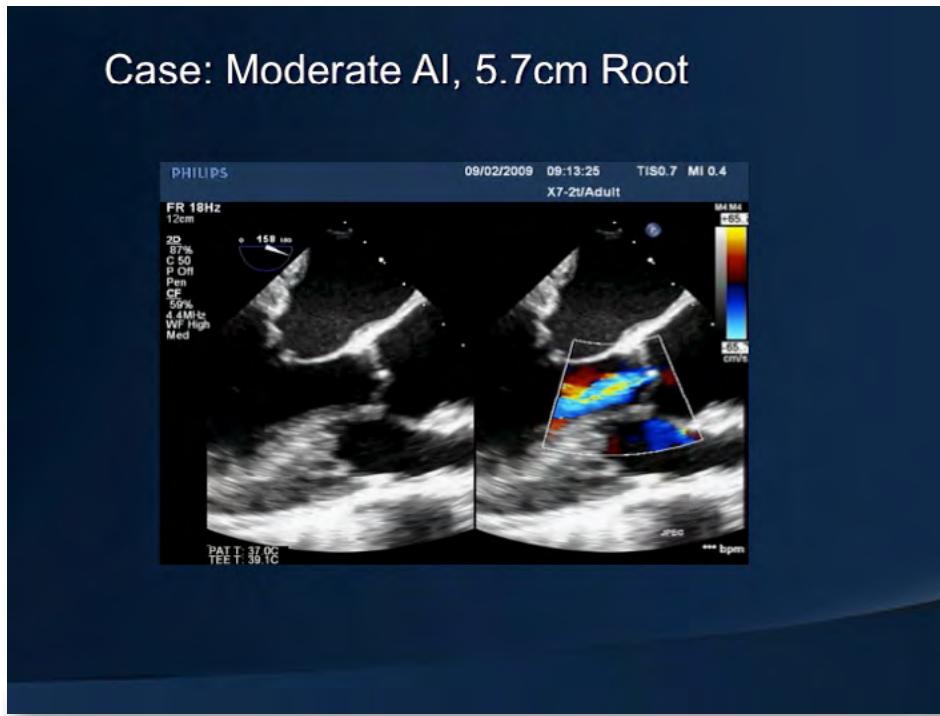
Aortic Valve Repair

Advantages:

- Patients are reluctant to be on Warfarin
- Potential for curative surgery
- All Bio-roots have a limited lifespan
- Safe and reproducible procedure

Dr. Stewart: Aortic valve repair is something that's really been developed in the last 10 to 15 years, and it really was responsible, or its inception was based upon patients being reluctant to be on Coumadin, a blood thinner that one would have to take for the rest of their life if they had a mechanical valve. Repairing the aortic valve has the potential to cure the problem. Because all biological valves will eventually wear out, and all mechanical valves will require Coumadin, we said, "Well, if we can cure the problem by rebuilding one's own valve and do it in a safe and reproducible manner, well, why not?" We started really perfecting this and in centers of excellence, such as ours, we do this operation every day very safely and we really are impressed with the results.

Patient Case & Success Stories



Dr. Stewart: This is a sample patient. This was somebody who I saw in the office, and you'll see that jet right in the middle on the right-hand side of the screen, is considered an incompetent valve. What I'm looking at here from a doctor's point of view is a valve that's leaking and an aorta that's just too big.

Adam Pick: Can I interrupt you again one more time? When you say a jet, I don't know if you can see my cursor, but are you taking about this, right here?

Dr. Stewart: Exactly. That's exactly what I'm talking about, Adam, is that color that's placed on it. What an echocardiogram is, which is what we're looking at, is essentially an ultrasound. Many women have had the same type of technology when they're having a baby. An ultrasound is a probe that's placed across the heart and with a Doppler signal, we can look at flow or turbulence, and that's what you're seeing is turbulence through that valve. That valve should normally have nothing going backwards through it. You'll see a rather large jet there where Adam's cursor is.

Adam Pick: Great. Thanks.

Dr. Stewart: Now when I looked at the patient, this is a young girl. She is a 31-year old Cosmopolitan model. She was in otherwise perfect health, had a dilated heart, and had this incompetent valve, and she was not keen on having heart surgery despite the fact that she had a fairly large aneurysm and hoped to wait.

Now, during the time -- since I met her to the period of time where she ultimately required an operation -- she developed the dreaded complication of what's called an aortic dissection. She came into the hospital emergently on essentially death's door with terrific back and chest pain and a very low blood pressure and had to be rushed into an operating room.

Options

1. Perform Valve-Sparing Root Replacement
2. Perform Mechanical Valve Bentall Procedure
3. Perform a Bio-Bentall
4. Replace Ascending Aorta with a Tubed Graft and Leave Root Aneurysm

The options now that she's arriving and she's very ill are – we had about four different options since she was a young patient. We could either try and repair her valve; we can perform the standard of care, which is to put a mechanical valve in her and replace her aorta; use a biological valve; or leave her with the aneurysm and just try and get out of the operation alive but really give her an incomplete surgery. Now, the standard of care would be option number two, but she was 31 years old, was keen on having more children and if you have a mechanical valve and are on Coumadin, it's very difficult to develop a pregnancy afterwards.

We Chose #1

- 1. Perform Valve-Sparing Root Replacement**
2. Perform Modified Bentall Procedure?
3. Perform a Bio-Root?
4. Replace Ascending Aorta with a Tubed Graft and Leave Root Aneurysm

We decided to do the first operation, a valve-sparing aortic root replacement, and what that operation is, if you go to the next slide, Adam, and play the movie, please. In this operation we, take apart the aorta, and I won't show all of this, but you'll see as we remove all of this aortic tissue here, we're going to see the normal aortic valve. Essentially what we're doing is isolating the aorta and looking at the valve, and as we look at that valve, we say, "Geez, that's a normal valve, and just because she's being rushed into an emergency operation doesn't mean that we can't go ahead and fix that, rebuild it, and give her a curative operation." So, with a little bit of tailoring and a little bit of artwork, we were able to take somebody who was really about an hour or two away from death, rebuild her aortic valve and fix her aorta. We did that through a very, very small cosmetic incision, as well.

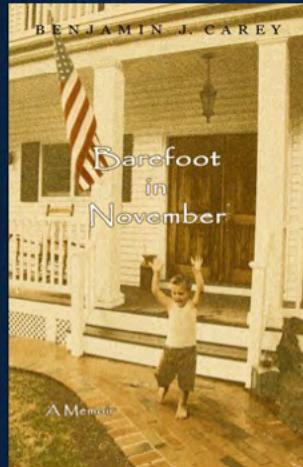


Adam Pick: Can I ask you, I just saw something, a white cable, it almost looked like a cord right there.

Dr. Stewart: Those are stitches. That tube there is the graft that we are using to replace the aorta. It's a woven tissue graft, and many patients ask me about this graft and they say, "How long does it last?" It's just woven fabric created on a loom. It lasts forever, 40 or 50 years. It's something we've been using since the 50s, and actually it was developed by a pioneering heart surgeon named Michael DeBakey, who took his wife's dining room curtains and made a tube out of it on a sewing machine, sterilized it, and put it inside of a patient and in fact, it worked. We've been using an iteration of that ever since. The body does not reject it. No drugs are needed to be given to a patient afterwards, and this is what I use every day. It doesn't fall apart. It doesn't deteriorate, and it works very, very well. In fact, this particular graft is something called the Valsalva graft, and it's called that because it mimics the aortic root, or the sinus of valsalva, as they are called. It's an innovative type of graft that we use here at Mount Sinai every day.

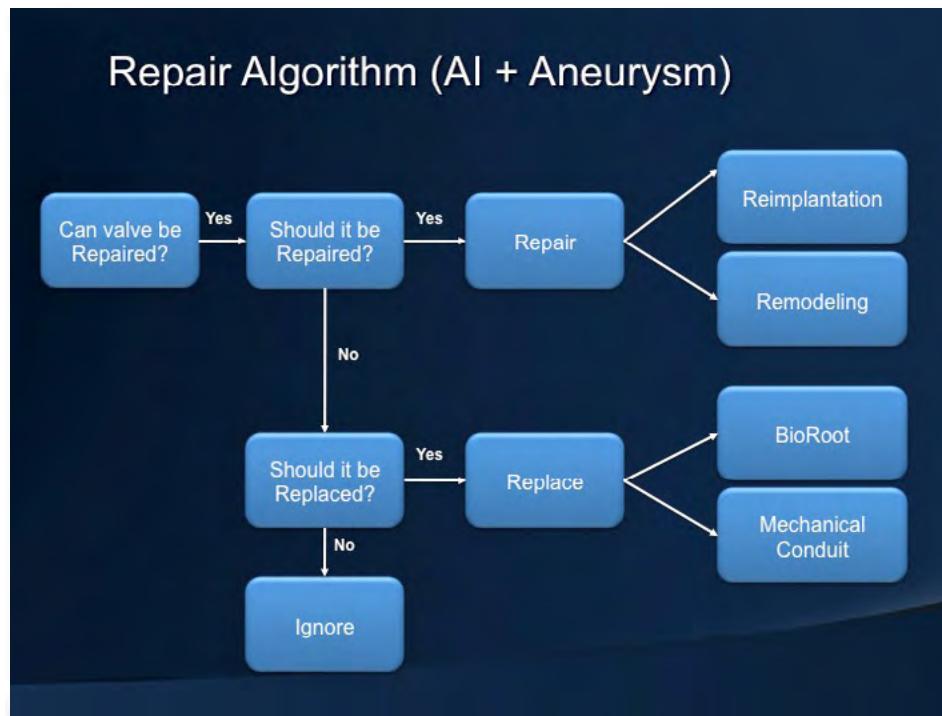
Adam Pick: Great.

Patients after Root Surgery



Dr. Stewart: This lady made a very quick, remarkable recovery and actually went back to professional modeling. Here's a couple of other examples of success stories. Adam showed the one on the left, which is Greg O'Keefe, who is a young patient of mine who did the triathlon with me after his surgery. Then, on the right-hand side, was another gentleman who we ran a marathon together, and he wrote this book about his experience called "Barefoot in November," which was running the marathon in November after having the same operation of valve-sparing root surgery.

Determining The Surgical Approach



Dr. Stewart: When I look at different valves, I say, “Can I repair the valve?” As surgeons, we often like to do new operations. But, just because you can do something doesn’t mean you should do it. So the first question I ask is, “Can I do this? Technically, is it possible?” The next question is, “Should I do it? Is there an indication to?” Then, the third question is, “Can I do it without opening the whole chest? Can I do it through a very cosmetic incision?” More and more frequently, the answer is yes. The standard operation that I do now is about five centimeters, about two or three inches, of a cut down the center of the chest. So, the days where people have a foot-long incision down the center of their chest are pretty well over. It allows people a quicker return to function. This algorithm is more for the doctors who are listening, but when they go through this discussion – and it’s a discussion that I go through each time I do an operation – is how to replace valves and how to repair valves. This is the decision-making process that I go through because you really don’t want to get on a plane from New York to California and invent the plane ride on the way. You want to have a thought process in your head before the operation starts.

Assessing A Valve Disorder

How Do I Assess The Valve?

- Aortic Leaflet Integrity
 - High failure rates in...
 - Severe AI
 - Multileaflet prolapse
 - Multiple fenestrations
 - Great results in supple leaflets
 - Great results with normal annular size
 - Bicuspid and trileaflets both have good 10-year data

Dr. Stewart: When I look at the valve, I want to make sure that if I'm going to repair the valve, that that valve repair is going to be better than anything I could take off the shelf. If there are damaged leaflets, if there's a lot of calcium that I don't think that I can get a decent repair, then we'll find something off the shelf and replace it with something that will last, because our goal is to maintain the quality of life and the longevity of life of someone who never had heart surgery. So, when we make our decisions on repair versus replacement, we make them and say, "Can I make sure that this patient is going to stay out of an operating room for as long as possible and have a wonderful quality of life?" These are the reasons, and this is how I go about assessing it.

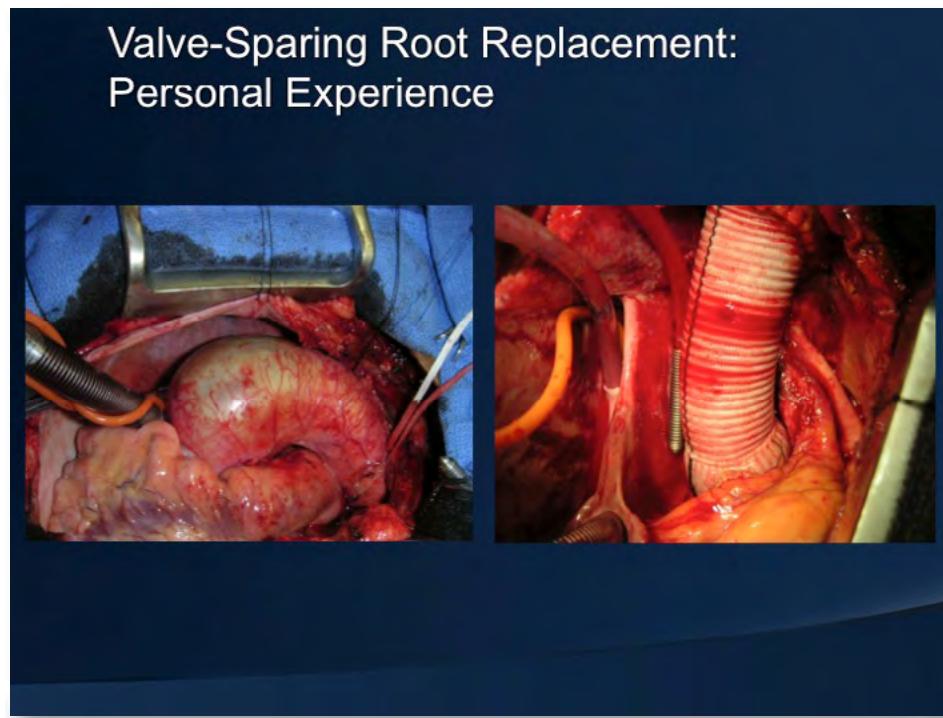
Bicuspid Aortic Valves

Considerations for Bicuspid Valves

- Advantages:
 - Easier repair due to one plane
 - Patients are frequently younger
 - A perfectly repaired bicuspid valve serve as a platform for TAVR
 - Often associated with root aneurysm

Dr. Stewart: People ask, and there some advanced questions, on bicuspid valves. Yes, bicuspid valves can be repaired. We don't take bicuspid valves and make them into tri-leafal valves. What we do is we rebuild the bicuspid valve to be a perfectly symmetrical valve that properly opens and closes because what happens with bicuspid valves – it's a design flaw by nature where the valve isn't formed properly, and what we can do is take it apart and reform it again. Patients are generally younger when they have bicuspid valves. They more frequently have aneurysms, but it actually is an easier technical operation to perform it and on top of it, it's one that can still be used for a platform for transcatheter valves going forward.

Valve Sparing Aortic Root Replacement



Dr. Stewart: So this is my personal experience. On the left, you'll see this is someone with a big aneurysm, and that angry-looking structure that's right next to the tube, and if you move your cursor – yes, as Adam wanders around there, you'll see that that's a large aneurysm, and on the right is that graft that made its cameo a few slides back in the movie. That's that Valsalva graft, and that's what the aorta looks like in that same patient after it's replaced. You'll see the aneurysm is gone, and the heart is on the bottom of the screen, the graft is on the top, and the whole aorta is replaced. The graft doesn't wrap around the aorta; the graft becomes the aorta. That's the new structure, which can never become an aneurysm again.

Adam Pick: Dr. Stewart, when you mentioned earlier in the conversation about John Ritter and Lucille Ball, the dissection of the aorta, is what you're talking about essentially this right here, just rips apart?

Dr. Stewart: Rips apart from the inside out. It's essentially if you imagine a room and filling a room up with water and then putting a cut right in the sheetrock of the wall. Blood will flow not only in the room but up into the walls itself, and that creates the damage. That becomes a life-threatening event. Unfortunately, for those folks, it was unrecognized until it was too late. It goes back to something I tell my patients all the time. When they come to me with aneurysms, I say, "You've been given a gift, in a way." They say, "Well how can facing heart surgery be a gift?" Because most people don't know aneurysms cause very little symptoms; maybe a little vague chest pain, a little back pain, but they're generally discovered while looking for something else. The ability to know that one has an aneurysm – and many of those patients don't need surgery right away.

Just because there's an aneurysm, it doesn't mean there's a need for an operation. Sometimes, just some lifestyle modification, some stress relief, some blood pressure control, or avoidance of heavy power lifting, will allow people to never need an operation. If they do, they can find the right surgeon, go to the right place, and control their destiny. Generally, find a convenient time in their life to have it. It doesn't need to be done urgently. There's room to get a few opinions. There's room to make travel plans if you want to go to a place such as New York for expertise. It doesn't require someone to rush to the nearest hospital and get fixed. There are advantages to having knowledge that one has a problem.

Success Rates, Factors & Opinions of Valve Sparing Procedures

Relevant Data Summary

Age (years)	58.5±12.9	46.5±13.4	<0.0001
CPB (min)	132.9±35.6	139.8±35.2	0.220
Ao X-Clamp (min)	100.1±31.9	113.1±26.7	0.0075
Post-op 2+AI (%)	4.8 (5/135)	2.3 (1/57)	0.358
Reop bleeding (%)	4.4 (6/135)	0 (0/57)	0.0065
Periop CVA (%)	1.5 (2/135)	0 (0/57)	0.153
30-day mortality (%)	0.7 (1/135)	0 (0/57)	0.324
5-year mortality (%)	2.9 (4/135)	0 (0/57)	0.053

Dr. Stewart: These numbers may not make sense to a lot of people, but you can see that we can do these operations quite safely and in fact, in looking at 200 patients who have all had valve repairs in the last couple of years, you see there's only been one person who died within 30 days of surgery, and that was because unfortunately, they had an automobile accident. So, there are a number of patients. It's become a safe operation. It's become something that we can do very readily and quickly and without any real adverse events.

Opinion on Valve-Sparing Root Replacement

- Can be Accomplished with Low Mortality or Morbidity
- Myriad Techniques for Leaflet Adjustment

Viable Alternative for:

- Young, active patients who wish to avoid Coumadin
- Patients with bicuspid valve disease
- Patients with normal tri-leaflet valves and root aneurysms
- 20 Year Data is Encouraging but Need More Careful Follow-up
- Freedom from Re-op Appears Superior to Bio-prostheses

Dr. Stewart: My opinion on these valve-sparing operations is that they can be done. They're done very, very well in centers of excellence. We have a variety of techniques that we continue to create, and there's about a half-dozen centers in the United States that are very, very good at this. It works very well for all age patients now. I used to only do it for young patients, but now I'm even doing valve repairs for patients who are in their 80s because people are now living – if you get to 80 and you're lucky enough to be healthy at 80, there's no reason why you shouldn't be alive another 10, 20 years. So valve repairs in these patients do quite well as they do in young patients. Patients with connective tissue disorders, people with bicuspid valves, all are patients that are potential candidates for valve repair.

Conclusions About Valve Repair

Conclusions About Valve Repair

1. Aortic Valve Repair is Feasible
2. The Learning Curve is Steep but Beneficial
3. Aortic Valve Repair can be Performed by more than Just a Select Few and Taught to Others
4. Repairs Should be Anatomically Based, Described in Detail, and Fastidiously Followed

Dr. Stewart: We've now been doing it in a handful of centers for about 20 years, and our 20-year data is probably better than anything we can take off the shelf. I believe it's something that's continued to gain traction and something that should be explored with your cardiologist or surgeon.

Aortic Valve Replacement



What if we Cannot Repair
the Valve?

Dr. Stewart: Along those lines, it is something that, when you are considering having your aortic valve repaired or replaced, that you talk to your surgeon and find out are they someone who's comfortable with repair and if they are... How many have they done? How long have they been doing it? What are their results? Your surgeon should be honest with you and say, "Hey, yeah, I've done a lot of these," or "I haven't done many," but if you're a candidate for it, it's something to explore. Many people are unwilling. They're willing to travel a hundred miles for a good restaurant, but they'll go to their nearest doctor, and it's something I've never understood. More and more now with the ubiquity of the internet, patients are more educated and willing to travel to centers of excellence, but repairs are best done by doctors who do it every day and do it with a reproducible expertise. So don't be afraid to ask your doctor, "What's your data? How long have you been doing it for? How many have you done? What are your results going forward?"

What if we can't repair the valve? How do we go about replacing the valve?

Here's just a quick movie just to show – if you play the movie, Adam – this is a typical operation now, and if you look, it's really just to show you how small the incisions are we're making now to do valve replacement. This is a tiny little incision, and forgive me for the saw; it may be a little abhorrent to some people, but that's how we open the chest, but you'll see it's a tiny incision. It gives us plenty of exposure. That's the aorta you're looking at here, and now we put all of our tubes for the heart/lung machine through separate little incision so that that way, it stays out of our working space. You can see that's what called a stenotic valve, what you're looking at there. We've removed that valve, and just to show you what a standard valve replacement looks like, we sized that valve so that it's the appropriate size for the person that we're operating on. We take out that sizer, and that shows us that the valve we're putting in will fit.

Then, it's just cutting and sewing. This is a standard tissue valve that we'll insert, and you'll see it there. Doesn't look much like a human valve, but it functions as a human valve. We sew that in, and you'll see that's a myriad of different-colored stitches that are sewn in. There's about 12 or 15 stitches there. Once the valve is implanted, we close up the aorta, shut that breastbone again, and the patient goes on to a normal level of function, again with a very cosmetic appearance and a very short hospital stay.

Where are we going forward now? We can do these operations with excellent results, but our goal as innovators and as surgeons is to press the field forward.

Transcatheter Aortic Valve Replacement (TAVR)



Dr. Stewart: Many of you must've seen on the news the concept of what's called – and play the movie, Adam – transcatheter valves, or TAVR, as it's called, and this is a cartoon of a heart, and you'll see in the center of the screen here, that's the aortic valve that has a lot of calcium on it. It's now working properly. Instead of opening the heart up as we just did before, what we're doing here is with a variety – and you'll see those circles – with a variety of methods of approach, we can, without going on the heart-lung machine, without opening the sternum, put a valve right across and insert it there, like you see. It takes about 10 minutes to do. We do not need to go on the heart/lung machine. Often the patients don't even go to sleep. We can do it with just a little bit of medicine to make the patient woozy. The valve gets inserted right inside of that old stuck valve, and we're finding that we can do this. First, we found we could do it in patients who are too sick for surgery, and we found that, in fact, it was much better than giving people just medicine. Then we said, "Well, if it's as good as – if it's better than medical management, how does it compare to surgery?"

What we found was that it was for the highest-risk patients, it was as good a surgery in the first type of valve we used, and now were finding that, in fact, for the highest-risk patients, it's better than surgery.

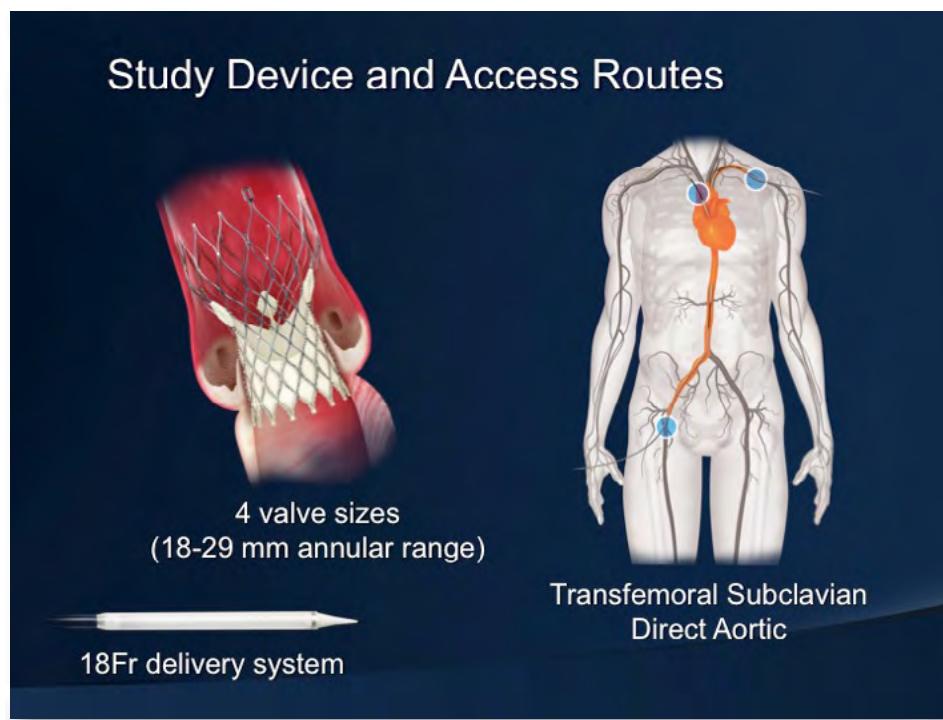
Now, we're looking at patients who are not so high risk, people who are at low or intermediate risk, and these patients here, when we first started doing it, you'll see these people had a myriad of problems. They were very, very ill patients, and they did very well after surgery. These were people who had cirrhosis, or who were on home oxygen, who had kidney failure, and they did very, very well. They got their quality of life back, and it was lifesaving for those folks. Then we started saying, "Well, what about people who aren't that sick?" We found that, in fact, it actually works pretty well.

Non-STS Co-Morbidity, Frailty, Disability

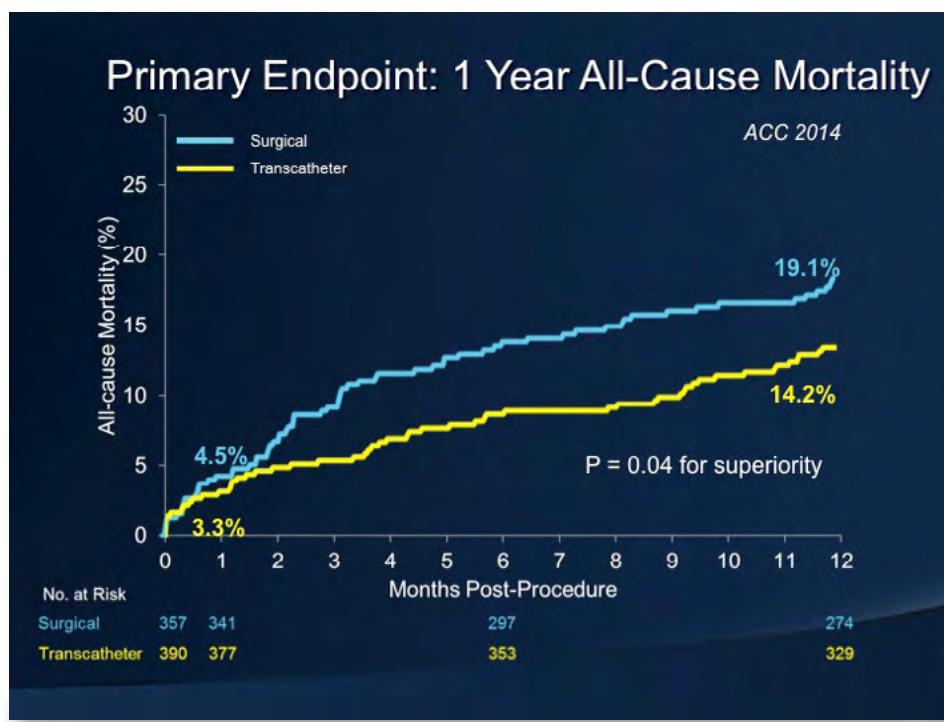
Assessment	TAVR N=390	SAVR N=357
Home Oxygen, %	12.9	11.5
Liver Cirrhosis, %	2.6	2.0
Anemia With Prior Transfusion, %	18.2	15.9
Severe (> 5) Charlson Co-Morbidity*, %	54.1	57.9
Falls in Past 6 Months, %	18.5	18.2
5 Meter Gait Speed > 6 secs, %	79.3	80.4
Assisted Living, %	9.7	10.9
Katz ≥ 1 ADLs Deficits, %	10.5	12.3

*Charlson Score: = 1 MI, CHF, PVD, CVD, dementia, chronic lung disease, connective tissue disease, ulcer, mild liver disease, DM; = 2 hemiplegia, mod-severe kidney disease, diabetes with end organ damage, leukemia, lymphoma; = 3 moderate or severe liver disease; = 6 metastatic solid tumor, AIDS

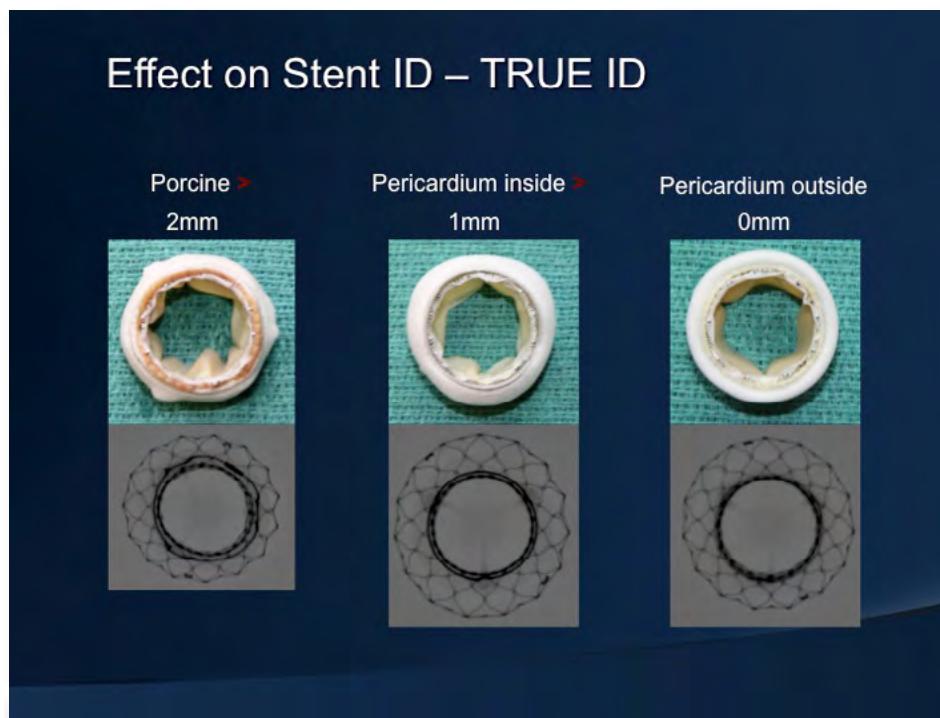
What we're showing here is that for patients who compared to surgery, you see here in the sickest of patients over the course of time, the primary endpoints when we compared this was that at one year, and these were sick people. We show that 20% of people who had surgery died at a year, but only 14% of patients who had the transcatheter valve died, and we found that it was better in those patients. Then we started backing it down, and we're showing for each group that we're looking at, we're finding that this transcatheter technology, when properly selected, is as good or better than surgery. What we're now saying, "Who is it good for and who isn't it?" The problem we have with it is we don't know how long it lasts. We're crimping the valve, we're putting in a different manner, and we don't really know if that's going to have an impact down the road. For patients who are going to be alive more than ten years, we're still recommending surgical replacements from minimally invasive incisions. As time goes on, this technology will replace surgery in my mind for all patients.



In looking at all of our trials that we've done so far, the results for surgery and even in the sickest of patients in centers of excellence who participated in all these trials was excellent. What we found is that the transcatheter technology was outstanding, and these are patients who in groups – and it's important to know that we now have a concept of the heart valve team where all of these patients are reviewed by cardiologists and cardiac surgeons together as a group. That way, all the areas of expertise can be provided and we can make the best decision for each patient. There's a good 20 or so centers that have these heart valve teams throughout the country that meet regularly and we decide is this patient better for a transcatheter valve or a minimally invasive surgical valve replacement?



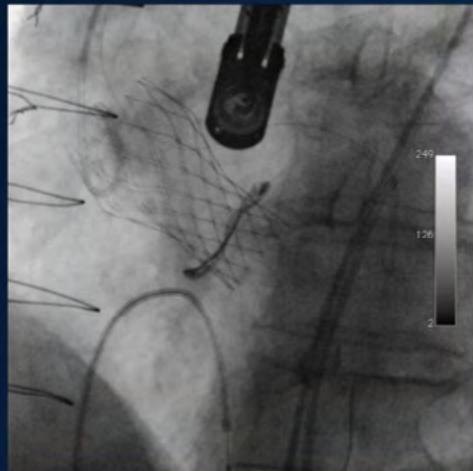
Valve-In-Valve Procedures



Dr. Stewart: The concept that many people now have is something called valve-in-valve, and I may've mentioned it earlier. What valve-in-valve means is that if someone had a surgical valve, or like Adam, had a Ross Procedure, or someone that had a valve-sparing procedure and then 20, 30 years down the line, these valves wear out, can they have what's called the valve rescue? Can a transcatheter valve be inserted inside of a biological valve? Can it be inserted inside of a valve-sparing or a Ross Procedure? The answer to that is yes.

We've now been taking these valves and these are examples on the top of the screen of biological valves that we implanted before and inside that, the screen you're seeing on the bottom are images of the new transcatheter valve being inserted inside of these valves.

23 mm CoreValve Evolut



You see here, this is a fluoroscopy image. If you see, Adam, if you can bring your cursor into the center, that little line right there, that circle is the old biological valve, and then that big cage is a Medtronic CoreValve that's sitting inside of an old biological valve. The biological valves wore out over the time and the patient developed some, some shortness of breath and fatigue, and we were able to insert this valve inside of the old valve in about 15 minutes. The patient did not need a re-operation. They did not need to go on the heart-lung machine and have their chest cut back open again. In fact, they left the hospital three days after this procedure with a dramatic increase in their quality of life.

The importance of – and I bring this up just to be a little provocative. This is a matryoshka doll where what we don't want to do is have patients who are too young having these procedures because again, we don't know how long these valves-in-valves will last, and what we don't want to do is have a biological valve then have a valve-in-valve-in-valve-in-valve and then crowd the area. It's not useful for everyone yet and in fact, we're still learning who the ideal person is to have this treatment paradigm. In patients who are young, valve repair is certainly the way to go. Biologically valves are certainly the way to go in younger and younger patients. The risk of needing a surgical re-operation or having a transcatheter rescue is an area that's a moving target and rapidly evolving.

TAVR Rescue in Patients Under 50



Thoughts On The Present & Future

Thoughts on the Present

- Aortic Valve Repair is a Viable Procedure:
 - Potentially curative surgery
 - Can be performed with minimally invasive approaches
 - Can be performed safely and reproducibly
 - Patients are appreciative of repair
- Aortic Aneurysm Surgery can be Safely Performed
 - Minimally invasive incision is my standard of care
 - 5cm is now an acceptable standard for intervention

Dr. Stewart: At the present, I think that valve repair is how we go about how it's a viable procedure. It's something that can cure most patients if it's selected properly. We don't need to cut the chest open to do either aneurysm repair or valve repair anymore. We do it through tiny incisions just at the top of the sternum. We can do it safely. We can do it reproducibly in certain centers of excellence, and people appreciate it because there's a potential for cure. As I said, aneurysms are my area of interest along with valve repairs, and my standard approach is to do it through a tiny incision, about two and a half inches in length. Patients generally leave the hospital on day three or day four, and they get back to golfing and get back to work quite early.

Thoughts on the Future

- TAVR
 - Easily implanted with excellent results
 - Will supplant SAVR as treatment of choice for intermediate risk patients
 - Role of valve team is essential in achieving success
- Mechanical Valves are Rapidly Approaching Extinction in US
- Patients Over 50 Years of Age
 - Bio-prosthetic valve via sternal sparing approach
 - Valve-in-valve rescue after deterioration

As the future progresses and where I think we're going – and this'll be my final slide before we start discussion – the transcatheter replacement is a major advance in valve reconstruction. It's easily performed through either a small needle stick in the groin or a tiny, little incision under the collarbone. Ultimately, it will rid us of needing standard open heart surgery for even the most low risk of cases. Right now, we're only using it for people who are intermediate or high risk, people who we believe we can get through an operation but they really aren't ever going to come back and say, "Thank you" for it. We want people to recover. We want them to gain health quickly. As I mentioned, there's about 20 or so valve teams throughout the country now, and more will crop up over time, but it's important to have a great relationship with the cardiologists and cardiac surgeons to create a successful treatment paradigm to say what's the best technology for each patient?

I would say I'd be very careful if I needed a valve replacement to avoid mechanical valves. They're rapidly approaching extinction, even in the youngest of patients, because of these new treatment options to rescue biological valves. I would say that if you're over 50 years old, you certainly should undergo either a valve repair or a minimally invasive bio-prosthetic valve because I believe that as the future evolves and these currently available biological valves should give you about 15 to 20 years of good, quality function and by that point in time, our technology will have advanced even further that will allow valve-in-valve rescue after these valves deteriorate. Thank you.

Questions And Answers

Adam Pick: Dr. Stewart, thanks so much for the prepared remarks. Really just so much great information here for anybody with a valvular issue or an aneurysm to really take note of, and no pun intended, but take to heart because this really is just so important for all the patients to get educated. We're going to transition now right into the Q & A, and we've got quite a flurry of questions here that have come in, and we're just going to go through them one by one.

Here, this comes in from Pam in Virginia and she says, "Have you ever done valve replacement surgery on a quadricuspid aortic valve? How does the valve stay in place? What possible complications would you consider when replacing a quadricuspid valve in a patient with connective tissue disorder?"

Dr. Stewart: Pam, in fact, I have done a number of patients with quadricuspid valves, and they're actually quite easy to repair because two of the cusps are generally very small, and the other two are quite normal. What I do is create a seam in two of the cusps and make it a trileaflet valve. Often times, people with quadricuspid valves also have an aortic root aneurysm. That graft that I showed earlier, that Valvsalva graft, figures into the plot of needing a root replacement done because they do have connective tissue disorders, and the aortic root should be removed in these people as well. So, the valve can be rebuilt, reformed into a trileaflet valve and the aortic root would be replaced at the same time. It can also be done without a full sternotomy through a cosmetic incision, so this is a very straightforward problem to fix.

Adam Pick: This came in from Valerie Allen, who is on the line with us, she says, "Can you always tell prior to surgery whether repair or replacement is needed? Does this ever change during surgery?"

Dr. Stewart: Yes, it can change during surgery. Now, it's important with today's echocardiograms, and we have the ability to do 3D echocardiograms here where I can get a very good image of the valve, so I can tell with a greater than 90% certainty that I can repair the valve. Now often times, they're – not often but ten out of a hundred, we might look and say, "I can repair the valve, but it's not the right thing for you." Leaving the operating room with a valve that's working perfectly, but it's falling apart in five or ten years is not success. If you do enough of this in places like ...my center, we do have enough of this to say I can look at the valve and you really can't make the decision until game time where you look at the leaflets and allow them to touch each other and see their quality to know if it's going to last. It's a so-called look test. Now about a 90% certainty on echo and then the last group are folks where I just believe in doing to other people what I'd have done to me, and I'd want my valve repair to last me at least 20 years and if I don't believe it's going to last 20 years, then I'd replace it.

Adam Pick: Next question, “Is it better to travel to find a surgeon in another state who may have more skill, or stay close to home? How should we evaluate the different types of valves?” Ed Ebner.

Dr. Stewart: I would say that you only have one heart. About 15% of the patients I operate on come from outside the United States. Really, it’s a five-day hospital stay and now with Facetime and with iPhones, I can do a lot of the follow-up remotely. I can look at people’s incisions and look at their echocardiograms real-time, or the surgeons or doctors in other countries can send me what a postoperative incision looks like, or an echocardiogram, and I can look at it and talk to patients with Facetime, which I do quite frequently. I believe that it’s – that I would not look at geography as a reason. Many of Adam’s patients who have contacted me have gotten on a plane to come to New York or driven several hours. I think for a very brief hospital stay, it is not a problematic experience. In places like ours in New York City or Cleveland at Mayo Clinic, there are clinic where there are affordable hotels around and the ability to easily travel into an airport should allow patients to all get the best healthcare available.

Adam Pick: Moving on, you talked a lot about TAVR, but here’s Mark again asking, “Can TAVRs be used for bicuspid valves? If yes, great.” I think you said they may be, but if no, why not?

Dr. Stewart: Yes. It’s a great question, Mark, and in the first iteration of TAVR, which was a valve called the Edward Sapien Valve. The valve is still inserted with a balloon. The balloon is expanded. Now, bicuspid valves have two leaflets rather than three and in the center of those joined leaflets is instenotic valves, which is really the only indication for TAVR, is a lot of calcium. Imagine it’s like an iron beam. When the valve gets inserted it goes through a path of least resistance and the valve could kink or turn in the Sapien valve. Now the newer – the valve that came out afterwards, the Medtronic core valve, can be used in bicuspid patients because it’s a larger stent and it’s self-expanding, so we have used it in bicuspid patients.

Now, the one reason it’s not used that often in bicuspid patients is bicuspid patients are generally younger. The valve generally fails in the early 60s and for either of the trans-catheter valve replacements, there are still criteria for them being allowed to be used. They have to be used in at least intermediate risk patients. There aren’t a lot of folks with bicuspid valves that are over 70, which has been our cut-off for many patients in implanting TAVR.

Adam Pick: Alice asks, “If Dr. Stewart’s mom needed aortic valve surgery and she was scared out of her mind, what would Dr. Stewart tell her to calm her nerves?”

Dr. Stewart: I look at patients every day and talk to them about what their risks are. I will tell people they’re going to be fine because almost all of them are; 999 out of 1,000 are going to be completely fine in having an aortic valve surgery. This is something – and if your surgeon is a busy, competent surgeon, it’s something they do every day. Now, obviously I would never give anyone a calm assurance if I had to land a crashing plane, but to replace the aortic valve is something that is an exceptionally low-risk procedure where they’re going to feel better. It’s the most gratifying operation that a heart surgeon does because the patient is coming because they have symptoms. They’re tired, they’re fatigued, they’re short of breath. It’s a very small incision, a very straightforward problem. On a scale of one to ten, an aortic valve replacement is about a 1.5 on a scale of difficulty. It’s something that with a very brief hospital stay, the patient’s going to feel so much better afterwards. They have such an improvement and a recapturing of the robustness of their life. I look at these patients who are often in their 70s, 80s, 90 years old and tell them, “You’re going to be fine, and you’re going to come back in a month, and you’re going to thank me.”

Adam Pick: What’s the oldest patient that you’ve ever operated on?

Dr. Stewart: Well, the oldest patient I did a TAVR on was 101 and just last week, I did a complex aortic valve – aortic repair in a woman who was 91, which people were very critical of the fact I was operating on a 90 year old and doing an aneurysm operation, but she left the hospital on day four and is already back to playing in her daily bridge game.

It’s not uncommon at all now because the human aortic valve is one of the best designed structures in the heart, and it typically lasts 75, 80 years, so the people who need this operation are generally over 75, and they do well. After having years of experience of operating on people in their 80s, you get good at it. They’re patients who, if they make it to 80, they generally have the right stuff in life. They generally do well, and they recover quite quickly.

Adam Pick: In terms of Ronald’s question, he’s asking about stem cells. He says, “With all the hype about stem cells, will that technology have any impact on aortic valve or aneurysm therapy?”

Dr. Stewart: Well, Ronald, we’ve used a homograph, a human aortic homograph as a

scaffold, and we've allowed the body to populate it with its own stem cells. It's something a company called Cryolife has been keen on developing. It's been used predominately in the Ross Procedure for the right side of the heart. It hasn't really gotten over to the left side. Stem cells have had great success in treating patients with heart failure to rebuild some of the muscle or repopulate scar tissue and recreate muscle and have a better functioning heart. It hasn't really gotten too far in the development of a genetically engineered aortic root or an aortic valve yet.

Adam Pick: John's question, "I am a 72 year old male. My aortic valve was replaced four and a half years ago. Since then, we've been monitoring my ascending aortic, which now measures 4.9 cm. My cardiologist suggested that it was time for surgery, but the surgeon who replaced the valve said that the risk of surgery at this time is greater than the risk of waiting. He mentioned scar tissue and recovery as issues. I'd be interested in Dr. Stewart's assessment regarding risks and surgical options."

Dr. Stewart: I would say that – I would be a little critical and say you probably should've had your aorta replaced at the same time you had your valve done four and a half years ago because your aorta couldn't have been much smaller than 4.9 at that point. It had to be at least above four and a half, and that's our cutoff. When we do an aortic valve surgery, we generally replace the aorta if it's greater than 4.5 cm; 4.9 after having heart surgery, I'd say you're right on the fence. If you were my brother or my dad, I'd say wait til you're comfortably over 5, 5.1, 5.2, and then I would start thinking about fixing it. The fact that as your aorta grows, you're also getting older and if you're healthy right now, you can find a convenient time in your life. I would suggest you are going to need your aorta replaced in your lifetime, so you're not gaining a lot by waiting until you get older or a little more debilitated. I wouldn't rush into it. I'd say you probably have a year or two before you need it.

Adam Pick: We have another question that's just coming in from Lori Beardon, and she writes – it goes back to what we were talking about earlier, Dr. Stewart. She writes, "I'm scheduled to have my bicuspid valve replaced by a mechanical valve next week and also have my aneurysm repaired. I'm 53 and healthy otherwise. I trust my surgeon. He is strongly recommending the mechanical valve. He says there is also research regarding Coumadin, and all patients may not require it in the future. Now I'm starting to question the mechanical valve. Should I trust my surgeon or request a tissue valve?"

Dr. Stewart: Again, I do what other people what I'd have done to me. I'm 45; I would have

a tissue valve. I believe especially at 53, today's tissue valves are specially sewn into a graft. The graft that I use, which is a Valsalva graft, I would typically use a stentless horse valve, an equine valve, which has excellent function and excellent longevity. If that gave me 20 years, I would believe that a transcatheter valve would get me through the next aspect of my life. I could live a robust age. I would not have a mechanical valve because although research exists, there is no alternative to Coumadin at this point in time, and there's no alternative to Coumadin that's in the near future. I would assume that if I were 53, the Coumadin I would be taking tomorrow would be the Coumadin I'd be taking for the rest of my life.

I would not have a mechanical valve because as time goes on, other things crop up; a fall with a broken hip, colon cancer, gallbladder remove. All these things complicate having a mechanical valve. If I were 53 years old, man or a woman, I would have a tissue valve. With a bicuspid, you want to make sure that your valve's not repairable, so I would get another opinion.

Adam Pick: Then a question coming in from Karen. "I'm monitored by my cardiologist at the University of Ottawa Heart Institute for my severe aortic stenosis. Again, I have a bicuspid aortic valve. I'm 57. I'm a woman with an opening of 0.73 cm and no major symptoms. If I hold steady at this state, I can go on for quite a while without surgery, right?"

Dr. Stewart: Karen, what I would recommend you do is find some reproducible exercise. What I mean by that is that find an area where you'd go for a walk and do that walk about three times a week. Make it some heart elevation exercise that it's at least 30 minutes in length so that you can get out and – because what we do is convince ourselves that we don't have symptoms. You have severe aortic stenosis based on your echo but if you feel fine, don't start altering your life so that you continue to feel fine, meaning that if you normally walk to the grocery store or walk to church and now you're taking a car, that means you have symptoms because you're altering your life to prevent yourself from feeling poorly. Get out there, find a reproducible method of exercise; walk around a track, get on a bicycle, swim, whatever it is that you like to do. Do that and keep track of how you feel afterwards so that as time goes on, you keep that pace. If you pace starts to drop off or you find excuses not to do it anymore, that's equivalent to having symptoms.

Adam Pick: Great, and this is going to be our final question coming in from Linda Har-

grove, who write, "What is recommended for aortic root aneurysm that has emerged after the Ross Procedure 12 years ago?"

Dr. Stewart: It's a great question, and I have a partner who's a world-renowned expert in the Ross, Dr. Stelzer. It really depends because we have to treat these aneurysms as if it's in the native aorta. We wait until they're about five and a half centimeters and then we'd intervene on them. The operation I do is I keep the valve, which is now the pulmonic valve, and do what's called a valve-sparing operation where I keep the pulmonic valve in place and then implant that graft over the top of it.

I'd say you can safely wait to five and a half centimeters because based upon the way the Ross is constructed, the coronary arteries are sewn into the pulmonic valve. The valve is sewn to the heart, and then the end of the pulmonary artery is sewn to the aorta. There's really nowhere where a dissection can progress because there's four different suture lines. Really, you're worried about bursting, and that's not going to happen under five and a half centimeters. My criteria is to wait until that pulmonic auto-graft will grow to five and a half and then I'd replace it.

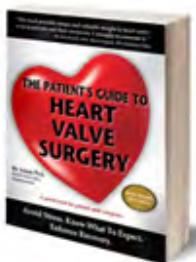
Adam Pick: Great, and with that response, we're going to conclude this excellent webinar, but please, please don't exit the webinar just yet. On behalf of the entire community at HeartValveSurgery.com and all the patients with heart valve disease and aneurysm defects, I'd like to extend an extraordinary thank-you to Dr. Allen Stewart and the entire team at Mt. Sinai for sharing all the great work that they're doing, all the research, and all the curative processes and the operations to help members from our community. Thank you so much, Dr. Stewart, for being with us today.

Dr. Stewart: My pleasure.

Adam Pick: As we close, I'd like to ask you to complete a very quick survey that is about to appear on your screen. As I always say here, keep on ticking. Thanks so much.

HeartValveSurgery.com Resources for Patients

Since 2006, HeartValveSurgery.com has developed several resources to help you better understand your diagnosis, your treatment options, your surgeon and cardiac clinic selection, and your recovery. Listed below, you will find resources created exclusively for patients and caregivers. We hope they educate and empower you.



[Read the 6th Revised Edition of *The Patient's Guide To Heart Valve Surgery*](#) – Since its initial publishing in 2006, this special book for heart valve surgery patients and their caregivers has been read by over 25,000 patients and caregivers. Written by Adam Pick, a former patient, this step-by-step guide helps patients avoid stress, know what to expect, and enhance recovery. [Learn more.](#)



[Use the Heart Valve Surgeon Finder](#) – Created by thousands of patients, caregivers, surgeons and cardiac centers, the Heart Valve Surgeon Finder is the world's only patient-recommended database of heart valve surgeons. You can search by location, by name, by problematic valve and by surgical procedure. [Learn more.](#)



[Research Heart Valve Clinics](#) – To help you research leading cardiac centers that specialize in heart valve treatment, our new 'Valve Clinics' section of the website was launched in April, 2012. Now, with a few simple clicks you can go on virtual tours, meet surgeons, meet nurses, see patient success stories and more. [Learn more.](#)



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